

PATIENTS' RIGHTS
IN THE JUDGMENTS OF THE COURT OF JUSTICE OF THE
EUROPEAN UNION
SELECTED CASE LAW

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VOLUME III

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European Court of Human Rights: <http://hudoc.echr.coe.int/sites/eng>

1. Financing of cross-border healthcare

1.2. European Commission v. Kingdom of Spain¹

Failure of a Member State to fulfil obligations – Article 49¹ EC – Social security – Hospital care needed during a temporary stay in another Member State – Lack of right to assistance from the competent institution to supplement that of the institution of the Member State of stay

1.2.1. Judgment

1 By its application, the Commission of the European Communities asks the Court to declare that the Kingdom of Spain has failed to fulfil its obligations under Article 49 EC by refusing persons insured under the Spanish national health scheme reimbursement of medical expenses which they have incurred in another Member State for hospital treatment received in accordance with Article 22(1)(a)(i)² of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996 (OJ 1997 L 28, p. 1), and as subsequently amended by Regulation (EC) No 1992/2006 of the European Parliament and of the Council of 18 December 2006 (OJ 2006 L 392, p. 1) ('Regulation No 1408/71'), in so far as the level of cover applicable in the Member State where the treatment is administered is lower than that provided for under the Spanish legislation.

¹ Judgment Of The Court (Grand Chamber) in case C 211/08 ; action under article 226 ec for failure to fulfil obligations, brought on 20 may 2008

1.2.2. Legal context

European Union legislation

2 Article 22 of Regulation No 1408/71², entitled ‘Stay outside the competent State – Return to or transfer of residence to another Member State during sickness or maternity – Need to go to another Member State in order to receive appropriate treatment’, provides:

‘1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:

(a) whose condition requires benefits in kind which become necessary on medical grounds during a stay in the territory of another Member State, taking into account the nature of the benefits and the expected length of the stay;

or

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition,

shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay ... in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

2. ...

The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resided and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.’

3 Article 34a of Regulation No 1408/71 provides:

‘... Articles 22(1)(a) and (c), ... 22(2), second subparagraph, ... shall apply by analogy to students and the members of their families as required.’

4 Article 36(1) of Regulation No 1408/71 provides:

‘Benefits in kind provided in accordance with the provisions of this chapter by the institution of one Member State on behalf of the institution of another Member State shall be fully refunded.’

5 Article 21(1) of Regulation (EEC) No 574/72 of the Council of 21 March 1972 laying down the procedure for implementing Regulation No 1408/71, as amended and updated by Regulation No 118/97, and as subsequently amended by Commission Regulation (EC) No 311/2007 of 19 March 2007 (OJ 2007 L 82, p. 6) (‘the Implementing Regulation’), provides:

‘In order to receive benefits in kind under Article 22(1)(a)(i) of [Regulation No 1408/71], an employed or self-employed person shall submit to the care provider a document issued by the competent institution certifying that he is entitled to benefits in kind. That document shall be drawn up in accordance with Article 2. ...

6 Article 34(1) of the Implementing Regulation states:

‘If it is not possible during an employed or self-employed person’s stay in a Member State other than the competent State to complete the formalities provided for in Articles 20 ... and ... 21 ... of the Implementing Regulation, his expenses shall, upon his application, be refunded by the competent institution in accordance with the refund rates administered by the institution of the place of stay.’

7 On the basis of Article 2(1) of the Implementing Regulation, the Administrative Commission on Social Security for Migrant Workers – set up pursuant to Article 80 of Regulation No 1408/71 – drew up a model for the certificate relating to the application of Article 22(1)(a)(i) of Regulation No 1408/71, namely, form ‘E 111’. Form E 111 was replaced, with effect from 1 June 2004, by the ‘European health insurance card’ pursuant to a number of decisions of the Administrative Commission of the European Communities on Social Security for Migrant Workers: Decision No 189 of 18 June 2003 aimed at introducing a European health insurance card to replace the forms necessary for the application of Council Regulations No 1408/71 and No 574/72 as regards access to health care during a temporary stay in a Member State other than the competent State or the State of residence (OJ 2003 L

276, p. 1); Decision No 190 of 18 June 2003 concerning the technical specifications of the European health insurance card (OJ 2003 L 276, p. 4); and Decision No 191 of 18 June 2003 concerning the replacement of forms E 111 and E 111 B by the European health insurance card (OJ 2003 L 276, p. 19).

8 The scope of Article 22(1)(a)(i) of Regulation No 1408/71 was defined by Decision No 194 of the Administrative Commission of the European Communities on Social Security for Migrant Workers of 17 December 2003 concerning the uniform application of Article 22(1)(a)(i) of Regulation No 1408/71 in the Member State of stay (OJ 2004 L 104, p. 127; ‘Decision No 194’).

9 The seventh recital in the preamble to Decision No 194 states:

‘The criteria set out in Article 22(1)(a)(i) ... cannot be interpreted in such a way that chronic or existing illnesses are excluded. The Court of Justice ruled [in Case C 326/00 IKA [2003] ECR I 1703] that the concept of “necessary treatment” cannot be interpreted “as meaning that [the benefit of that provision is] limited solely to cases where the treatment provided has become necessary because of a sudden illness. In particular, the circumstance that the treatment necessitated by developments in the insured person’s state of health during his temporary stay in another Member State may be linked to a pre-existent pathology of which he is aware, such as a chronic illness, does not mean that the conditions for the application of these provisions are not fulfilled”.’

10 The enacting terms of Decision No 194 provide:

‘1. Benefits in kind which become medically necessary and which are granted to a person staying temporarily in another Member State, are covered by the provisions of Article 22(1)(a)(i) ... with a view to preventing an insured person from being forced to return before the end of the planned duration of stay to the competent State to obtain the treatment he/she requires.

The purpose of benefits of this type is to enable the insured person to continue his/her stay under safe medical conditions, taking account of the planned length of the stay.

However, the situation where the aim of the temporary stay is to receive medical treatment is not covered by these provisions.

2. In order to determine whether a benefit in kind meets the requirements set out in Article 22(1)(a)(i), ... only medical factors within the context of a temporary stay, taking into account the medical condition and past history of the person considered, shall be considered.

1.2.3. National legislation

11 Article 43 of the Spanish Constitution³ enshrines the right to the protection of health and confers upon the public authorities responsibility for organising the health system and protecting public health through the provision of the necessary benefits and services.

12 To that end, General Law on health No 14/1986 (Ley 14/1986, General de Sanidad) of 25 April 1986 (BOE No 102, 29 April 1986, p. 15207; ‘the General Law on Health’) lays the foundations for a national health service which is public, universal and free of charge.

13 The benefits provided by the national health service to persons covered by that system are entirely free of charge. However, under Article 17 of the General Law on Health, benefits provided outside that system are, as a general rule, to be paid for by the insured person and are not to be reimbursed by bodies within the national health system.

14 Article 5 of Royal Decree 63/1995 on the organisation of health benefits within the national health service (Real Decreto 63/1995, sobre ordenación de prestaciones sanitarias del Sistema Nacional de Salud) of 20 January 1995 (BOE No 35, 10 February 1995, p. 4538), provided:

‘1. The means available within the national health service shall be used for the provision of benefits ...

2. The provision of benefits ... may be required only of the personnel and [facilities] of the national health service, whether internal or under contract, without prejudice to the provisions laid down in international agreements.

3. In cases where immediate, urgent, life-saving treatment has been administered outside the national health system, the related costs shall be reimbursed provided that it is shown that it was not possible to use the services of that system in good time and that the treatment does not amount to an inappropriate use or an abuse of this exception.’

15 Law 16/2003 on the consistency and quality of the national health service (Ley 16/2003, de cohesión y calidad del Sistema Nacional de Salud) of 28 May 2003 (BOE No 128, 29 May 2003, p. 20567) catalogues the benefits and services to be available under that system.

16 In accordance with Article 14 of the General Law on Health, Article 9 of Law 16/2003 provides:

‘Without prejudice to the provisions of international agreements to which Spain is party, medical benefits and services under the national health system shall be provided only by the staff lawfully authorised to do so, using the [facilities], whether in-house or under contract, of the national health service, except in life-threatening situations where it is shown that it was not possible to use the facilities of that system.’

17 Provisions for the implementation of Law 16/2003 have been laid down in Royal Decree 1030/2006 establishing the catalogue of common services available under the national health system and the procedure for its revision (Real Decreto 1030/2006, por el que se establece la cartera de servicios comunes del Sistema Nacional de Salud y el procedimiento para su actualización) of 15 September 2006 (BOE No 222, 16 September 2006, p. 32650). Royal Decree 1030/2006 repealed and replaced Royal Decree 63/1995.

18 Article 4(3) of Royal Decree 1030/2006 states:

‘All common services shall be provided solely by facilities belonging to the national health system or under contract thereto, except in life-threatening situations where it is shown that it was not possible to use the facilities of that system. In cases where immediate, urgent, life-saving treatment has been administered outside the national health system, the related costs shall be reimbursed provided that it is shown that it was not possible to use the facilities of that system in good time and that the treatment does not amount to an inappropriate use or an abuse of this exception. The present paragraph shall be without prejudice to the provisions of international agreements to which Spain is party or the provisions of domestic law governing treatment in the event of services being provided abroad.’

19 It follows from those provisions that, where a person insured under the Spanish national health system receives hospital treatment in another Member State, the necessity for which was brought about by changes in his state of health during a temporary stay in that Member State, the institution to which he is affiliated covers the costs of that treatment only within the

limits of its obligation under the combined provisions of Articles 22(1)(a)(i) and 36 of Regulation No 1408/71, except in the circumstances described in the second sentence of Article 4(3) of Royal Decree 1030/2006 and subject to the conditions set out therein. That exception aside, therefore, such a person has no right to insurance cover at the expense of the Spanish institution in respect of that part of the cost of the treatment which is not covered by the institution of the Member State of stay.

1.2.4. Pre-litigation procedure

20 The Commission received a complaint from a French citizen resident at the material time in Spain and insured under the Spanish national health system. On returning to Spain after being admitted to hospital during a stay in France, under cover of form E 111, that person met with refusal on the part of the Spanish institution to reimburse the portion of the hospitalisation costs which, in accordance with the French legislation, the French institution had left him to pay.

21 After requesting the Kingdom of Spain, in vain, for information concerning its legislation on the refunding of costs incurred for healthcare received in another Member State, the Commission asked that Member State by letter of 19 December 2005 to provide a satisfactory response within two months.

22 By letter of 13 February 2006, the Kingdom of Spain replied that its legislation did not provide for the possibility that a person insured under the Spanish national health system could obtain reimbursement from the competent institution for healthcare costs incurred outside that system, save in the exceptional circumstances envisaged, at that time, in Article 5 of Royal Decree 63/1995.

23 On 18 October 2006, the Commission sent the Kingdom of Spain a letter of formal notice in which it drew Spain's attention to the incompatibility of its domestic legislation with Article 49¹ EC in so far as that legislation precluded, with exceptions, the reimbursement pursuant to Article 22(1)(a)(i)² of Regulation No 1408/71 – by the competent institution to the person insured under the national health system – of costs incurred for hospital treatment received in another Member State, where there was a positive difference between the levels of cover respectively applicable in Spain and in that other Member State.

24 By letter of 29 December 2006, the Kingdom of Spain essentially stated in reply to that letter of formal notice that the position taken by its administrative authorities vis-à-vis the complainant referred to in paragraph 20 above was in conformity with Regulation No 1408/71; that the circumstances of the person concerned were different from those of the dispute which led to the judgment in Case C 368/98 Vanbraekel and Others [2001] ECR I 5363; and that the interpretation argued for by the Commission would affect the financial balance of its national health system.

25 Dissatisfied with that reply, the Commission sent the Kingdom of Spain a reasoned opinion on 19 July 2007, in which it stated that the Spanish legislation was contrary to Article 49 EC and requested that Member State to adopt the measures necessary to put an end to the infringement within two months of receiving the reasoned opinion.

26 Since, in its reply of 19 September 2007 to the reasoned opinion, the Kingdom of Spain maintained its position, the Commission decided to bring the present action.

1.2.5. Admissibility

27 The Kingdom of Spain contests the admissibility of the action.

28 It argues that the submissions made by the Commission are confused, as the Commission alleges infringement of Article 49 EC¹ while acknowledging that the practice of the Spanish administration is in conformity with Regulations No 1408/71 and No 574/72. Not only that, but the application contains a complaint alleging that the second sentence of Article 4(3) of Royal Decree 1030/2006 does not comply with Article 49 EC, whereas circumstances such as those of the complainant referred to in paragraph 20 above fall within the scope of the last sentence of Article 4(3) of the decree, which refers to European Union law ('EU law').

29 The Kingdom of Spain also argues that, in so far as the Commission complains that Spain is in breach of Article 34⁴ of the Implementing Regulation because the Spanish administration refuses to pay persons insured under its national health system the difference between the total cost of hospital treatment received in another Member State and the costs covered by the competent Spanish institution in relation to that treatment, the fact that this complaint was put forward out of time renders it inadmissible.

30 In addition, the Kingdom of Spain contends that the application contains a complaint which was not put forward during the pre-litigation procedure, alleging that Article 4(3) of Royal Decree 1030/2006 is incompatible with Article 22(1)(a) of Regulation No 1408/71².

31 The Kingdom of Belgium contends that Article 49 EC¹ was not mentioned at all in the reasoned opinion and, in consequence, the application may not contain an argument based on that provision.

32 In that regard, it should be borne in mind that it follows from Article 38(1)(c)⁵ of the Rules of Procedure of the Court of Justice and from the case-law relating to that provision that the application initiating proceedings must state the subject-matter of the dispute and a summary of the pleas in law on which the application is based and that that statement must be sufficiently clear and precise to enable the defendant to prepare its defence and the Court to rule on the application. It is therefore necessary for the essential points of law and of fact on which a case is based to be indicated coherently and intelligibly in the application itself and for the heads of claim to be set out unambiguously so that the Court does not rule *ultra petita* or indeed fail to rule on a claim (Case C 195/04 *Commission v Finland* [2007] ECR I 3351, paragraph 22 and the case-law cited, and Case C 343/08 *Commission v Czech Republic* [2010] ECR I 0000, paragraph 26).

33 Moreover, the subject-matter of an action brought under Article 226 EC⁶ is circumscribed by the pre-litigation procedure laid down in that provision. Consequently, the Commission's reasoned opinion and its application must be based on the same complaints (*Commission v Finland*, paragraph 18).

34 In the present case, the application and the submissions made by the Commission meet those various requirements.

35 Neither the reasoned opinion nor the application sets out a complaint alleging failure by the Kingdom of Spain to fulfil its obligations under Regulations No 1408/71 and No 574/72. In furtherance of the position consistently maintained by the Commission during the pre-litigation procedure, the application seeks only a declaration that Spain has failed to fulfil its obligations under Article 49 EC¹.

36 It is quite clear from the Commission's application and from its submissions that the shortcoming which the Commission alleges resides in the fact that, in the case of persons insured under the Spanish national health system whose state of health makes hospital

treatment necessary during a temporary stay in another Member State, for the purposes of Article 22(1)(a)(i)² of Regulation No 1408/71, the legislation at issue denies – except in the case of life-saving treatment, as referred to in the second sentence of Article 4(3) of Royal Decree 1030/2006 – the right, which derives from Article 49 EC, to receive complementary reimbursement from the Spanish institution where the level of cover applicable in the Member State of stay is lower than that which is applicable in Spain.

37 In that context, the reference which the Commission makes, inter alia, in its submissions to Article 22(1)(a)(i) of Regulation No 1408/71 is not intended to form the basis for an autonomous complaint, but to define the group of insured persons to whose detriment the legislation at issue constitutes, in the view of the Commission, an infringement of Article 49 EC.

38 It follows that the action is admissible.

1.2.6. Substance

Arguments of the parties

39 The Commission submits that Article 49 EC¹ applies to the healthcare services covered by the Spanish legislation, including where the need for such treatment arises during the insured person's temporary stay in another Member State.

40 After pointing out that Article 22² of Regulation No 1408/71 and Article 49 EC are complementary, the Commission asserts that, in the present case, the effect of the Spanish legislation is to restrict not only the provision of hospital care, but also the provision of tourist or educational services, the obtaining of which can be the reason for a temporary stay in another Member State.

41 Pointing out that the situation envisaged in Article 22(1)(a) of Regulation No 1408/71 covers all cases where treatment becomes necessary during a temporary stay in another Member State owing to a deterioration in the health of the insured person, the Commission submits that the legislation at issue is liable to induce a person insured under the Spanish national health system, who is faced with such a situation and has a choice between going to hospital in the Member State of stay and an early return to Spain to be treated there, to choose

the second option whenever the level of cover applicable in the Member State of stay is less favourable than that applicable in Spain.

42 The Commission adds that the legislation at issue is such as to dissuade elderly insured persons or those suffering from a chronic illness – with the attendant risk of having to be admitted to hospital – from travelling, as tourists or students, to a Member State in which the conditions governing insurance cover for hospital treatment are less advantageous than in Spain.

43 The Commission argues that the restriction brought about by that legislation is not justified. In particular, it has not been shown that there is a need for such a restriction in the light of the objective of ensuring that the financial balance of the national health system is maintained, given that the costs supported by the Spanish national health service in respect of hospital care administered in another Member State to a person insured under the Spanish system cannot, in any case, exceed the cost of equivalent treatment in Spain.

44 The Spanish Government, supported by the Belgian, Finnish and United Kingdom Governments, challenges the view that the legislation at issue constitutes a restriction on the freedom to provide medical, tourist or educational services and contends that, in any event, the alleged restriction is justified by overriding reasons relating to the public interest in maintaining the financial balance of the national health system concerned.

1.2.7. Findings of the Court

45 First of all, it should be borne in mind that the applicability of Article 22² of Regulation No 1408/71 – and specifically, in the present case, of Article 22(1)(a)(i) – does not mean that Article 49 EC cannot apply at the same time. The fact that national legislation may be in conformity with Regulation No 1408/71 does not have the effect of removing that legislation from the scope of the provisions of the EC Treaty (see, to that effect, Case C 372/04 Watts [2006] ECR I 4325, paragraphs 46 and 47).

46 That said, it must first be determined whether, in the case of a person insured under the national health system whose state of health makes hospital care necessary during a temporary stay in another Member State, the services identified by the Commission in its action are

cross-border services and, as such, within the scope of Article 49 EC¹ (see, to that effect, Case 352/85 *Bond van Adverteerders and Others* [1988] ECR 2085, paragraph 13).

47 With regard, on the one hand, to healthcare services, it should be noted that, according to settled case-law, medical services provided for consideration fall within the scope of the provisions on the freedom to provide services, including situations where care is provided in a hospital environment (see, to that effect, *Watts*, paragraph 86 and the case-law cited, and Case C 444/05 *Stamatelaki* [2007] ECR I 3185, paragraph 19). Furthermore, the provision of medical services does not cease to be a provision of services for the purposes of Article 49 EC simply because, after paying the foreign provider for the care received, the insured person subsequently seeks reimbursement of the related costs through a social security system (see, to that effect, *Watts*, paragraph 89 and the case-law cited).

48 The Court has also held that Article 49 EC applies where the person providing the service and the recipient are established in different Member States (see Case C 55/98 *Vestergaard* [1999] ECR I 7641, paragraph 19). Services which the provider carries out without moving from the Member State in which he is established for recipients established in other Member States constitute the provision of cross-border services for the purposes of Article 49 EC (see, *inter alia*, Case C-384/93 *Alpine Investments* [1995] ECR I-1141, paragraphs 21 and 22 and Case C 243/01 *Gambelli and Others* [2003] ECR I 13031, paragraph 53).

49 Furthermore, the Court has consistently held that the freedom to provide services involves not only the freedom of the provider to carry out services for recipients established in a Member State other than that in which the provider is established but also the freedom to receive or to benefit, as recipient, from the services carried out by a provider established in another Member State, without being hampered by restrictions (see, *inter alia*, *Gambelli and Others*, paragraph 55 and the case-law cited).

50 It follows that hospital services which are carried out in a Member State by a provider established there for a recipient established in another Member State are covered by the notion of the provision of services, for the purposes of Article 49 EC, including where – as in the present case – the reasons for which the recipient was staying temporarily in the Member State of establishment of the provider were not medical.

51 On the other hand, with regard to services other than medical services, such as tourist and educational services as specifically referred to by the Commission in its action, it is necessary to bear in mind, in addition to the case-law referred to in paragraph 48 above, that persons established in a Member State who travel to another Member State as tourists or on a study trip must be regarded as recipients of services for the purposes of Article 49 EC (Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, paragraph 16; Case 186/87 *Cowan* [1989] ECR 195, paragraph 15; and Case C 348/96 *Calfa* [1999] ECR I 11, paragraph 16).

52 It follows from the above considerations that the freedom to provide services encompasses the freedom of an insured person established in a Member State to travel – as a tourist or student, for example – to another Member State for a temporary stay and to receive hospital care there from a provider established in the latter Member State, where the need for such care during that stay arises because of his state of health.

53 Whilst it is established that EU law does not detract from the power of the Member States to organise their social security systems and that, in the absence of harmonisation at European Union level, it is for the legislation of each Member State to determine the conditions for the grant of social security benefits, the fact nevertheless remains that, when exercising that power, Member States must comply with EU law and, in particular, with the provisions on the freedom to provide services (see, in particular, *Watts*, paragraph 92 and the case-law cited).

54 In those circumstances, it is appropriate, secondly, to consider whether the legislation at issue constitutes a failure to comply with those provisions.

55 It is settled law that Article 49 EC¹ precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services entirely within a single Member State (see, *inter alia*, *Stamatelaki*, paragraph 25 and the case-law cited).

56 In that connection, the Court has held that the fact that national legislation does not guarantee an insured person who has been authorised to receive hospital care in another Member State, in accordance with Article 22(1)(c) of Regulation No 1408/71, a level of insurance cover equivalent to that to which he would have been entitled had he received hospital treatment in the Member State of affiliation is a restriction of the freedom to provide

services, for the purposes of Article 49 EC, in that it may deter, or even prevent, that person from applying to providers of services established in other Member States (see, to that effect, *Vanbraekel and Others*, paragraph 45). The Court stated, with regard to national legislation under which hospital care was to be free of charge if provided within the national health service, that such a level of cover corresponds to the cost, in the system of the Member State of affiliation, of care equivalent to that provided to the insured person in the Member State of stay (see, to that effect, *Watts*, paragraphs 131 and 133).

57 The Court has held that, in so far as complementary reimbursement, which depends on the rules governing social insurance cover in the Member State of affiliation, does not by definition impose any additional financial burden on the sickness insurance scheme of that Member State as compared with the reimbursement to be made or the costs to be borne if hospital care had been provided in that State, it cannot be argued that making that sickness insurance scheme bear the costs of complementary reimbursement would be liable to have a significant effect on the financing of the social security system of that Member State (*Vanbraekel and Others*, paragraph 52).

58 However, with regard at least to hospital care, which is all that is at issue in the present case, cases of ‘unscheduled treatment’, as referred to in Article 22(1)(a) of Regulation No 1408/71 – and at issue in the present case – must be distinguished, in the light of Article 49 EC, from cases of ‘scheduled treatment’, as referred to in Article 22(1)(c) of that regulation, at issue both in *Vanbraekel and Others* and in *Watts*.

59 First of all, it should be noted that scheduled hospital treatment is received in another Member State under Article 22(1)(c) of Regulation No 1408/71 where – as is clear from the second subparagraph of Article 22(2) of that regulation – an objective finding has been made that the treatment in question, or treatment which is comparable in terms of effectiveness, is not available in the Member State of affiliation within a medically acceptable length of time (see, to that effect, *Watts*, paragraphs 57 and 59). In such circumstances, as the Court held in *Vanbraekel and Others*, the Member State of affiliation must, if it is not to find itself in breach of the rules on freedom to provide services, ensure – in addition to meeting its obligations under Article 22(1)(c) of Regulation No 1408/71, read in conjunction with Article 36 thereof – that, should the case arise, the insured person has a level of cover which is equally as advantageous as the level of cover which would have been recognised if that treatment had

been available under its own national health system within a medically acceptable length of time.

60 However, the situation is different in the case of unscheduled treatment, as referred to in Article 22(1)(a) of Regulation No 1408/71.

61 With regard to an insured person whose travel to another Member State is for reasons relating to tourism or education, for example, and not to any inadequacy in the health service to which he is affiliated, the rules of the Treaty on freedom of movement offer no guarantee that all hospital treatment services which may have to be provided to him unexpectedly in the Member State of stay will be neutral in terms of cost. Given the disparities between one Member State and another in matters of social security cover and the fact that the objective of Regulation No 1408/71 is to coordinate the national laws but not to harmonise them, the conditions attached to a hospital stay in another Member State may, according to the circumstances, be to the insured person's advantage or disadvantage (see, by analogy, Joined Cases C 393/99 and C 394/99 *Hervein and Others* [2002] ECR I 2829, paragraphs 50 to 52; Case C 387/01 *Weigel* [2004] ECR I 4981, paragraph 55; and Case C 392/05 *Alevizos* [2007] ECR I 3505, paragraph 76).

62 Next, it should be pointed out that, in the case of scheduled hospital treatment in another Member State, the insured person is, as a general rule, able to obtain an overall estimate of the cost of that treatment, in the form of a quote, enabling him to compare the levels of cover respectively applicable in the Member State of stay and the Member State of affiliation.

63 In those circumstances, the fact that the legislation of the Member State of affiliation does not guarantee the insured person the right to receive reimbursement from the competent institution of any positive difference between the level of cover applicable in that Member State and the level of cover applicable in the Member State in which the hospital treatment is scheduled to take place is likely to induce the insured person to cancel the treatment planned in that other Member State, which amounts to a restriction on the freedom to provide services, as the Court held in *Vanbraekel and Others* and in *Watts*.

64 However, as the Spanish Government has pointed out, the case of unscheduled treatment envisaged in Article 22(1)(a) of Regulation No 1408/71 covers, in particular, an indefinite number of cases in which the state of health of the insured person makes hospital

treatment necessary, during a temporary stay in another Member State, because of circumstances – relating, *inter alia*, to the urgency of the situation, the seriousness of the illness or the accident, or even the fact that a return to the Member State of affiliation is ruled out for medical reasons – which, objectively, leave no alternative but to provide the insured person with hospital treatment in an establishment in the Member State of stay.

65 In all those cases, the legislation at issue cannot be regarded as having any restrictive effect on the provision of hospital treatment services by providers established in another Member State.

66 It is true that, as the Commission pointed out, the situation envisaged in Article 22(1)(a) of Regulation No 1408/71 also covers cases where the deterioration in the health of the insured person during a temporary stay in another Member State, while unexpected, is not such as to deprive him of the choice between going to hospital in that State and an early return to Spain to receive the necessary hospital treatment there.

67 Nevertheless, as paragraph 1 of the enacting terms of Decision No 194 makes clear, the system established under Article 22(1)(a)(i) of Regulation No 1408/71 is intended precisely to prevent the insured person from being constrained in such cases to return early to the Member State of affiliation to receive the necessary treatment there, by conferring on that person the right – which he would not otherwise have – of access to hospital treatment in the Member State of stay on conditions of reimbursement as favourable as those enjoyed by insured persons covered by the legislation of that State (see, by analogy, Case C 56/01 *Inizan* [2003] ECR I 12403, paragraphs 21 and 22).

68 In addition, it should be noted that the potential effect of the legislation at issue on the situation of an insured person in that position depends on a factor which is uncertain at the time when that person is faced with such a choice, that is to say, the possibility that the level of cover applicable in the Member State of stay for hospital treatment there – the overall cost of which is, at that time, not known – is lower than the cost of equivalent treatment in Spain.

69 As regards services other than medical services, such as tourist or educational services, it should be pointed out that cases of unscheduled treatment for the purposes of Article 22(1)(a) of Regulation No 1408/71 imply by definition that, at the time when the insured person plans to travel to another Member State – as a tourist or a student, for example – there

is uncertainty as to whether hospital treatment will be needed during his temporary stay in that other Member State.

70 The situation of elderly insured persons and the situation of those suffering from chronic or pre-existing illness, both of which – according to paragraph 1 of the enacting terms of Decision No 194 and the seventh recital in the preamble to that decision – fall within the scope of Article 22(1)(a) of Regulation No 1408/71, is similarly uncertain in that regard.

71 Although they may run a higher risk of deterioration in their state of health, those insured persons, in common with other insured persons, are likely to be affected by the legislation at issue only if their state of health actually necessitates hospital treatment, other than the treatment referred to in the second sentence of Article 4(3) of Royal Decree 1030/2006, during a temporary stay in another Member State or if the level of cover applicable in that Member State is lower than the cost of equivalent treatment in Spain.

72 It follows that the possibility that persons insured under the Spanish national health system might be induced to return early to Spain in order to receive hospital treatment there which has been made necessary by a deterioration in their health during a temporary stay in another Member State, or to cancel a trip to another Member State – for tourism or study, for example – because, if their case does not fall within the scope of the second sentence of Article 4(3) of Royal Decree 1030/2006, they cannot count on the competent institution making a complementary contribution if the cost of equivalent treatment in Spain exceeds the level of cover applicable in that other Member State, appears too uncertain and indirect. Accordingly, the legislation at issue cannot, in general terms, be regarded as restricting the freedom to provide hospital treatment services, tourist services or educational services (see, by analogy, regarding the free movement of goods and freedom of movement for workers respectively, Case C 69/88 Krantz [1990] ECR I 583, paragraph 11, and Case C 190/98 Graf [2000] ECR I 493, paragraphs 24 and 25).

73 The case of the complainant referred to in paragraph 20 above confirms that conclusion. It shows that the effect of the legislation at issue is hypothetical, inasmuch as the application for complementary reimbursement submitted by the person concerned proved to be unfounded, as is apparent from the documents before the Court, because the cost of equivalent treatment in Spain is lower than the level of cover applied in the Member State of stay.

74 Lastly, it should be pointed out that, in contrast with the cases covered by point (c) of Article 22(1) of Regulation No 1408/71, those covered by point (a) of that provision are, for the Member States and the institutions responsible for social security in those States, unforeseeable.

75 In its capacity as the Member State of affiliation, every Member State is free, within the framework of its powers under Articles 153 TFEU and 168 TFEU to organise its public health and social security system (see to that effect, Watts, paragraphs 92 and 146, and Joined Cases C 570/07 and C 571/07 Blanco Pérez and Chao Gómez [2010] ECR I 0000, paragraph 43), to adopt measures affecting the extent and the conditions – especially regarding time-limits – of the offer of hospital treatment in its own territory, so as to be able to control the number of authorisations to be issued, under Article 22(1)(c) of Regulation No 1408/71, for treatment in another Member State which has been scheduled by persons insured under its own system.

76 However, as the Danish and Finnish Governments have pointed out, the ever-increasing mobility of citizens within the European Union, particularly for reasons of tourism or education, is likely to mean an ever greater number of cases of unscheduled hospital treatment, for the purposes of Article 22(1)(a) of Regulation No 1408/71, which the Member States can in no way control.

77 In that context, where every Member State relies, as Member State of affiliation, on the application of the legislation of the Member State of stay as regards the level of cover, for which the competent institution is ultimately responsible, in respect of hospital treatment which becomes necessary owing to the state of health of the insured person during his temporary stay in the latter Member State, the combined application of Article 22(1)(a) of Regulation No 1408/71 and of Article 36 thereof, concerning the mechanism for reimbursement between the institutions concerned, is based on the principle of overall compensation of risk.

78 Thus, cases in which unscheduled hospital treatment provided to an insured person during a temporary stay in another Member State bring about – as a consequence of the application of the legislation of the Member State of stay – a heavier financial burden for the Member State of affiliation than if that treatment had been provided in one of its own establishments, are deemed to be counterbalanced overall by cases in which, on the contrary, application of the legislation of the Member State of stay leads the Member State of affiliation

to incur lower costs for the hospital treatment in question than those which would have resulted from the application of its own legislation.

79 Consequently, the fact of imposing on a Member State the obligation to guarantee to persons insured under the national system that the competent institution will provide complementary reimbursement whenever the level of cover applicable in the Member State of stay in respect of the unscheduled hospital treatment in question proves to be lower than that applicable under its own legislation would ultimately undermine the very fabric of the system which Regulation No 1408/71 sought to establish. In every case concerning such treatment, the competent institution of the Member State of affiliation would be systematically exposed to the highest financial burden, whether through the application, in accordance with Article 22(1)(a) of that regulation, of the legislation of a Member State of stay under which the level of cover is higher than that provided for under its own or through the application of its own legislation in the contrary situation.

80 In the light of all the above considerations, the Commission has failed to show that, viewed globally, the legislation at issue constitutes a failure by the Kingdom of Spain to fulfil its obligations under Article 49 EC.

81 The action must therefore be dismissed.

1.2.8. Costs

82 Under Article 69(2) of the Rules of Procedure⁷, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Kingdom of Spain has applied for costs to be awarded against the Commission and the latter has been unsuccessful, the Commission must be ordered to pay the costs. Pursuant to the first subparagraph of Article 69(4) of the Rules of Procedure, the Kingdom of Belgium, the Kingdom of Denmark, the Republic of Finland and the United Kingdom, which have intervened in the proceedings, must bear their own costs.

1.2.9. The Court's decision

On those grounds, the Court (Grand Chamber) hereby:

1. Dismisses the action;
2. Orders the European Commission to pay the costs;
3. Orders the Kingdom of Belgium, the Kingdom of Denmark, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland to bear their own costs.

1.3. Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa²

Social security – Freedom to provide services – Sickness insurance – Hospital treatment provided in another Member State – Prior authorisation – Conditions of application of the second subparagraph of Article 22(2) of Regulation (EEC)² No 1408/71 – Methods of reimbursement to the insured person of hospital expenses incurred in another Member State – Obligation on a lower court to comply with the directions of a higher court

REFERENCE for a preliminary ruling under Article 234 EC⁸ from the Administrativen sad Sofia-grad (Bulgaria), made by decision of 28 April 2009, received at the Court on 14 May 2009, in the proceedings

² Judgment Of The Court (Grand Chamber) In Case C 173/09 5 October 2010

1.3.1. Judgment

1 This reference for a preliminary ruling concerns the interpretation of Articles 49 EC¹ and 22 of Regulation (EEC)² No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996 (OJ 1997 L 28, p. 1), as amended by Regulation (EC) No 1992/2006 of the European Parliament and of the Council of 18 December 2006 (OJ 2006 L 392, p. 1) ('Regulation No 1408/71').

2 The reference has been made in proceedings between Mr Elchinov and the Natsionalna zdravnoosigurnitelna kasa (national social security fund; 'NZOK') concerning its refusal to authorise him to receive hospital treatment in Germany.

1.3.2. Legal context

European Union legislation

3 Article 22 of Regulation No 1408/71, entitled 'Stay outside the competent State – Return to or transfer of residence to another Member State during sickness or maternity – Need to go to another Member State in order to receive appropriate treatment', provides:

'1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:

...

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition, shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay ... in accordance with the provisions of the legislation which it administers,

as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

...

2. ...

The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.

...'

4 Article 36(1)⁹ of Regulation No 1408/71 provides:

'Benefits in kind provided in accordance with the provisions of this chapter by the institution of one Member State on behalf of the institution of another Member State shall be fully refunded.'

5 On the basis of Article 2(1) of Regulation (EEC) No 574/72 of the Council of 21 March 1972 fixing the procedure for implementing Regulation (EEC) No 1408/71 (OJ, English Special Edition, 1972 (I), p. 159), the Administrative Commission on Social Security for Migrant Workers, set up pursuant to Article 80 of Regulation No 1408/71, adopted a model for the certificate necessary for the application of Article 22(1)(c)(i) of that regulation, that is to say, form 'E 112'.

1.3.3. National legislation

6 Under Article 224 of the Bulgarian Code of Administrative Procedure:

'The directions of the Supreme Administrative Court on the interpretation and the application of the law are mandatory for the subsequent examination of the case'.

7 Under Article 81(1) of the Law on health (DV No 70 of 10 August 2004):

‘Every Bulgarian citizen has the right of access to health care on the terms and in accordance with the conditions laid down in the present law and by the Law on sickness insurance.’

8 By virtue of Article 33 of the Law on sickness insurance (DV No 70 of 19 June 1998), all Bulgarian citizens who are not also citizens of another State are compulsorily covered by NZOK.

9 Article 35 of that law provides that insured persons are entitled to obtain the document required for the exercise of their sickness insurance rights in compliance with the rules on the coordination of social security schemes.

10 Article 36(1) of that law provides:

‘Persons insured under the compulsory scheme shall be entitled to obtain reimbursement in part or in full of expenses incurred for medical treatment abroad only if they have obtained prior authorisation to that end from NZOK.’

11 The types of healthcare benefits covered by NZOK are listed in Article 45 of the Law on sickness insurance, paragraph 2 of which provides that the basic package of healthcare benefits is to be determined by a decree of the Minister for Health. On that basis, that Minister adopted Decree No 40 of 24 November 2004 on the determination of the package of basic healthcare benefits guaranteed by the NZOK budget (DV No 88, 2006), the single article of which states that that basic package is to include those benefits the type and range of which are set out in Annexes 1 to 10 to that Decree. Annex 5 thereto, entitled ‘List of clinical treatments’, refers, under number 136, to ‘other operations on the eyeball’ and, under number 258, to ‘high-technology radiotherapy for oncological and non-oncological conditions’.

The dispute in the main proceedings and the questions referred for a preliminary ruling

12 Mr Elchinov, a Bulgarian citizen covered by NZOK, suffers from a serious illness, on account of which he asked that fund, on 9 March 2007, to issue form E 112 with a view to his undergoing advanced treatment in a specialist clinic in Berlin (Germany), since such treatment was not available in Bulgaria.

13 Given his state of health, however, Mr Elchinov was admitted to hospital in Germany on 15 March 2007 and was treated there before receiving NZOK’s answer.

14 By decision of 18 April 2007, taken after the opinion of the Minister of Health had been obtained, the director of NZOK refused to give Mr Elchinov the authorisation sought, on the ground, inter alia, that the conditions for grant of such authorisation laid down in the Article 22 of Regulation No 1408/71 were not met, since that treatment, in the director's view, was not one of the benefits provided for by the Bulgarian legislation and reimbursed by NZOK.

15 Mr Elchinov appealed against that decision to the Administrativen sad Sofia-grad (Administrative Court of Sofia). An expert medical opinion obtained during the proceedings confirmed that the treatment in question was an advanced therapy which was not yet available in Bulgaria.

16 By judgment of 13 August 2007, the Administrativen sad Sofia-grad annulled that decision, taking the view that the conditions for grant of authorisation laid down by Article 22(2) of Regulation No 1408/71 were met in the present case. That court found, inter alia, that the treatment in question did not exist in Bulgaria, but corresponded to the services numbered 136 and 258 in the list of clinical treatments.

17 NZOK appealed against that judgment before the Varchoven administrativen Sad (Supreme Administrative Court), which, by judgment of 4 April 2008, set aside the judgment and referred the case back to a different chamber of the lower court. The Varchoven administrativen Sad held that the finding of the court at first instance that the treatment received by Mr Elchinov fell within the services numbered 136 and 258 in the list of clinical treatments was incorrect. In addition it pointed out that if the specific treatment for which the issue of form E 112 had been applied for was reimbursable by NZOK, it had to be presumed that such treatment could be given in a Bulgarian healthcare institution, so that the lower court should have ruled on whether such treatment could be given in such an institution within a period which would not endanger the state of health of the person concerned.

18 In the course of re-examination of the case by the Administrativen sad Sofia-grad, a fresh medical report confirmed that treatment such as that given to Mr Elchinov in Germany was not available in Bulgaria.

19 In those circumstances, the Administrativen sad Sofia-grad decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

‘1. Is the second subparagraph of Article 22(2) of ... Regulation ... No 1408/71 ... to be interpreted as meaning that, where it is impossible to give in a Bulgarian healthcare institution

the specific treatment that has been the subject of an application for the issue of form E 112, it is to be assumed that this treatment is not financed from the budget of [NZOK] or the Ministry of Health or, conversely, where such treatment is financed from the budget of NZOK or the Ministry of Health it is to be assumed that it can be given in a Bulgarian healthcare institution?

2. Is the phrase “the treatment in question cannot be provided for the person concerned within the territory of the Member State in which he resides” in the second paragraph of Article 22(2) of Regulation ... No 1408/71 to be interpreted as encompassing cases in which the treatment that is given in the territory of the Member State in which the insured person resides is much less effective and more radical than the treatment that is given in another Member State, or does it encompass only those cases in which the person concerned cannot be treated without undue delay?

3. Having regard to the principle of procedural autonomy: is the national court obliged to take account of binding directions given to it by a higher court when its decision is set aside and the case referred back for reconsideration if there is reason to assume that such directions are inconsistent with Community law?

4. If the particular treatment concerned cannot be given on the territory of the Member State in which the person with medical insurance resides is it then sufficient, in order for that Member State to be obliged to issue authorisation for treatment in another Member State under Article 22(1)(c) of Regulation ... No 1408/71, for the type of treatment concerned to be included within the benefits provided for under the legislation of the first mentioned Member State even if that legislation does not expressly stipulate the specific method of treatment?

5. Are Article 49 EC¹ and Article 22² of Regulation ... No 1408/71 inconsistent with a national provision such as Article 36(1) of the Law on health insurance, according to which persons insured under the compulsory scheme have the right to receive in part or in full [reimbursement of] the value of the expenses for medical care abroad only if they have received a preliminary permit?

6. Must the national court oblige the competent institution of the State in which the patient has medical insurance to issue the document for treatment abroad (form E 112) if it considers the refusal to issue such a document to be unlawful, where the application for the issue of the

document has been lodged before the treatment was carried out abroad and the treatment has been completed by the date on which the court decision is pronounced?

7. If the aforementioned question should be answered in the affirmative and the court should consider the refusal of authorisation for treatment abroad to be unlawful how is the person with medical insurance to be reimbursed the costs of his treatment:

(a) directly by the State in which he is insured or by the State in which the treatment has been given, following submission of authorisation for treatment abroad?

(b) to what extent, if the range of benefits that are provided for under the legislation of the Member State where he resides should differ from the range of benefits provided for under the legislation of the Member State in which the treatment is given, in the light of Article 49 EC, which prohibits restrictions on freedom to provide services?’

1.3.4. The questions referred

20 It is appropriate to answer the third question first, before examining the other six questions, which relate to the interpretation of Articles 49 EC¹ and 22² of Regulation No 1408/71.

The third question

21 It is apparent from the order for reference that the Administrativen sad Sofia-grad has doubts as to the interpretation of Articles 49 EC and 22 of Regulation No 1408/71 and, in particular, with regard to the interpretation of Article 22 adopted by the Varchoven administrativen sad in its judgement of 4 April 2008. While making a reference to the Court for a preliminary ruling on the interpretation of the abovementioned provisions, the national court questions whether the court dealing with the substance of the case is bound by the legal rulings of a higher court, if there is reason to assume that such rulings are inconsistent with European Union law.

22 The national court states that, pursuant to Article 224 of the Bulgarian Code of administrative procedure, directions given by the Varchoven administrativen sad on the interpretation and application of the law are binding on the Administrativen sad Sofia-grad on

re-examination of the case by that court. It also notes that European Union law observes the principle of the procedural autonomy of the Member States.

23 Although the question which it refers to the Court does not appear to exclude the possibility that a national court might consider adjudicating without making a preliminary reference, departing from legal rulings given in the same case by the higher national court, which it regards as inconsistent with European Union law, it must be noted that that is not the situation in the present case, since the national court has made a reference for a preliminary ruling to the Court seeking clarification of the doubts which it has as to the correct interpretation of European Union law.

24 Accordingly, by its third question, the national court asks whether European Union law precludes a national court which is called upon to decide a case referred back to it by a higher court hearing an appeal from being bound, in accordance with national procedural law, by legal rulings of the higher court, if it considers, having regard to the interpretation which it has sought from the Court, that those rulings are inconsistent with European Union law.

25 In that regard, it must be borne in mind, firstly, that the existence of a rule of national procedure such as that applicable in the case in the main proceedings cannot call into question the discretion of national courts not ruling at final instance to make a reference to the Court for a preliminary ruling where they have doubts, as in the present case, as to the interpretation of European Union law.

26 It is settled case-law that Article 267 TFEU gives national courts the widest discretion in referring matters to the Court if they consider that a case pending before them raises questions involving interpretation of provisions of European Union law, or consideration of their validity, which are necessary for the resolution of the case (see, to that effect, Case 166/73 *Rheinmühlen-Düsseldorf* [1974] ECR 33, paragraph 3; Case C 348/89 *Mecanarte* [1991] ECR I 3277, paragraph 44; Case C 261/95 *Palmisani* [1997] ECR I 4025, paragraph 20; Case C 210/06 *Cartesio* [2008] ECR I 9641, paragraph 88; and Joined Cases C 188/10 *Melki and Abdeli* [2010] ECR I 0000, paragraph 41). National courts are, moreover, free to exercise that discretion at whatever stage of the proceedings they consider appropriate (see, to that effect, *Melki and Abdeli*, paragraphs 52 and 57).

27 The Court has thus concluded that a rule of national law, pursuant to which courts that are not adjudicating at final instance are bound by legal rulings of a higher court, cannot take

away from those courts the discretion to refer to the Court questions of interpretation of the point of European Union law concerned by such legal rulings. The Court has held that a court which is not ruling at final instance must be free, if it considers that a higher court's legal ruling could lead it to give a judgment contrary to European Union law, to refer to the Court questions which concern it (see, to that effect, *Rheinmühlen-Düsseldorf*, paragraphs 4 and 5; *Cartesio*, paragraph 94; *Case C 378/08 ERG and Others* [2010] ECR I 0000, paragraph 32; and *Melki and Abdeli*, paragraph 42).

28 However, it must be pointed out that the possibility thus given to the national court by the second paragraph of Article 267 TFEU of asking the Court for a preliminary ruling before, if necessary, disapplying directions from a higher court which prove to be contrary to European Union law cannot be transformed into an obligation (see, to that effect, *Case C 555/07 Küçükdeveci* [2010] ECR I 0000, paragraphs 54 and 55).

29 Secondly, it must be borne in mind that it is settled case-law that a judgment in which the Court gives a preliminary ruling is binding on the national court, as regards the interpretation or the validity of the acts of the European Union institutions in question, for the purposes of the decision to be given in the main proceedings (see, *inter alia*, *Case 29/68 Milch-, Fett- und Eierkontor* [1969] ECR 165, paragraph 3; *Case 52/76 Benedetti v Munari* [1977] ECR 163, paragraph 26; order in *Case 69/85 Wünsche Handelsgesellschaft* [1986] ECR 947, paragraph 13; and *Case C 446/98 Fazenda Pública* [2000] ECR I 11435, paragraph 49).

30 It follows from those considerations that the national court, having exercised the discretion conferred on it by the second paragraph of Article 267 TFEU, is bound, for the purposes of the decision to be given in the main proceedings, by the interpretation of the provisions at issue given by the Court and must, if necessary, disregard the rulings of the higher court if it considers, having regard to that interpretation, that they are not consistent with European Union law.

31 In addition, it is appropriate to point out that, in accordance with settled case-law, a national court which is called upon, within the exercise of its jurisdiction, to apply provisions of European Union law is under a duty to give full effect to those provisions, if necessary refusing of its own motion to apply any conflicting provision of national legislation, that is to say, in the present case, the national procedural rule set out in paragraph 24 of this judgment, and it is not necessary for the court to request or await the prior setting aside of that national

provision by legislative or other constitutional means (see, to that effect, Case 106/77 Simmenthal [1978] ECR 629, paragraph 24, and Case C 314/08 Filipiak [2009] ECR I 0000, paragraph 81).

32 In the light of the foregoing, the answer to the third question is that European Union law precludes a national court which is called upon to decide a case referred back to it by a higher court hearing an appeal from being bound, in accordance with national procedural law, by legal rulings of the higher court, if it considers, having regard to the interpretation which it has sought from the Court, that those rulings are inconsistent with European Union law.

The questions regarding the interpretation of Articles 49 EC and 22 of Regulation No 1408/71

33 It is appropriate to examine first the fifth question, concerning the extent of the power of Member States to make reimbursement in respect of hospital treatment given in another Member State subject to prior authorisation, next, the first, second and fourth questions, concerning the conditions set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 and, finally, together, the sixth and seventh questions, concerning the means of reimbursement in respect of that treatment to the person insured.

The fifth question, concerning the extent of the power of Member States to make reimbursement in respect of hospital treatment given in another Member State subject to prior authorisation

34 By its fifth question, the national court asks, in essence, whether Articles 49 EC and 22 of Regulation No 1408/71 preclude legislation of a Member State which excludes, in all cases, reimbursement in respect of hospital treatment given in another Member State without prior authorisation.

35 The national court, recalling that Mr Elchinov had treatment in Germany before he had received NZOK's response to his request for authorisation, asks whether an insured person can seek reimbursement in respect of hospital treatment given in a Member State other than that in which he resides without having first obtained authorisation from the competent institution, where his state of health so required, or whether obtaining the treatment without such prior authorisation entails the insured person losing his right to seek reimbursement of its cost. Pointing out that Article 36 of the Law on sickness insurance permits reimbursement for treatment given in another Member State only if the insured person has obtained prior

authorisation for that treatment, it asks whether that provision is consistent with Articles 49 EC and 22 of Regulation No 1408/71.

36 In that regard, firstly, it should be noted that, according to settled case-law, medical services provided for consideration fall within the scope of the provisions on the freedom to provide services, including situations where care is provided in a hospital environment (see, to that effect, Case C 372/04 Watts [2006] ECR I 4325, paragraph 86 and the case-law cited, and Case C 211/08 Commission v Spain [2010] ECR I 0000, paragraph 47 and the case-law cited).

37 It has also been held that the freedom to provide services includes the freedom for the recipients of services, including persons in need of medical treatment, to go to another Member State in order to receive those services there (Watts, paragraph 87 and the case-law cited, and Commission v Spain, paragraphs 48 to 50 and the case-law cited).

38 The applicability of Article 22 of Regulation No 1408/71 to the situation in this case does not mean that provisions on the freedom to provide services and, in the circumstances, Article 49 EC, cannot apply at the same time. On the one hand, the fact that national legislation may possibly be in conformity with a provision of secondary legislation, in this case Article 22 of Regulation No 1408/71, does not have the effect of removing that legislation from the scope of the provisions of the EC Treaty (see, to that effect, Watts, paragraphs 46 and 47, and Commission v Spain, paragraph 45).

39 On the other hand, the purpose of Article 22(1)(c)(i) of Regulation No 1408/71 is to confer a right to the benefits in kind provided, on behalf of the competent institution, by the institution of the place where the insured person is staying, in accordance with the provisions of the legislation of the Member State in which the benefits are provided as if the person concerned were registered with that institution (see, to that effect, Case C 120/95 Decker [1998] ECR I 1831, paragraphs 28 and 29; Case C 158/96 Kohll [1998] ECR I 1931, paragraphs 26 and 27; Case C 368/98 Vanbraekel and Others [2001] ECR I 5363, paragraphs 32 and 36; Case C 56/01 Inizan [2003] ECR I 12403, paragraphs 19 and 20; and Watts, paragraph 48). The sole purpose of the second subparagraph of Article 22(2) of Regulation No 1408/71 is to identify the circumstances in which the competent national institution is precluded from refusing authorisation sought on the basis of Article 22(1)(c) (see, to that effect, Vanbraekel and Others, paragraph 31).

40 Secondly, it must also be borne in mind that, as submitted by the Governments which have submitted observations in the present case, it is established that European Union law does not detract from the power of the Member States to organise their social security systems and that, in the absence of harmonisation at European Union level, it is for the legislation of each Member State to determine the conditions for the grant of social security benefits. The fact nevertheless remains that, when exercising that power, Member States must comply with European Union law and, in particular, with the provisions on the freedom to provide services which prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector (see in particular, to that effect, Watts, paragraph 92 and the case-law cited; Case C 444/05 Stamatelaki [2007] ECR I 3185, paragraph 23; and Commission v Spain, paragraph 53).

41 Although prior authorisation, such as that required by Article 36 of the Law on sickness insurance, constitutes, for both patients and service providers, an obstacle to the freedom to provide services (see, to that effect, Kohll, paragraph 35; Case C 157/99 Smits and Peerbooms [2001] ECR I 5473, paragraph 69; Case C 385/99 Müller-Fauré and van Riet [2003] ECR I 4509, paragraph 44; and Watts, paragraph 98), the Court has nevertheless held that Article 49 EC does not in principle preclude the right of a patient to receive hospital treatment in another Member State at the expense of the system with which he is registered from being subject to prior authorisation (Smits and Peerbooms, paragraph 82, and Watts, paragraph 113).

42 The Court has held that it cannot be excluded that the possible risk of seriously undermining the financial balance of a social security system may constitute an overriding reason in the public interest capable of justifying an obstacle to the freedom to provide services. The Court has likewise acknowledged that the objective of maintaining a balanced medical and hospital service open to all may also fall within the derogations on grounds of public health under Article 46 EC in so far as it contributes to the attainment of a high level of health protection. It has also held that Article 46 EC permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for public health, and even the survival of the population (see, to that effect, Kohll, paragraphs 41, 50 and 51; Smits and Peerbooms, paragraphs 72 to 74; Müller-Fauré and van Riet, paragraphs 67 and 73; and Watts, paragraphs 103 to 105).

43 The Court has also pointed out that the number of hospitals, their geographical distribution, the mode of their organisation and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning, generally designed to satisfy various needs, must be possible. For one thing, such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the State concerned. For another thing, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. Such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied (Smits and Peerbooms, paragraphs 76 to 79, and Watts, paragraphs 108 and 109).

44 Thirdly, it must also be borne in mind that, although European Union law does not preclude, in principle, a system of prior authorisation, it is nevertheless necessary that the conditions attached to the grant of such authorisation must be justified in the light of the imperatives mentioned above, that they do not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules. Such a system must, in addition, be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily (see, to that effect, Smits and Peerbooms, paragraphs 82 and 90; Müller-Fauré and van Riet, paragraphs 83 to 85; and Watts, paragraphs 114 to 116).

45 In the present case, it is clear that a national rule excluding, in all cases, payment for hospital treatment given in another Member State without prior authorisation deprives the insured person who, for reasons relating to his state of health or to the need to receive urgent treatment in a hospital, was prevented from applying for such authorisation or was not able, like Mr Elchinov, to wait for the answer of the competent institution, of reimbursement from that institution in respect of such treatment, even though all other conditions for such reimbursement to be made are met.

46 Reimbursement in respect of such treatment, in the particular situations described in the preceding paragraph, is not likely to compromise achievement of the objectives of hospital planning referred to in paragraph 43 above, nor seriously to undermine the financial balance

of the social security system. It does not affect the maintenance of a balanced hospital service accessible to all, or that of treatment capacity and medical competence on national territory.

47 Consequently, such legislation is not justified by such imperatives and, in any event, does not satisfy the requirement of proportionality referred to in paragraph 44 of this judgment. Thus, it constitutes an unjustified restriction on the freedom to provide services.

48 In addition, with regard to the application of Article 22(1)(c) of Regulation No 1408/71, the Court held, in paragraph 34 of *Vanbraekel and Others*, that, where the request of an insured person for authorisation on the basis of that provision has been refused by the competent institution and it is subsequently established, either by the competent institution itself or by a court decision, that that refusal was unjustified, that person is entitled to be reimbursed directly by the competent institution in an amount equivalent to that which it would ordinarily have borne if authorisation had been properly granted at the outset.

49 It follows that the legislation of a Member State cannot exclude, in all cases, reimbursement in respect of hospital treatment given in another Member State without prior authorisation.

50 With regard to the legislation at issue in the case in the main proceedings, as the Advocate General observed, in essence, in points 49 and 50 of his Opinion, Article 36 of the Law on sickness insurance is ambiguous. In any event, it is for the national court to assess, in the light of the guidance given in the present judgment, whether that article is consistent with Articles 49 EC and 22 of Regulation No 1408/71 as interpreted by the Court and, in so far as the said Article 36 may be subject to a number of interpretations, to interpret it in a way which accords with European Union law (see, to that effect, *Melki and Abdeli*, paragraph 50 and the case-law cited).

51 In the light of all the foregoing, the answer to the fifth question is that Articles 49 EC and 22 of Regulation No 1408/71 preclude legislation of a Member State which is interpreted as excluding, in all cases, reimbursement in respect of hospital treatment given in another Member State without prior authorisation.

The first, second and fourth questions, concerning the conditions set out in the second subparagraph of Article 22(2) of Regulation No 1408/71

52 By its first, second and fourth questions, the national court asks, in essence, whether, with regard to medical treatment which cannot be given in the Member State in whose territory the insured person resides, the second subparagraph of Article 22(2) of Regulation No 1408/71 must be interpreted as meaning that the authorisation required under Article 22(1)(c)(i) cannot be refused where, on the one hand, the treatment in question is among the benefits provided for under the legislation of the Member State on whose territory the person concerned resides, but that legislation does not expressly and precisely stipulate the method of treatment applied, and, on the other hand, he cannot be given alternative treatment offering the same level of effectiveness without undue delay. In addition, it wishes to know whether that article is to be interpreted as precluding the national bodies called upon to rule on an application for prior authorisation from presuming, in the application of that provision, that the hospital treatment which cannot be given in that Member State is not included in the benefits for which reimbursement is provided for by the legislation of that State or, conversely, that the hospital treatment included in those benefits can be given in that Member State.

53 The second subparagraph of Article 22(2) of Regulation No 1408/71 lays down two conditions which, if both are satisfied, render mandatory the grant by the competent institution of the prior authorisation applied for on the basis of Article 22(1)(c)(i) (see, to that effect, *Inizan*, paragraph 41, and *Watts*, paragraph 55).

54 The first condition requires the treatment in question to be among the benefits provided for by the legislation of the Member State on whose territory the insured person resides, whereas the second condition requires that the treatment which the latter plans to undergo in a Member State other than that on the territory of which he resides cannot be given within the time normally necessary for obtaining the treatment in question in the Member State of residence, taking account of his current state of health and the probable course of his disease (*Inizan*, paragraphs 42 and 44, and *Watts*, paragraphs 56 and 57).

55 Since the fourth question referred to the Court concerns the first of those conditions, it is appropriate to consider it first. Next, the second question, which concerns the second of those conditions, will be analysed and, finally, the first question, which concerns the presumption referred to in the order for reference, will be examined, since the answer to that question follows from those given to the other two questions.

– The fourth question, concerning the first condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71

56 In order to establish whether the first condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 is met, it is necessary to ascertain whether the ‘the treatment in question’, namely as appears from the documents presented to the Court, the treatment for the eye prescribed by medical prescription and consisting of the attachment of radioactive applicators or proton therapy, is among the ‘benefits provided for by the legislation of the Member State on whose territory the person concerned resides’, that is to say among the benefits for which the Bulgarian social security scheme provides for reimbursement.

57 In that regard, it must be pointed out that, as recalled in paragraph 40 of the present judgment, European Union law does not detract from the power of the Member States to organise their social security systems and that, in the absence of harmonisation at European Union level, it is for the legislation of each Member State to determine the conditions for the grant of social security benefits.

58 Thus, it has already been held that it is not, in principle, incompatible with European Union law for a Member State to establish exhaustive lists of the medical benefits reimbursed under its social security scheme and that that right cannot, in principle, have the effect of requiring a Member State to extend such lists of medical benefits (see, to that effect, *Smits and Peerbooms*, paragraph 87).

59 It follows that, as submitted by the Governments which have made observations in the present case, it is for each Member State to decide which medical benefits are reimbursed by its own social security system. To that end, the Member State concerned is entitled to list precisely treatments or treatment methods or to state more generally the categories or types of treatments or treatment methods.

60 In that context, it is only those national bodies called upon to rule on an application for authorisation to receive treatment in a Member State other than that on the territory of which the insured person resides which can determine whether that treatment is included on such a list. In the present case, it is for the national court to decide whether the treatment received by Mr Elchinov in Germany is included in the clinical treatments listed in Annex 5 to Decree No 40.

61 Nevertheless, the fact remains that, since the Member States are required not to disregard European Union law in the exercise of their powers, it must be ensured that the second subparagraph of Article 22(2) of Regulation No 1408/71 is applied in a way which accords with that law, in compliance with the requirements set out in paragraph 44 of the present judgment.

62 It follows from the above, where the list of medical benefits reimbursed does not expressly and precisely specify the treatment method applied but defines types of treatment, on the one hand, that it is for the competent institution of the Member State of residence of the insured person to assess, applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and the available scientific data, whether that treatment method corresponds to benefits provided for by the legislation of that Member State. It also follows, on the other hand, that, if such is the case, an application for prior authorisation cannot be refused on the ground that such a treatment method is not available in the Member State of residence of the insured person, since such a ground, if it were accepted, would imply a restriction on the scope of the second subparagraph of Article 22(2) of Regulation No 1408/71.

– The second question, concerning the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71

63 In order to establish whether the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 is met, it is necessary to ascertain whether the treatment in question can be given to the insured person within the time normally necessary for obtaining that treatment in the Member State of residence, taking account of his current state of health and the course of the disease.

64 In the present case, the national court states that the treatment in question cannot be given in the Member State of residence of the person concerned, where he would have undergone surgery which, in its opinion, cannot be considered an identical treatment or one having the same degree of effectiveness. Although the fact that the treatment proposed in another Member State is not carried out in the Member State of residence of the insured person does not imply, per se, that the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 is met, clearly and conversely, that it must be the case where no treatment having the same degree of effectiveness can be given without undue delay.

65 The Court has already held that the second subparagraph of Article 22(2) of Regulation No 1408/71 must be interpreted as meaning that the authorisation to which that provision refers cannot be refused when it appears that the first condition set out therein is met and that the same or equally effective treatment cannot be given without undue delay in the Member State of residence of the insured person (see, to that effect, *Inizan*, paragraphs 45, 59 and 60, and *Watts*, paragraphs 59 to 61).

66 The Court has pointed out in that regard that, in order to determine whether treatment which is equally effective for the patient can be obtained without undue delay in the Member State of residence, the competent institution is required to have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history (*Inizan*, paragraph 46, and *Watts*, paragraph 62).

67 Thus, in a situation where the treatment in question cannot be given in the Member State on whose territory the insured person resides and the benefits provided for by the legislation of that Member State are not given as an exact list of treatments or treatment methods but as a more general definition of categories or types of treatment or treatment methods, the second subparagraph of Article 22(2) of Regulation No 1408/71 implies that, if it is established that the treatment proposed in another Member State falls within one of those categories or corresponds to one of those types, the competent institution is required to give the insured person the authorisation necessary for the reimbursement of the cost of that treatment, when the alternative treatment which can be given without undue delay in the Member State of his residence is not, as in the situation described by the national court, equally effective.

– The first question, concerning the presumption referred to in the order for reference

68 As background to that question, the national court states that, according to the indications given in the case in the main proceedings by the Varchoven administrativen sad, if the hospital treatment under consideration cannot be given in Bulgaria, it is appropriate to presume that that treatment is not included in the medical treatment reimbursed by NZOK and, conversely, if such treatment is reimbursed by NZOK, it may be presumed that it can be given in Bulgaria. That court is doubtful where such a presumption is consistent with Article

22 of Regulation No 1408/71, since in its view it means that the two conditions set out in the second subparagraph of Article 22(2) can be met only if treatment that is equally effective is available in the Member State of residence, but cannot be given without undue delay.

69 In that regard, it must be noted that it follows from the interpretation of the second subparagraph of Article 22(2) of Regulation No 1408/71 given in the context of the examination of the fourth and second questions that a decision on an application for authorisation required under Article 22(1)(c)(i) cannot be based on such a presumption.

70 Firstly, it follows from the findings in paragraph 62 of the present judgment, on the one hand, that in each case an assessment must be made, applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and the available scientific data, as to whether the treatment method in question corresponds to benefits provided for by national legislation and, on the other, that an application for prior authorisation cannot be refused on the ground that such a treatment method is not available in the Member State of residence of the insured person.

71 Secondly, it follows from what has been stated in paragraphs 64 to 67 of the present judgment that an application for authorisation cannot be refused where the same or equally effective treatment as that proposed cannot be given in the Member State of residence without undue delay, which must also be ascertained in each case.

72 Apart from the fact that use of the presumption referred to in the first question referred by the national court would have the effect of restricting the scope of the second subparagraph of Article 22(2) of Regulation No 1408/71, it would lead to the creation of an obstacle to the freedom to provide services in the health sector which could not be justified by the imperatives referred to in paragraphs 42 and 43 of the present judgment.

73 In the light of those considerations, the answer to the first, second and fourth questions is that, with regard to medical treatment which cannot be given in the Member State on whose territory the insured person resides, the second subparagraph of Article 22(2) of Regulation No 1408/71 must be interpreted as meaning that authorisation required under Article 22(1)(c)(i) cannot be refused:

– if, where the list of benefits for which the national legislation provides does not expressly and precisely specify the treatment method applied but defines types of treatment

reimbursed by the competent institution, it is established, applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and the available scientific data, that the treatment method in question corresponds to types of treatment included in that list, and

– if no alternative treatment which is equally effective can be given without undue delay in the Member State on whose territory the insured person resides.

That article precludes the national bodies called upon to rule on an application for prior authorisation from presuming, in the application of that provision, that the hospital treatment which cannot be given in the Member State on whose territory the insured person resides is not included in the benefits for which reimbursement is provided for by the legislation of that State and, conversely, that the hospital treatment included in those benefits can be given in that Member State.

The sixth and seventh questions, concerning the arrangements for reimbursement of the insured person for hospital treatment given in another Member State

74 By its sixth and seventh questions, the referring court asks whether the national court must oblige the competent institution to issue the insured person with form E 112 if it considers, even where the treatment has been completed by the date on which the court decision is pronounced, the refusal to issue such a document to be unlawful. In addition, it asks whether, in that case, the cost of the hospital treatment must be reimbursed to the insured person by the competent institution or by the institution of the place where the treatment was given and to what extent the reimbursement must be made, where the range of the benefits provided for by the legislation of the Member State of residence of the insured person differs from that of the benefits provided for by the Member State on whose territory the treatment was given.

75 In that regard, it is appropriate to note that the issue of prior authorisation such as that given under form E 112 does not appear to serve any purpose where the hospital treatment has already been given to the insured person except, possibly, if the insured person has not yet received the invoice for the treatment or has not paid it. If that is not the case, as has been pointed out in paragraph 48 of the present judgment, the insured person is entitled to be reimbursed directly by the competent institution in an amount equivalent to that which it

would ordinarily have reimbursed if authorisation had been properly granted before treatment began.

76 In any event, it is for the national court to oblige the competent institution, in accordance with national procedural rules, to reimburse the amount referred to in the preceding paragraph.

77 That amount is equal to that determined in accordance with the provisions of the legislation to which the institution of the Member State on whose territory the hospital treatment was given is subject (see, to that effect, *Vanbraekel and Others*, paragraph 32).

78 If the amount of the reimbursement of the expenses incurred for hospital treatment provided in a Member State other than that of residence, resulting from the rules in force in that State, is less than that which would have resulted from application of the legislation in force in the Member State of residence if hospital treatment had been provided there, pursuant to Article 49 EC, as interpreted by the Court, complementary reimbursement corresponding to the difference between those two amounts must, in addition, be made by the competent institution (see, to that effect, *Vanbraekel and Others*, paragraphs 38 to 52, and *Commission v Spain*, paragraphs 56 and 57).

79 The Court has stated that where, under the legislation of the competent Member State, hospital treatment provided under the national health service is to be free of charge, and where the legislation of the Member State in which a patient registered with that service was or should have been authorised to receive hospital treatment at the expense of that service does not provide for the reimbursement in full of the cost of that treatment, the competent institution must reimburse that patient the difference (if any) between the cost, objectively quantified, of equivalent treatment in a hospital covered by the service in question up to the total amount invoiced for the treatment provided in the host Member State and the amount which the institution of the latter Member State is required to reimburse under Article 22(1)(c)(i) of Regulation No 1408/71 on behalf of the competent institution pursuant to the legislation of that Member State (*Watts*, paragraph 143).

80 It is appropriate to add, as the Advocate General observed in point 85 of his Opinion, that where insured persons receive hospital treatment in a Member State other than that of residence without applying for authorisation under Article 22(1)(c)(i) of Regulation No 1408/71, they can claim reimbursement of the cost of the treatment given to them, on the

basis of Article 49 EC, only within the limits of the cover provided by the sickness insurance scheme to which they are affiliated (see, to that effect, Müller-Fauré and van Riet, paragraphs 98 and 106). The same applies where a refusal to issue the prior authorisation required under Article 22 is justified.

81 In the light of those considerations, the answer to the sixth and seventh questions is:

– Where it is established that a refusal to issue the authorisation required under Article 22(1)(c)(i) of Regulation No 1408/71 was unjustified, when the hospital treatment has been completed and the related expenses incurred by the insured person, the national court must oblige the competent institution, in accordance with national procedural rules, to reimburse that insured person in the amount which it would ordinarily have paid if authorisation had been properly granted.

– That amount is equal to that determined in accordance with the provisions of the legislation to which the institution of the Member State on whose territory the hospital treatment was given is subject. If that amount is less than that which would have resulted from application of the legislation in force in the Member State of residence if hospital treatment had been provided there, a complementary reimbursement corresponding to the difference between those two amounts must in addition be made by the competent institution.

1.3.5. Costs

82 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

1.3.6. The Court's decision

1. European Union law precludes a national court which is called upon to decide a case referred back to it by a higher court hearing an appeal from being bound, in accordance with

national procedural law, by legal rulings of the higher court, if it considers, having regard to the interpretation which it has sought from the Court, that those rulings are inconsistent with European Union law.

2. Articles 49 EC¹ and 22² of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996, as amended by Regulation (EC) No 1992/2006 of the European Parliament and of the Council of 18 December 2006, preclude a rule of a Member State which is interpreted as excluding, in all cases, payment for hospital treatment given in another Member State without prior authorisation.

3. With regard to medical treatment which cannot be given in the Member State on whose territory the insured person resides, the second subparagraph of Article 22(2)² of Regulation No 1408/71, as amended and updated by Regulation No 118/97, as amended by Regulation No 1992/2006, must be interpreted as meaning that that authorisation required under Article 22(1)(c)(i) cannot be refused:

- if, where the list of benefits for which the national legislation provides does not expressly and precisely specify the treatment method applied but defines types of treatment reimbursed by the competent institution, it is established, applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and the available scientific data, that the treatment method in question corresponds to types of treatment included in that list, and
- if no alternative treatment which is equally effective can be given without undue delay in the Member State on whose territory the insured person resides.

That article precludes the national bodies called upon to rule on an application for prior authorisation from presuming, in the application of that provision, that the hospital treatment which cannot be given in the Member State on whose territory the insured person resides is not included in the benefits for which reimbursement is provided for by the legislation of that State or, conversely, that the hospital treatment included in those benefits can be given in that Member State.

4. Where it is established that a refusal to issue the authorisation required under Article 22(1)(c)(i)² of Regulation No 1408/71, as amended and updated by Regulation No 118/97, as

amended by Regulation No 1992/2006, was unjustified, when the hospital treatment has been completed and the related expenses incurred by the insured person, the national court must oblige the competent institution, in accordance with national procedural rules, to reimburse that insured person in the amount which it would ordinarily have paid if authorisation had been properly granted.

That amount is equal to that determined in accordance with the provisions of the legislation to which the institution of the Member State on whose territory the hospital treatment was given is subject. If that amount is less than that which would have resulted from application of the legislation in force in the Member State of residence if hospital treatment had been provided there, complementary reimbursement corresponding to the difference between those two amounts must in addition be made by the competent institution.

1.4. **Kohll v Union Des Caisses De Maladie**³

REFERENCE to the Court under Article 177¹⁰ of the EC Treaty by the Cour de Cassation (Luxembourg) for a preliminary ruling in the proceedings pending before that court between Raymond Kohll and Union des Caisses de Maladie on the interpretation of Articles 59¹¹ and 60¹² of the EC Treaty,

1.4.1. Judgment

1 By judgment of 25 April 1996, received at the Court on 9 May 1996, the Luxembourg Cour de Cassation (Court of Cassation) referred to the Court for a preliminary ruling under Article 177 of the EC Treaty two questions on the interpretation of Articles 59 and 60^{11 12} of that Treaty.

2 Those questions arose in proceedings between Mr Kohll, a Luxembourg national, and the Union des Caisses de Maladie (hereinafter 'UCM'), with which he is insured, concerning a request by a doctor established in Luxembourg for authorisation for his daughter, who is a minor, to receive treatment from an orthodontist established in Trier (Germany).

³ Judgment Of The Court 28 April 1998' In Case C-158/96

3 By decision of 7 February 1994 following a negative opinion of the social security medical supervisors, the request was rejected on the grounds that the proposed treatment was not urgent and that it could be provided in Luxembourg. That decision was confirmed on 27 April 1994 by a decision of the UCM board.

4 Mr Kohll appealed against that decision to the Conseil Arbitral des Assurances Sociales (Social Insurance Arbitration Council), arguing that the provisions relied on were contrary to Article 59 of the Treaty. The appeal was dismissed by decision of 6 October 1994.

5 Mr Kohll appealed against the latter decision to the Conseil Supérieur des Assurances Sociales (Higher Social Insurance Council), which by judgment of 17 July 1995 upheld the contested decision on the ground that Article 20 of the Luxembourg Codes des Assurances Sociales (Social Insurance Code) and Articles 25 and 27 of the UCM statutes were consistent with Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community (see the version amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996, OJ 1997 L 28, p. 1).

6 It appears from Article 20(1) of the Code des Assurances Sociales, as amended by the Law of 27 July 1992, which entered into force on 1 January 1994, that with the exception of emergency treatment received in the event of illness or accident abroad, insured persons may be treated abroad or approach a treatment centre or centre providing ancillary facilities abroad only after obtaining the prior authorisation of the competent social security institution.

7 The terms and conditions for granting authorisation are laid down by Articles 25 to 27 of the UCM statutes, in the version which entered into force on 1 January 1995. Article 25 prescribes in particular that authorisation may not be given for services which are not reimbursable under the national rules. Article 26 states that the cost of duly authorised treatment is to be reimbursed in accordance with the tariffs applicable to persons insured under the social security system of the State in which the treatment is provided. Under Article 27, finally, authorisation will be granted only after a medical assessment and on production of a written request from a doctor established in Luxembourg indicating the doctor or hospital centre recommended and the facts and criteria which make it impossible for the treatment in question to be carried out in Luxembourg. 8 Article 22² of Regulation No 1408/71 provides in particular:

' 1 . An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition, shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

(ii) to cash benefits provided by the competent institution in accordance with the provisions of the legislation which it administers. However, by agreement between the competent institution and the institution of the place of stay or residence, such benefits may be provided by the latter institution on behalf of the former, in accordance with the provisions of the legislation of the competent State.

2. ...

The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.

3. The provisions of paragraphs 1 and 2 shall apply by analogy to members of the family of an employed or self-employed person.

...'

9 Mr Kohll appealed against the judgment of the Conseil Supérieur des Assurances Sociales, arguing in particular that it had considered only whether the national rules were consistent with Regulation No 1408/71, and not whether they were consistent with Articles 59¹¹ and 60¹² of the Treaty.

10 Since it considered that that argument raised a question concerning the interpretation of Community law, the Cour de Cassation stayed the proceedings and referred the following two questions to the Court for a preliminary ruling:

' 1 . Are Articles 59 and 60 of the Treaty establishing the EEC to be interpreted as precluding rules under which reimbursement of the cost of benefits is subject to authorisation by the insured person's social security institution if the benefits are provided in a Member State other than the State in which that person resides?

2. Is the answer to Question 1 any different if the aim of the rules is to maintain a balanced medical and hospital service accessible to everyone in a given region?'

1 1 By those questions, which should be taken together, the national court essentially asks whether Articles 59 and 60 of the Treaty preclude the application of social security rules such as those at issue in the main proceedings.

1 2 Mr Kohll submits that Articles 59¹¹ and 60¹² of the Treaty preclude such national rules which make reimbursement, in accordance with the scale of the Member State of insurance, of the cost of dental treatment provided by an orthodontist established in another Member State subject to authorisation by the insured person's social security institution.

13 UCM and the Luxembourg, Greek and United Kingdom Governments contend that those provisions are not applicable, or, in the alternative, do not preclude the rules in question from being maintained. The German, French and Austrian Governments agree with the alternative submission.

14 The Commission submits that the rules constitute a barrier to the freedom to provide services but may be justified, under certain conditions, by overriding reasons relating to the general interest.

15 Having regard to the observations submitted, the questions to be considered concern first the application of the principle of freedom of movement in the field of social security, then the effect of Regulation No 1408/71, and finally the application of the provisions on freedom to provide services.

Application of the fundamental principle of freedom of movement in the field of social security

16 The Luxembourg, Greek and United Kingdom Governments submit that the rules at issue in the main proceedings do not fall within the scope of the Community provisions on freedom to provide services, in that they concern social security, and so should be examined solely from the point of view of Article 22² of Regulation No 1408/71.

17 It must be observed, first of all, that, according to settled case-law, Community law does not detract from the powers of the Member States to organise their social security systems (Case 238/82 Duphar and Others v Netherlands [1984] ECR 523, paragraph 16, and Case C-70/95 Sodemare and Others v Regione Lombardia [1997] ECR I-3395, paragraph 27).

18 In the absence of harmonisation at Community level, it is therefore for the legislation of each Member State to determine, first, the conditions concerning the right or duty to be insured with a social security scheme (Case 110/79 Coonan v Insurance Officer [1980] ECR 1445, paragraph 12, and Case C-349/87 Paraschi v Landesversicherungsanstalt Württemberg [1991] ECR I-4501, paragraph 15) and, second, the conditions for entitlement to benefits (Joined Cases C-4/95 and C-5/95 Stöber and Piosa Pereira v Bundesanstalt für Arbeit [1997] ECR I-511, paragraph 36).

19 As the Advocate General observes in points 17 to 25 of his Opinion, the Member States must nevertheless comply with Community law when exercising those powers.

20 The Court has held that the special nature of certain services does not remove them from the ambit of the fundamental principle of freedom of movement (Case 279/80 Webb [1981] ECR 3305, paragraph 10).

21 Consequently, the fact that the national rules at issue in the main proceedings fall within the sphere of social security cannot exclude the application of Articles 59 and 60 of the Treaty. Effect of Regulation No 1408/71

22 UCM and the Luxembourg Government submit that Article 22² of Regulation No 1408/71 lays down the principle that prior authorisation is required for any treatment in another Member State. To challenge the national provisions relating to reimbursement of the cost of services obtained abroad amounts to calling into question the validity of the corresponding provision in Regulation No 1408/71.

23 In the proceedings before the Court, Mr Kohll submitted that he sought reimbursement by UCM of the amount he would have been entitled to if the treatment had been carried out by the only specialist established in Luxembourg at the material time.

24 On that point, UCM considers that the principle that a person is subject to one social security tariff only would indeed be complied with if the Luxembourg tariff were applied, but claims that Regulation No 1408/71 would compel it to reimburse expenditure according to the tariffs in force in the State in which the service was provided.

25 It must be stated that the fact that a national measure may be consistent with a provision of secondary legislation, in this case Article 22 of Regulation No 1408/71, does not have the effect of removing that measure from the scope of the provisions of the Treaty.

26 Moreover, as the Advocate General observes in points 55 and 57 of his Opinion, Article 22(1)² of Regulation No 1408/71 is intended to allow an insured person, authorised by the competent institution to go to another Member State to receive there treatment appropriate to his condition, to receive sickness benefits in kind, on account of the competent institution but in accordance with the provisions of the legislation of the State in which the services are provided, in particular where the need for the transfer arises because of the state of health of the person concerned, without that person incurring additional expenditure.

27 On the other hand, Article 22 of Regulation N o 1408/71, interpreted in the light of its purpose, is not intended to regulate and hence does not in any way prevent the reimbursement by Member States, at the tariffs in force in the competent State, of costs incurred in connection with treatment provided in another Member State, even without prior authorisation.

28 Consequently, the Court must examine the compatibility of national rules such as those at issue in the main proceedings with the Treaty provisions on freedom to provide services.
Application of the provisions on freedom to provide services

29 The dispute before the national court concerns treatment provided by an orthodontist established in another Member State, outside any hospital infrastructure. That service, provided for remuneration, must be regarded as a service within the meaning of Article 60¹² of the Treaty, which expressly refers to activities of the professions.

30 It must therefore be examined whether rules such as those at issue in the main proceedings constitute a restriction on freedom to provide services, and if so, whether they may be objectively justified. Restrictive effects of the rules at issue

31 Mr Kohll and the Commission submit that the fact that reimbursement of the cost of medical services, in accordance with the legislation of the State of insurance, is subject to prior authorisation by the institution of that State where the services are provided in another Member State constitutes a restriction on freedom to provide services within the meaning of Articles 59 and 60 of the Treaty.

32 The Member States which have submitted observations consider, on the contrary, that the rules at issue do not have as their purpose or effect to restrict freedom to provide services, but merely lay down the conditions for the reimbursement of medical expenses.

33 It should be noted that, according to the Court's case-law, Article 59¹¹ of the Treaty precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within one Member State (Case C-381/93 *Commission v France* [1994] ECR I-5145, paragraph 17).

34 While the national rules at issue in the main proceedings do not deprive insured persons of the possibility of approaching a provider of services established in another Member State, they do nevertheless make reimbursement of the costs incurred in that Member State subject to prior authorisation, and deny such reimbursement to insured persons who have not obtained that authorisation. Costs incurred in the State of insurance are not, however, subject to that authorisation.

35 Consequently, such rules deter insured persons from approaching providers of medical services established in another Member State and constitute, for them and their patients, a barrier to freedom to provide services (see *Joined Cases 286/82 and 26/83 Luisi and Carbone v Ministero del Tesoro* [1984] ECR 377, paragraph 16, and *Case C-204/90 Bachmann v Belgium* [1992] ECR I-249, paragraph 31).

36 The Court must therefore examine whether a measure of the kind at issue in this case may be objectively justified.

1.4.2. Justification of the rules at issue

37 UCM and the Governments of the Member States which have submitted observations submit that freedom to provide services is not absolute and that reasons connected with the control of health expenditure must be taken into consideration.

The requirement of prior authorisation constitutes the only effective and least restrictive means of controlling expenditure on health and balancing the budget of the social security system.

38 According to UCM, the Luxembourg Government and the Commission, the risk of upsetting the financial balance of the social security scheme, which aims to ensure a balanced medical and hospital service available to all its insured, constitutes an overriding reason in the general interest capable of justifying restrictions on freedom to provide services.

39 The Commission adds that the refusal of the national authorities to grant prior authorisation must be justified by a genuine and actual risk of upsetting the financial balance of the social security scheme.

40 On the latter point, Mr Kohll submits that the financial burden on the budget of the Luxembourg social security institution is the same whether he approaches a Luxembourg orthodontist or one established in another Member State, since he asked for medical expenses to be reimbursed at the rate applied in Luxembourg. The rules at issue therefore cannot be justified by the need to control health expenditure.

41 It must be recalled that aims of a purely economic nature cannot justify a barrier to the fundamental principle of freedom to provide services (see, to that effect, Case C-398/95 *SETTG v Ypourgos Ergasias* [1997] ECR I-3091, paragraph 23). However, it cannot be excluded that the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest capable of justifying a barrier of that kind.

42 But, contrary to the submissions of UCM and the Luxembourg Government, it is clear that reimbursement of the costs of dental treatment provided in other Member States in accordance with the tariff of the State of insurance has no significant effect on the financing of the social security system.

43 The Luxembourg Government also relies on grounds based on the protection of public health, arguing, first, that the rules at issue are necessary to guarantee the quality of medical services, which in the case of persons going to another Member State can be ascertained only at the time of the request for authorisation, and, second, that the Luxembourg sickness insurance system aims to provide a balanced medical and hospital service open to all insured persons.

44 Mr Kohll submits, on the other hand, that there is no scientific reason to conclude that treatment provided in Luxembourg is more effective, now that the pursuit of the medical professions is the subject of mutual recognition between Member States. He further submits that the reference to a balanced medical and hospital sector open to all must above all be categorised as an economic aim intended to protect UCM's financial resources.

45 It should be noted, first of all, that under Articles 56¹³ and 66¹⁴ of the EC Treaty Member States may limit freedom to provide services on grounds of public health.

46 However, that does not permit them to exclude the public health sector, as a sector of economic activity and from the point of view of freedom to provide services, from the application of the fundamental principle of freedom of movement (see Case 131/85 *Gül v Regierungspräsident Düsseldorf* [1986] ECR 1573, paragraph 17).

47 The conditions for taking up and pursuing the profession of doctor and dentist have been the subject of several coordinating or harmonising directives (see Council Directive 78/686/EEC of 25 July 1978 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of practitioners of dentistry, including measures to facilitate the effective exercise of the right of establishment and freedom to provide services (OJ 1978 L 233, p. 1); Council Directive 78/687/EEC of 25 July 1978 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of the activities of dental practitioners (OJ 1978 L 233, p. 10); and Council Directive 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications (OJ 1993 L 165, p. 1)).

48 It follows that doctors and dentists established in other Member States must be afforded all guarantees equivalent to those accorded to doctors and dentists established on national territory, for the purposes of freedom to provide services.

49 Consequently, rules such as those applicable in the main proceedings cannot be justified on grounds of public health in order to protect the quality of medical services provided in other Member States.

50 As to the objective of maintaining a balanced medical and hospital service open to all, that objective, although intrinsically linked to the method of financing the social security system, may also fall -within the derogations on grounds of public health under Article 56 of the Treaty, in so far as it contributes to the attainment of a high level of health protection.

51 Article 56 of the Treaty permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of a treatment facility or medical service on national territory is essential for the public health and even the survival of the population (see, with respect to public security within the meaning of Article 36¹⁵ of the Treaty, Case 72/83 *Campus Oil v Minister for Industry and Energy* [1984] ECR 2727, paragraphs 33 to 36).

52 However, neither UCM nor the Governments of the Member States which have submitted observations have shown that the rules at issue were necessary to provide a balanced medical and hospital service accessible to all. None of those who have submitted observations has argued that the rules were indispensable for the maintenance of an essential treatment facility or medical service on national territory.

53 The conclusion must therefore be drawn that the rules at issue in the main proceedings are not justified on grounds of public health.

54 In those circumstances, the answer must be that Articles 59¹¹ and 60¹² of the Treaty preclude national rules under which reimbursement, in accordance with the scale of the State of insurance, of the cost of dental treatment provided by an orthodontist established in another Member State is subject to authorisation by the insured person's social security institution.

1.4.3. Costs

55 The costs incurred by the Luxembourg, German, Greek, French, Austrian and United Kingdom Governments and by the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the

parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court.

1.4.4. The Court's decision

On those grounds, THE COURT, in answer to the questions referred to it by the Luxembourg Cour de Cassation by judgment of 25 April 1996, hereby rules:

Articles 59¹¹ and 60¹² of the EC Treaty preclude national rules under which reimbursement, in accordance with the scale of the State of insurance, of the cost of dental treatment provided by an orthodontist established in another Member State is subject to authorisation by the insured person's social security institution.

1.5. B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen⁴

1.5.1. Judgment

1 By order of 28 April 1999, received at the Court on 30 April 1999, the Arrondissementsrechtbank te Roermond (District Court, Roermond) referred to the Court for a preliminary ruling under Article 177¹⁶ of the EC Treaty (now Article 234 EC) two questions on the interpretation of Article 59¹¹ of the EC Treaty (now, after amendment, Article 49 EC) and Article 60¹² of the Treaty (now Article 50 EC).

2 The two questions have been raised in proceedings between Mrs Geraets-Smits and Stichting Ziekenfonds VGZ (Stichting VGZ) and between Mr Peerbooms and Stichting CZ Groep Zorgverzekeringen (Stichting CZ) concerning the reimbursement of hospital treatment costs incurred in Germany and Austria respectively.

⁴ Judgment of the Court of 12 July 2001. - B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen

1.5.2. National legal framework

3 In the Netherlands, the sickness insurance scheme is based principally on the Ziekenfondswet of 15 October 1964 (Law on Sickness Funds, Staatsblad 1964, No 392, as subsequently amended, the ZFW), the Algemene Wet Bijzondere Ziektekosten of 14 December 1967 (Law on general insurance for special sickness costs, Staatsblad 1967, No 617, as subsequently amended, the AWBZ) and the Wet op de toegang tot ziektekostenverzekeringen (Law on access to sickness insurance, the WTZ). Both the ZFW and the AWBZ establish a system of benefits in kind under which an insured person is entitled not to reimbursement of costs incurred for medical treatment but to free treatment. Both laws are based on a system of agreements made between sickness funds and providers of health care. The WTZ, on the other hand, establishes a system under which insured persons are reimbursed costs and is not based on a system of agreements.

4 Under Articles 2 to 4 of the ZFW, workers whose annual income does not exceed an amount determined by law (NLG 60 750 in 1997), persons treated as such and persons in receipt of social benefits and dependent members of their families living with them in the same household are compulsorily and automatically insured under that law.

5 Article 5(1) of the ZFW provides that any person coming within its scope who wishes to claim entitlement under that law must register with a sickness fund operating in the municipality in which he resides.

6 Article 8 of the ZFW provides:

1. An insured person shall be entitled to benefits in the form of necessary medical care, provided that he is not entitled to such care under the Algemene Wet Bijzondere Ziektekosten ... Sickness funds shall ensure that any insured person registered with them is able to rely on that right.

2. The nature, content and extent of the benefits shall be defined by or pursuant to a Royal Decree, it being understood that they shall in any event include medical assistance, the extent of which remains to be defined, and also the care and treatment provided in categories of institutions to be defined. Furthermore, the grant of a benefit may be conditional on a financial contribution by the insured person; this contribution need not be the same for all insured persons.

...

7 The Verstrekkingsbesluit Ziekenfondsverzekering of 4 January 1966 (Decree on sickness insurance benefits in kind, Staatsblad 1966, No 3, as subsequently amended, the Verstrekkingsbesluit) implements Article 8(2) of the ZFW.

8 The Verstrekkingsbesluit thus determines entitlement to benefits and the extent of such benefits for various categories of care, including in particular the categories medical and surgical assistance and in-patient hospital treatment.

9 Article 2(3) of the Verstrekkingsbesluit provides that entitlement to benefit cannot be claimed unless the insured person, in the light of his needs and with a view to effective therapy, has no reasonable choice other than to seek a benefit of that nature, content and extent.

10 Under Article 3 of the Verstrekkingsbesluit, the category of medical and surgical care is to include care provided by a general practitioner and a specialist, the extent [of which] shall be determined in accordance with what is normal in the professional circles concerned.

11 As regards in-patient hospital treatment, Articles 12 and 13 of the Verstrekkingsbesluit provide, first, that such treatment may involve, inter alia, medical, surgical and obstetric examination, treatment and care and, second, that there must be evidence that hospital treatment is justified. The Besluit ziekenhuisverpleging ziekenfondsverzekering of 6 February 1969 (Decree on care provided in hospitals under sickness insurance, Staatscourant 1969, No 50), determines the cases in which evidence justifying hospital treatment is established.

12 The ZFW is applied by sickness funds, which are legal persons approved by the Minister in accordance with Article 34 of the ZFW. The Ziekenfondsraad is responsible for advising and informing the Minister concerned and with overseeing the management and administration of the sickness funds. Where a complaint is lodged against a sickness fund decision concerning entitlement to a benefit, the sickness fund is required to obtain the opinion of the Ziekenfondsraad before reaching a decision on the complaint.

13 The ZFW provides for the establishment of a system of agreements, the principal features of which are as follows.

14 Article 44(1) of the ZFW provides that the sickness funds are to enter into agreements with persons and establishments offering one or more forms of care, as referred to in the Royal Decree adopted to implement Article 8.

15 Article 44(3) of the ZFW provides that such agreements are to include at least provisions concerning the nature and extent of the parties' mutual obligations and rights, the categories of care to be provided, the quality and effectiveness of the care and supervision of compliance with the terms of the agreement, including supervision of the benefits provided or to be provided and the accuracy of the amounts charged for those benefits, and also an obligation to communicate the information necessary for that supervision.

16 The agreements do not, however, apply to the scales of charges for health care. These are governed exclusively by the *Wet tarieven gezondheidszorg* (Law on the scales of charges for health care). According to the explanations provided by the Netherlands Government, however, that does not mean that agreements on costs cannot be entered into between the sickness funds and care providers. All the factors which influence the level of costs and hospital budgets can form the subject of an agreement between the parties.

17 The sickness funds are free to enter into agreements with any care provider, subject to a twofold reservation. First, it follows from Article 47 of the ZFW that any sickness fund is required to enter into an agreement ... with any establishment in the area in which it operates or which the population of that area regularly attend. Second, agreements can only be entered into with establishments which are duly authorised to provide the care in question or with persons lawfully authorised to do so.

18 Article 8a of the ZFW provides:

1. An establishment providing services such as those referred to in Article 8 must be authorised to do so.
2. A Royal Decree may provide that an establishment belonging to a category to be defined by Royal Decree is to be regarded as authorised for the purposes of this Law. ...

19 It follows from Article 8c(a) of the ZFW that approval of an establishment operating hospitals must be refused if that establishment does not meet the requirements of the *Wet ziekenhuisvoorzieningen* (Law on hospital equipment) on distribution and needs. That law, its implementing directives (in particular the directive based on Article 3 of the law,

Staatscourant 1987, No 248) and also the district plans determine in greater detail the national needs in relation to various categories of hospitals and their distribution between the various regions defined within the Netherlands for health purposes.

20 As regards the specific implementation of the right to benefits, Article 9 of the ZFW provides:

1. Save as provided for in the Royal Decree referred to in Article 8, an insured person wishing to claim entitlement to a benefit shall apply to a person or an establishment with whom or with which the sickness insurance fund with which he is registered has entered into an agreement for that purpose, subject to the provisions of paragraph 4.

2. The insured person may choose from among the persons and establishments mentioned in paragraph 1, subject to the provisions of paragraph 5 and the provision regarding conveyance by ambulance, as laid down in the Wet ambulancevervoer ((Law on conveyance by ambulance), Staatsblad 1967, No 369).

3. [repealed]

4. A sickness insurance fund may, by way of derogation from paragraphs 1 and 2 hereof, authorise an insured person, for the purpose of claiming entitlement to a benefit, to apply to another person or establishment in the Netherlands where this is necessary for his medical treatment. The Minister may determine the cases and circumstances in which an insured person may be granted authorisation, in claiming entitlement to a benefit, to apply to a person or an establishment outside the Netherlands.

...

21 The Minister exercised the powers conferred on him by the final sentence of Article 9(4) of the ZFW in adopting the Regeling hulp in het buitenland ziekenfondsverzekering of 30 June 1988 (Regulation on care provided abroad under the sickness insurance rules, Staatscourant 1988, No 123, the Rhbz). Article 1 of the Rhbz provides:

A sickness insurance fund may authorise an insured person claiming entitlement to a benefit to apply to a person or establishment outside the Netherlands in those cases in which the sickness insurance fund shall determine that such action is necessary for the health care of the insured person.

22 The national court states that, under the case-law of the Centrale Raad van Beroep (Netherlands appellate court in social security matters) on applications for authorisation to receive medical treatment abroad funded under the ZFW, two conditions must be satisfied here.

23 First, the treatment in question must be capable of being regarded as a qualifying benefit within the meaning of Article 8 of the ZFW and of the Verstrekkingsbesluit. As stated above, the relevant test under Article 3 of the Verstrekkingsbesluit is whether the proposed treatment is regarded as normal in the professional circles concerned (decision of the Centrale Raad van Beroep of 23 May 1995, RZA 1995, No 126). For example, as regards a particular type of treatment in Germany, the Centrale Raad van Beroep has held that the basis [for the treatment] is not (yet) sufficiently recognised in scientific circles and, according to current thinking in the Netherlands, is regarded as experimental (decision of 19 December 1997, RZA 1998, No 48). It is thus clear from the case-law that in practice reference is made to the views prevailing within professional circles in the Netherlands in order to determine whether treatment can be held to be normal and not experimental.

24 Second, it must be determined whether the treatment is necessary for the medical treatment of the insured person within the meaning of Article 9(4) of the ZFW and Article 1 of the Rhbz. The national court states that in practice it is necessary to take into account the methods of treatment available in the Netherlands (see, in particular, the decision of the Centrale Raad van Beroep of 13 December 1994, RZA 1995, No 53) and to ascertain whether adequate treatment can be available without undue delay in the Netherlands.

1.5.3. The main proceedings

The Geraets-Smits case

25 Mrs Geraets-Smits suffers from Parkinson's disease. By letter of 5 September 1996, she requested Stichting VGZ to reimburse the costs of care received at the Elena-Klinik in Kassel in Germany for specific, multidisciplinary treatment of that disease. That method involves, inter alia, examinations and treatment to determine the ideal medical treatment, physiotherapy and ergotherapy and socio-psychological support.

26 By decisions of 30 September and 28 October 1996, Stichting VGZ informed Mrs Geraets-Smits that the costs of the treatment would not be refunded under the ZFW. The reasons stated were that satisfactory and adequate treatment for Parkinson's disease was available in the Netherlands, that the specific clinical treatment provided at the Elena-Klinik provided no additional advantage and that there was therefore no medical necessity justifying treatment in that clinic.

27 Mrs Geraets-Smits sought the opinion of the Ziekenfondsraad on 14 November 1996. On 7 April 1997, the Ziekenfondsraad issued an opinion stating that it regarded the decision of Stichting VGZ refusing her request as proper.

28 Mrs Geraets-Smits then lodged an appeal with the Arrondissementsrechtbank te Roermond against the decision of 30 September 1996. She claims, in substance, that the specific clinical treatment provided in Germany has a number of advantages over the symptomatic approach used in the Netherlands, whereby the various manifestations of the disease are treated individually, on a symptom-by-symptom basis.

29 In its examination, the Arrondissementsrechtbank finds that the decision refusing to reimburse Mrs Geraets-Smits's costs was based, first, on the fact that the specific clinical method is not regarded as normal treatment within the professional circles concerned and is therefore not one of the benefits covered by Article 8 of the ZFW. Should the treatment, or part of it, none the less be regarded as normal, the refusal is based, second, on the consideration that, since satisfactory and adequate treatment was available in the Netherlands at an establishment having contractual arrangements with the sickness insurance fund, the treatment in Kassel was not necessary within the meaning of Article 9(4) of the ZFW and Article 1 of the Rhbz.

30 The national court appointed a neurologist as an expert witness. In the report which he filed on 3 February 1998, the expert concluded that there was no clinical or scientific evidence that the specific clinical approach was more appropriate and that therefore there was no strictly medical justification for the treatment received by Mrs Geraets-Smits in Germany.

The Peerbooms case

31 Mr Peerbooms fell into a coma following a road accident on 10 December 1996. He was taken to hospital in the Netherlands and then transferred in a vegetative state to the University Clinic in Innsbruck in Austria on 22 February 1997.

32 The Innsbruck clinic gave Mr Peerbooms special intensive therapy using neurostimulation. In the Netherlands, that technique is used only experimentally at two medical centres and patients over the age of 25 years are not allowed to undergo this therapy. It is therefore common ground that if Mr Peerbooms, who was born in 1961, had remained in the Netherlands, he would not have been able to receive such treatment.

33 By letter of 24 February 1997, Mr Peerbooms's neurologist requested Stichting CZ to pay the costs of the treatment at the University Clinic in Innsbruck.

34 That request was rejected by decision of 26 February 1997, delivered after consideration of the opinion of the medical consultant, on the ground that adequate treatment could have been obtained in the Netherlands from a care provider and/or an establishment with which Stichting CZ had entered into an agreement.

35 Mr Peerbooms's neurologist repeated his request, which was again refused on 5 March 1997. The complaint lodged against those decisions was rejected by Stichting CZ on 12 June 1997.

36 In the meantime, Mr Peerbooms came out of his coma. He was able to leave the Innsbruck clinic on 20 June 1997 and was transferred to the clinic in Hoensbroeck (Netherlands) to continue his rehabilitation.

37 Mr Peerbooms lodged an appeal before the Arrondissementsrechtbank te Roermond against Stichting CZ's decision of 12 June 1997 rejecting his complaint.

38 According to the explanations provided by that court, Stichting CZ's refusal was based, first, on the fact that, owing to the experimental nature of therapy using neurostimulation and the absence of scientific evidence of its effectiveness, that type of treatment was not regarded as normal within the professional circles concerned nor, consequently, as a benefit qualifying for reimbursement under Article 8 of the ZFW. Should that treatment none the less be held to be normal, the refusal was based, second, on the consideration that, since satisfactory and adequate treatment was available without undue delay in the Netherlands at an establishment with which the sickness insurance fund had contractual arrangements, the treatment at Innsbruck was not necessary within the meaning of Article 9(4) of the ZFW and Article 1 of the Rhbz.

39 The neurologist appointed as an expert witness by the Arrondissementsrechtbank concluded in his report submitted on 12 May 1998 that appropriate and adequate treatment, such as that provided to Mr Peerbooms in Innsbruck, was not available in the Netherlands owing to his age and that he would not have been able to receive adequate therapy in another hospital centre in the Netherlands. The neurologist advising Stichting CZ stated in reply that that method of treatment was experimental and had not so far been approved in scientific circles. However, the court expert stated in a further report filed on 31 August 1998 that he stood by his conclusions.

Questions referred to the Court

40 By order of 28 April 1999, the Arrondissementsrechtbank te Roermond decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

1. (a) Must Articles 59¹¹ and 60¹² of the EC Treaty be interpreted as meaning that a provision such as Article 9(4) of the ZFW in conjunction with Article 1 of the Rhbz is inconsistent with those Treaty provisions where the national rules cited provide that a person insured under the sickness insurance fund requires prior authorisation from the sickness insurance fund in order to claim his entitlement to benefits from a person or establishment outside the Netherlands?

(b) What is the answer to Question 1(a) where the authorisation referred to therein is refused or does not apply, because the relevant treatment in the other Member State is not regarded "as normal in professional circles" and thus is deemed not to constitute a benefit within the meaning of Article 8 of the ZFW? Does it make any difference in that connection whether regard is had solely to the conceptions of Netherlands professional circles and whether national or international scientific yardsticks are applied and, if so, in what respect? Is it also relevant whether the relevant treatment is reimbursed under the social security system provided for under the law of that other Member State?

(c) What is the answer to Question 1(a) where the treatment abroad is deemed to be normal and therefore to constitute a benefit but the requisite authorisation is refused on the ground that timely and adequate care can be obtained from a contracted Netherlands care provider and treatment abroad is therefore not necessary for the health care of the person concerned?

2. If the requirement to obtain authorisation constitutes a barrier to the freedom to provide services enshrined in Articles 59 and 60 of the EC Treaty, are the overriding reasons in the

general interest relied on by the defendants ... sufficient in order for the barrier to be regarded as justified?

41 The national court observes that, although the requirements relating to the approval of hospital establishments provided for in the ZFW do not appear to preclude approval of foreign establishments, for example those in border areas, it can be inferred from those requirements, and in particular from the principle of the geographical distribution governing approval, that it is essentially establishments in the Netherlands which will be approved.

42 The national court goes on to state that particular attention must be paid to what is actually meant by normal treatment where it is a matter of deciding whether or not Netherlands sickness insurance funds should authorise the assumption of costs of treatment provided outside the Netherlands. If the sickness insurance funds have regard solely to what is considered normal within Netherlands professional circles, that may mean that certain methods of treatment, which are none the less generally accepted in other Member States and for which reimbursement is made because professional circles in those Member States hold views different from those prevailing in the Netherlands, will not be regarded as benefits covered by the ZFW, so that authorisation will have to be refused.

The questions referred to the Court

43 By its two questions, which fall to be dealt with together, the national court is asking essentially whether Articles 59 and 60 of the Treaty are to be interpreted as precluding legislation of a Member State, such as the legislation at issue in the main proceedings, which makes the assumption of the costs of care provided in a hospital establishment in another Member State conditional upon prior authorisation by the sickness insurance fund with which the insured person is registered, that authorisation being granted only in so far as the following two conditions are satisfied. First, the proposed treatment must be among the benefits for which the sickness insurance scheme of the first Member State assumes responsibility, which means that the treatment must be regarded as normal in the professional circles concerned. Second, the treatment abroad must be necessary in terms of the medical condition of the person concerned, which supposes that adequate care cannot be provided without undue delay by a care provider which has entered into an agreement with a sickness insurance fund in the first Member State.

The power of the Member States to arrange their social security systems and the obligation to comply with Community law in exercising that power

44 In order to answer the questions as thus reformulated, it should be remembered at the outset that, according to settled case-law, Community law does not detract from the power of the Member States to organise their social security systems (Case 238/82 Duphar and Others [1984] ECR 523, paragraph 16, Case C-70/95 Sodemare and Others [1997] ECR I-3395, paragraph 27, and Case C-158/96 Kohll [1998] ECR I-1931, paragraph 17).

45 In the absence of harmonisation at Community level, it is therefore for the legislation of each Member State to determine, first, the conditions concerning the right or duty to be insured with a social security scheme (Case 110/79 Coonan [1980] ECR 1445, paragraph 12, Case C-349/87 Paraschi [1991] ECR I-4501, paragraph 15, and Kohll, paragraph 18) and, second, the conditions for entitlement to benefits (Joined Cases C-4/95 and C-5/95 Stöber and Piosa Pereira [1997] ECR I-511, paragraph 36, and Kohll, paragraph 18).

46 Nevertheless, the Member States must comply with Community law when exercising that power.

Application to hospital care of the provisions on freedom to provide services

47 It is first necessary to determine whether the situations at issue in the main proceedings do indeed fall within the ambit of the freedom to provide services provided for in Articles 59 and 60 of the Treaty.

48 A number of the governments which have submitted written observations to the Court have argued that hospital services cannot constitute an economic activity within the meaning of Article 60 of the Treaty, particularly when they are provided in kind and free of charge under the relevant sickness insurance scheme.

49 Relying in particular on Case 263/86 Humbel [1988] ECR 5365, paragraphs 17 to 19, and Case C-159/90 Society for the Protection of Unborn Children Ireland [1991] ECR I-4685, paragraph 18, they argue, in particular, that there is no remuneration within the meaning of Article 60 of the Treaty where the patient receives care in a hospital infrastructure without having to pay for it himself or where all or part of the amount he pays is reimbursed to him.

50 Some of those governments also maintain that it follows from Case 293/83 Gravier [1985] ECR 593 and Case C-109/92 Wirth [1993] ECR I-6447, paragraph 17, that a further condition

to be satisfied before a service can constitute an economic activity within the meaning of Article 60¹² of the Treaty is that the person providing the service must do so with a view to making a profit.

51 The German Government considers that the structural principles governing the provision of medical care are inherent in the organisation of the social security systems and do not come within the sphere of the fundamental economic freedoms guaranteed by the EC Treaty, since the persons concerned are unable to decide for themselves the content, type and extent of a service and the price they will pay.

52 None of those arguments can be upheld.

53 It is settled case-law that medical activities fall within the scope of Article 60 of the Treaty, there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment (see Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, paragraph 16; *Society for the Protection of Unborn Children Ireland*, paragraph 18, concerning advertising for clinics involved in the deliberate termination of pregnancies; and *Kohll*, paragraphs 29 and 51).

54 It is also settled case-law that the special nature of certain services does not remove them from the ambit of the fundamental principle of freedom of movement (Case 279/80 *Webb* [1981] ECR 3305, paragraph 10, and *Kohll*, paragraph 20), so that the fact that the national rules at issue in the main proceedings are social security rules cannot exclude application of Articles 59 and 60 of the Treaty (*Kohll*, paragraph 21).

55 With regard more particularly to the argument that hospital services provided in the context of a sickness insurance scheme providing benefits in kind, such as that governed by the ZFW, should not be classified as services within the meaning of Article 60¹² of the Treaty, it should be noted that, far from falling under such a scheme, the medical treatment at issue in the main proceedings, which was provided in Member States other than those in which the persons concerned were insured, did lead to the establishments providing the treatment being paid directly by the patients. It must be accepted that a medical service provided in one Member State and paid for by the patient should not cease to fall within the scope of the freedom to provide services guaranteed by the Treaty merely because reimbursement of the costs of the treatment involved is applied for under another Member State's sickness insurance legislation which is essentially of the type which provides for benefits in kind.

56 Furthermore, the fact that hospital medical treatment is financed directly by the sickness insurance funds on the basis of agreements and pre-set scales of fees is not in any event such as to remove such treatment from the sphere of services within the meaning of Article 60 of the Treaty.

57 First, it should be borne in mind that Article 60 of the Treaty does not require that the service be paid for by those for whom it is performed (Case 352/85 *Bond van Adverteerders and Others* [1988] ECR 2085, paragraph 16, and Joined Cases C-51/96 and C-191/97 *Deliège* [2000] ECR I-2549, paragraph 56).

58 Second, Article 60 of the Treaty states that it applies to services normally provided for remuneration and it has been held that, for the purposes of that provision, the essential characteristic of remuneration lies in the fact that it constitutes consideration for the service in question (*Humbel*, paragraph 17). In the present cases, the payments made by the sickness insurance funds under the contractual arrangements provided for by the ZFW, albeit set at a flat rate, are indeed the consideration for the hospital services and unquestionably represent remuneration for the hospital which receives them and which is engaged in an activity of an economic character.

59 Since the provisions of services at issue in the main proceedings do fall within the scope of the freedom to provide services within the meaning of Articles 59 and 60 of the Treaty, it is necessary to consider whether the rules at issue in the main proceedings place restrictions on that freedom and, if so, whether those restrictions can be objectively justified.

The restrictive effects of the legislation at issue in the main proceedings

60 It is necessary to determine whether there is a restriction on freedom to provide services within the meaning of Article 59 of the Treaty where the costs of treatment provided in a hospital in another Member State is assumed under the sickness insurance scheme only on condition that the person receiving the treatment obtains prior authorisation, which is granted only if the treatment concerned is covered by the sickness insurance scheme of the Member State in which the patient is insured, which requires that the treatment be normal within the professional circles concerned, and where the insured person's sickness fund has decided that his medical treatment requires that he be treated in the hospital establishment concerned, presupposing that adequate timely treatment cannot be provided by a contracted care provider in the Member State in which the patient is insured.

61 According to settled case-law, Article 59 of the Treaty precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within one Member State (Case C-381/93 *Commission v France* [1994] ECR I-5145, paragraph 17, and *Kohll*, paragraph 33).

62 In the present case, while the ZFW does not deprive insured persons of the possibility of using a provider of services established in another Member State, it does nevertheless make reimbursement of the costs incurred in another Member State subject to prior authorisation and provides for such reimbursement to be refused where the two requirements referred to in paragraph 60 above are not satisfied.

63 As regards the first of those requirements, namely that the proposed treatment must be treatment covered by the ZFW, in other words treatment which can be regarded as normal in the professional circles concerned, it is sufficient to point out that by its very essence such a condition is liable to lead to refusals of authorisation. It is only the precise frequency with which authorisation is refused, not refusal itself, that will be determined by the interpretation of normal treatment and the professional circles concerned.

64 As regards the second requirement, namely that provision of hospital treatment in another Member State must be a medical necessity, which will be the case only if adequate treatment cannot be obtained without undue delay in contracted hospitals in the Member State in which the person seeking treatment is insured, this requirement by its very nature will severely limit the circumstances in which such authorisation can be obtained.

65 The Netherlands Government and the Commission have stressed, however, that it was open to the sickness insurance funds to enter into agreements with hospital establishments outside the Netherlands and that in such a case no prior authorisation would be required in order for the cost of treatment provided by such establishments to be assumed under the ZFW.

66 Even disregarding the fact that no such possibility is apparent from the provisions of national law to which the Court has been referred, the order for reference points out that in practice, having regard, in particular, to the contracting conditions, it will be mainly hospital establishments in the Netherlands that will strike contractual arrangements with the sickness insurance funds. It must also be recognised that, with the exception of hospitals situated in areas adjoining the Netherlands, it seems unlikely that a significant number of hospitals in other Member States would ever enter into agreements with the Netherlands sickness

insurance funds, their prospects of admitting patients insured by those funds remaining uncertain and limited.

67 It is therefore accepted that in the majority of cases the assumption of costs, under the ZFW, of hospital treatment provided by establishments in Member States other than the Member State in which a person is insured will have to be subject to prior authorisation, as is indeed the case for the treatment at issue in the main proceedings, and that this authorisation will be refused if the two requirements set out in paragraph 60 above are not satisfied.

68 By comparison, treatment provided in contracted hospitals situated in the Netherlands, which represents the greater part of the hospital treatment provided there to persons covered by the ZFW, is paid for by the sickness insurance funds without any prior authorisation being required.

69 It follows from the foregoing considerations that rules such as those at issue in the main proceedings deter, or even prevent, insured persons from applying to providers of medical services established in another Member State and constitute, both for insured persons and service providers, a barrier to freedom to provide services (see, to that effect, *Luisi and Carbone*, paragraph 16, *Case C-204/90 Bachmann* [1992] ECR I-249, paragraph 31, and *Kohll*, paragraph 35).

70 Consequently, it is necessary to examine whether, in so far as they concern medical services provided within a hospital infrastructure, such as those at issue in the main proceedings, such rules can be objectively justified.

71 In that regard, it is first necessary to determine whether there are overriding reasons which can be accepted as justifying barriers to freedom to provide medical services supplied in the context of a hospital infrastructure, then to determine whether the prior authorisation principle is justifiable in the light of such overriding needs and last to consider whether the conditions governing the grant of prior authorisation can themselves be justified.

Overriding considerations which may be relied on to justify barriers to the exercise of freedom to provide services in the sphere of hospital treatment

72 As all the governments which have submitted observations to the Court have pointed out, the Court has held that it cannot be excluded that the possible risk of seriously undermining a social security system's financial balance may constitute an overriding reason in the general

interest capable of justifying a barrier to the principle of freedom to provide services (Kohll, paragraph 41).

73 The Court has likewise recognised that, as regards the objective of maintaining a balanced medical and hospital service open to all, that objective, even if intrinsically linked to the method of financing the social security system, may also fall within the derogations on grounds of public health under Article 56 of the EC Treaty (now, after amendment, Article 46 EC), in so far as it contributes to the attainment of a high level of health protection (Kohll, paragraph 50).

74 The Court has further held that Article 56 of the Treaty permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for the public health, and even the survival of, the population (Kohll, paragraph 51).

75 It is therefore necessary to determine whether the national rules at issue in the main proceedings can actually be justified in the light of such overriding reasons and, in such a case, in accordance with settled case-law, to make sure that they do not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules (Case 205/84 *Commission v Germany* [1986] ECR 3755, paragraphs 27 and 29; Case C-180/89 *Commission v Italy* [1991] ECR I-709, paragraphs 17 and 18; and Case C-106/91 *Ramrath* [1992] ECR I-3351, paragraphs 30 and 31).

The prior authorisation requirement

76 As regards the prior authorisation requirement to which the ZFW subjects the assumption of the costs of treatment provided in another Member State by a non-contracted care provider, the Court accepts, as all the governments which have submitted observations have argued, that, by comparison with medical services provided by practitioners in their surgeries or at the patient's home, medical services provided in a hospital take place within an infrastructure with, undoubtedly, certain very distinct characteristics. It is thus well known that the number of hospitals, their geographical distribution, the mode of their organisation and the equipment with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible.

77 As may be seen, in particular, from the contracting system involved in the main proceedings, this kind of planning therefore broadly meets a variety of concerns.

78 For one thing, it seeks to achieve the aim of ensuring that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the State concerned.

79 For another thing, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. Such wastage is all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for health care are not unlimited, whatever the mode of funding applied.

80 From both those perspectives, a requirement that the assumption of costs, under a national social security system, of hospital treatment provided in another Member State must be subject to prior authorisation appears to be a measure which is both necessary and reasonable.

81 Looking at the system set up by the ZFW, it is clear that, if insured persons were at liberty, regardless of the circumstances, to use the services of hospitals with which their sickness insurance fund had no contractual arrangements, whether they were situated in the Netherlands or in another Member State, all the planning which goes into the contractual system in an effort to guarantee a rationalised, stable, balanced and accessible supply of hospital services would be jeopardised at a stroke.

82 Although, for the considerations set out above, Community law does not in principle preclude a system of prior authorisation, the conditions attached to the grant of such authorisation must none the less be justified with regard to the overriding considerations examined and must satisfy the requirement of proportionality referred to in paragraph 75 above. The condition that the proposed treatment be normal

83 As observed above, the rules at issue in the main proceedings subject the grant of authorisation to the condition that the proposed medical or surgical treatment can be regarded as normal in the professional circles concerned.

84 It should be emphasised at the outset that, under Article 3 of the Verstrekingenbesluit, this condition applies generally to the assumption of costs, under the ZFW, of all medical and surgical treatment, so that in principle it applies regardless of whether the proposed treatment is to be provided in a contracted establishment or outside such an establishment, within the Netherlands or outside the Netherlands.

85 With that point in mind, it should also be remembered, as already stated in paragraphs 44 and 45 above, that it is for the legislation of each Member State to organise its national social security system and in particular to determine the conditions governing entitlement to benefits.

86 The Court has thus held, in particular, that it is not in principle incompatible with Community law for a Member State to establish, with a view to achieving its aim of limiting costs, limitative lists excluding certain products from reimbursement under its social security scheme (*Duphar and Others*, paragraph 17).

87 The same principle must apply to medical and hospital treatment when it is a matter of determining which treatments will be paid for by the social security system of the Member State concerned. It follows that Community law cannot in principle have the effect of requiring a Member State to extend the list of medical services paid for by its social insurance system: the fact that a particular type of medical treatment is covered or not covered by the sickness insurance schemes of other Member States is irrelevant in this regard.

88 None the less, as observed in paragraph 46 above, in exercising that power the Member State must not disregard Community law.

89 Thus it follows from the Court's case-law that the list of medicinal preparations excluded from reimbursement must be drawn up in accordance with Article 30¹⁷ of the EC Treaty (now, after amendment, Article 28 EC) and that this will be so only where the list is drawn up in accordance with objective criteria, without reference to the origin of the products (*Duphar*, paragraph 21).

90 It likewise follows from settled case-law that a scheme of prior authorisation cannot legitimise discretionary decisions taken by the national authorities which are liable to negate the effectiveness of provisions of Community law, in particular those relating to a fundamental freedom such as that at issue in the main proceedings (see, to that effect, *Joined Cases C-358/93 and C-416/93 Bordessa and Others* [1995] ECR I-361, paragraph 25; *Joined Cases C-163/94, C-165/94 and C-250/94 Sanz de Lera and Others* [1995] ECR I-4821, paragraphs 23 to 28, and *Case C-205/99 Analir and Others* [2001] ECR I-1271, paragraph 37). Therefore, in order for a prior administrative authorisation scheme to be justified even though it derogates from such a fundamental freedom, it must, in any event, be based on objective, non-discriminatory criteria which are known in advance, in such a way as to

circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily (Analir and Others, paragraph 38). Such a prior administrative authorisation scheme must likewise be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings.

91 The actual system of sickness insurance laid down by the ZFW is not based on a pre-established list of types of treatment issued by the national authorities for which payment will be guaranteed. The Netherlands legislature has enacted a general rule under which the costs of medical treatment will be assumed provided that the treatment is normal in the professional circles concerned. It has therefore left it to the sickness insurance funds, acting where necessary under the supervision of the Ziekenfondsraad and the courts, to determine the types of treatment which actually satisfy that condition.

92 In the present two cases, it is clear from the arguments submitted to the national court, reflected in part (b) of the first preliminary question, and from the observations submitted to the Court that the expression normal in the professional circles concerned is open to a number of interpretations, depending, in particular, on whether it is considered that regard should be had to what is considered normal only in Netherlands medical circles, which, to judge by the order for reference, seems to be the interpretation favoured by the national court (see paragraph 23 above) or, on the other hand, to what is considered normal according to the state of international medical science and medical standards generally accepted at international level.

93 In that regard, the Netherlands Government has explained that when a specific treatment constitutes professionally appropriate treatment having a valid scientific basis, it is regarded as a qualifying benefit for the purposes of the ZFW, so that the application of the normal criterion must not have the consequence that only treatment normally available in the Netherlands can qualify for reimbursement. According to the Netherlands Government, professional opinion in the Netherlands is also based on the state of the art and on scientific thinking at international level and depends on whether, in the light of the state of national and international science, the treatment is regarded as normal treatment. That criterion thus applies, it says, without distinction to the various types of treatment provided in the Netherlands and also to those for which the insured person wishes to go abroad.

94 Only an interpretation on the basis of what is sufficiently tried and tested by international medical science can be regarded as satisfying the requirements set out in paragraphs 89 and 90 above.

95 It follows from the those requirements that the institution of a system such as that at issue in the main proceedings, under which the authorisation decision needed to undergo hospital treatment in another Member State is entrusted to the sickness insurance funds, means that the criteria which those funds must apply in reaching that decision must be objective and independent where the providers of treatment are established.

96 To allow only treatment habitually carried out on national territory and scientific views prevailing in national medical circles to determine what is or is not normal will not offer those guarantees and will make it likely that Netherlands providers of treatment will always be preferred in practice.

97 If, on the other hand, the condition that treatment must be regarded as normal is extended in such a way that, where treatment is sufficiently tried and tested by international medical science, the authorisation sought under the ZFW cannot be refused on that ground, such a condition, which is objective and applies without distinction to treatment provided in the Netherlands and to treatment provided abroad, is justifiable in view of the need to maintain an adequate, balanced and permanent supply of hospital care on national territory and to ensure the financial stability of the sickness insurance system, so that the restriction of the freedom to provide services of hospitals situated in other Member States which might result from the application of that condition does not infringe Article 59¹¹ of the Treaty.

98 Further, where, as in the present case, a Member State decides that medical or hospital treatment must be sufficiently tried and tested before its cost will be assumed under its social security system, the national authorities called on to decide, for authorisation purposes, whether hospital treatment provided in another Member States satisfies that criterion must take into consideration all the relevant available information, including, in particular, existing scientific literature and studies, the authorised opinions of specialists and the fact that the proposed treatment is covered or not covered by the sickness insurance system of the Member State in which the treatment is provided.

The condition concerning the necessity of the proposed treatment

99 Under the rules at issue in the main proceedings, the grant of authorisation allowing assumption of the costs of a medical service provided abroad is subject to a second condition, namely that it be proved that the insured person's medical treatment requires that service.

100 As the national court states, it follows from the wording of Article 9(4) of the ZFW and Article 1 of the Rhbz that in principle that condition applies irrespective whether the request for authorisation relates to treatment in an establishment located in the Netherlands with which the sickness insurance fund has no contractual arrangements or in an establishment located in another Member State.

101 As regards the provision of hospital treatment outside the Netherlands, the national court states, however, that in practice this condition often appears to be interpreted as meaning that the provision of such treatment is not to be authorised unless it appears that appropriate treatment cannot be provided without undue delay in the Netherlands. No distinction is therefore drawn in this respect between whether the treatment could be provided by a contracted establishment or by a non-contracted establishment.

102 The Netherlands Government explains that the legislation at issue in the main proceedings does not compel refusal of a request for authorisation if the treatment sought is available in the Netherlands. Under Article 9(4) of the ZFW, read in conjunction with Article 1 of the Rhbz, authorisation must be refused only where the treatment required by the insured person's state of health is available from contracted providers of treatment. The Netherlands Government points out that the sickness insurance funds appear, however, to regard a care provider's country of establishment as a relevant factor, an interpretation which it considers inappropriate.

103 In view of what is stated in paragraph 90 above, it can be concluded that the condition concerning the necessity of the treatment, laid down by the rules at issue in the main proceedings, can be justified under Article 59 of the Treaty, provided that the condition is construed to the effect that authorisation to receive treatment in another Member State may be refused on that ground only if the same or equally effective treatment can be obtained without undue delay from an establishment with which the insured person's sickness insurance fund has contractual arrangements.

104 Furthermore, in order to determine whether equally effective treatment can be obtained without undue delay from an establishment having contractual arrangements with the insured

person's fund, the national authorities are required to have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought but also of his past record.

105 Such a condition can allow an adequate, balanced and permanent supply of high-quality hospital treatment to be maintained on the national territory and the financial stability of the sickness insurance system to be assured.

106 Were large numbers of insured persons to decide to be treated in other Member States even when the hospitals having contractual arrangements with their sickness insurance funds offer adequate identical or equivalent treatment, the consequent outflow of patients would be liable to put at risk the very principle of having contractual arrangements with hospitals and, consequently, undermine all the planning and rationalisation carried out in this vital sector in an effort to avoid the phenomena of hospital overcapacity, imbalance in the supply of hospital medical care and logistical and financial wastage.

107 However, once it is clear that treatment covered by the national insurance system cannot be provided by a contracted establishment, it is not acceptable that national hospitals not having any contractual arrangements with the insured person's sickness insurance fund be given priority over hospitals in other Member States. Once such treatment is *ex hypothesi* provided outside the planning framework established by the ZFW, such priority would exceed what is necessary for meeting the overriding requirements referred to in paragraph 105 above.

108 In view of all the foregoing considerations, the answer to be given to the national court must be that Articles 59 and 60 of the Treaty do not preclude legislation of a Member State, such as that at issue in the main proceedings, which makes the assumption of the costs of treatment provided in a hospital located in another Member State subject to prior authorisation from the insured person's sickness insurance fund and the grant of such authorisation subject to the condition that (i) the treatment must be regarded as normal in the professional circles concerned, a criterion also applied in determining whether hospital treatment provided on national territory is covered, and (ii) the insured person's medical treatment must require that treatment. However, that applies only in so far as

- the requirement that the treatment must be regarded as normal is construed to the effect that authorisation cannot be refused on that ground where it appears that the treatment concerned is sufficiently tried and tested by international medical science, and

- authorisation can be refused on the ground of lack of medical necessity only if the same or equally effective treatment can be obtained without undue delay at an establishment having a contractual arrangement with the insured person's sickness insurance fund.

1.5.4. Costs

109 The costs incurred by the Netherlands, Belgian, Danish, German, French, Irish, Austrian, Portuguese, Finnish, Swedish, United Kingdom, Icelandic and Norwegian Governments, and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

1.5.5. The Court's decision

On those grounds,

THE COURT,

in answer to the questions referred to it by the Arrondissementsrechtbank te Roermond by order of 28 April 1999, hereby rules:

Article 59¹¹ of the EC Treaty (now, after amendment, Article 49 EC) and Article 60¹² of the EC Treaty (now Article 50 EC) do not preclude legislation of a Member State, such as that at issue in the main proceedings, which makes the assumption of the costs of treatment provided in a hospital located in another Member State subject to prior authorisation from the insured person's sickness insurance fund and the grant of such authorisation subject to the condition that (i) the treatment must be regarded as normal in the professional circles concerned, a criterion also applied in determining whether hospital treatment provided on national territory is covered, and (ii) the insured person's medical treatment must require that treatment. However, that applies only in so far as

- the requirement that the treatment must be regarded as normal is construed to the effect that authorisation cannot be refused on that ground where it appears that the treatment concerned is sufficiently tried and tested by international medical science, and

- authorisation can be refused on the ground of lack of medical necessity only if the same or equally effective treatment can be obtained without undue delay at an establishment having a contractual arrangement with the insured person's sickness insurance fund.

1.6. Patricia Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine⁵

1.6.1. Judgment

1

By order of 23 November 2000, received at the Court on 9 February 2001, the Tribunal des affaires de sécurité sociale (Social Security Court), Nanterre, referred to the Court of Justice for a preliminary ruling under Article 234 EC⁸, a question on the validity and interpretation of Article 22² of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996 (OJ 1997 L 28, p. 1; hereinafter Regulation No 1408/71), and on the interpretation of Articles 49 EC¹ and 50 EC¹⁸.

2

That question was raised in the context of proceedings between Ms Inizan and the Caisse primaire d'assurance maladie des Hauts-de-Seine (the CPAM) regarding the refusal by the

⁵ Judgment Of The Court (Fifth Chamber) 23 October 2003 (1) In Case C-56/01, Patricia Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine

CPAM to reimburse the cost of hospital treatment that the claimant in the main proceedings intends to undergo in Germany.

1.6.2. Legal background

3

Under the heading Stay outside the competent State — Return to or transfer of residence to another Member State during sickness or maternity — Need to go to another Member State in order to receive appropriate treatment, Article 22² of Regulation No 1408/71 states in paragraphs 1 and 2:

1.

An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:

...

(c)

who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition,

shall be entitled:

(i)

to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

...2. ...The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.

1.6.3. National law

4

The first paragraph of Article L.332-3 of the French Social Security Code states: Without prejudice to agreements and international rules, or to Article L.766-1, where medical treatment is given outside France to insured persons and their dependants, the corresponding benefits under the sickness and maternity insurance scheme shall not be provided.

5

By way of derogation from that rule, Article R.332-2 of that code provides: Sickness insurance funds may reimburse, at a flat rate, the costs of treatment given outside France to insured persons, and members of their families, who are taken ill unexpectedly, provided that the amount does not exceed the total sum which would have been paid to them had they been treated in France. Where it is not possible for an insured person or his dependants to receive in France the treatment appropriate to their condition, the agreements between the French competent bodies and certain hospitals abroad may, with the joint authorisation of the Minister for Social Security and the Minister for Health, lay down the conditions on which patients may stay in those hospitals and the methods of reimbursing the costs of the treatment received. Notwithstanding the cases referred to in the previous paragraph, in exceptional circumstances and subject to a favourable opinion from the medical supervisory body, sickness insurance funds may reimburse, at a flat rate, the cost of treatment provided outside France to an insured person or his dependants, where the person concerned establishes that he could not receive in French territory the treatment appropriate to his condition.

6

It is moreover apparent from the order for reference that, under French law, the authority competent to authorise the reimbursement of costs for treatment received during a stay at an establishment in a Member State of the European Union other than the French Republic is the Médecin Conseil national (National Medical Officer).

1.6.4. The question submitted

7

Ms Inizan, who is resident in France and is covered for medical insurance by the CPAM, asked the latter to reimburse the cost of multidisciplinary pain treatment which she intended to undergo at the Berlin Moabit hospital (Germany).

8

That request was refused by the CPAM by decision of 6 July 1999, confirmed by decision of the Commission de Recours Amiable (Arbitration Committee) of the CPAM of 7 October 1999, on the ground that the requirements of the second subparagraph of Article 22(2)² of Regulation No 1408/71 had not been satisfied.

9

Ms Inizan challenged those decisions before the Tribunal des affaires de sécurité sociale, Nanterre, where she stated that she now wished to follow that treatment in Essen Hospital (Germany).

10

By interlocutory judgment of 6 July 2000, that court, first, requested Ms Inizan to provide evidence that the treatment in question is reimbursed by the German social security scheme and, secondly, sought the opinion of the National Medical Officer as to whether the CPAM should reimburse the cost of treatment.

11

On 17 August 2000, the National Medical Officer gave an adverse opinion regarding reimbursement of costs finding that a wide range of treatments was available in France which could be considered equivalent to that offered by Essen Hospital, without involving undue delay. Furthermore, pain treatment implies long-term, regular treatment which could not therefore be provided by a hospital far from the patient's home.

12

For her part, Ms Inizan proved, to the satisfaction of the national court, that the treatment in question is reimbursed by the German social security scheme. She claims that her state of health requires her to follow such treatment and that it is not available in France.

13

The national court, noting the wording of Article 22(1)(c)(i)² and the second subparagraph of Article 22(2) of Regulation No 1408/71 and pointing out that the opinion of the National Medical Officer was that the prior authorisation referred to in those provisions should not be granted, wonders none the less whether, by thus making reimbursement of the costs of health services provided in another Member State subject to a prior authorisation, the aforementioned provisions constitute a restriction on freedom to provide services, contrary to Articles 49 EC and 50 EC.

14

In those circumstances, the Tribunal des affaires de sécurité sociale de Nanterre decided to stay proceedings and to refer the following question to the Court for a preliminary ruling: Is Article 22 of Regulation (EEC) No 1408/71 compatible with Articles [49 EC]¹ and [50 EC]¹⁸? Consequently, is the CPAM of the Hauts de Seine entitled to refuse Ms Inizan reimbursement of the costs of psychosomatic pain treatment in Essen (Germany), following an adverse opinion from the National Medical Officer[?]

The first part of the question

15

By the first part of its question, the national court raises the question of the validity of Article 22(1)(c)(i) of Regulation No 1408/71. In particular, the court wonders whether, in so far as that provision makes the grant of the benefits in kind to which it guarantees entitlement subject to prior authorisation, it is consistent with Articles 49 EC and 50 EC on the freedom to provide services.

16

First, according to settled case-law, medical activities fall within the scope of Article 50 EC¹⁸, there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment (see, among others, Case C-

368/98 Vanbraekel and Others [2001] ECR I-5363, paragraph 41; Case C-157/99 Smits and Peerbooms [2001] ECR I-5473, paragraph 53, and Case C-385/99 Müller-Fauré and Van Riet [2003] ECR I-4509, paragraph 38).

17

Moreover, although it is not disputed that Community law does not detract from the power of the Member States to organise their social security systems and that, in the absence of harmonisation at Community level, it is for the legislation of each Member State to determine the conditions on which social security benefits are granted, it is nevertheless the case that, when exercising that power, the Member States must comply with Community law (see, among others, Smits and Peerbooms , paragraphs 44 to 46, and Müller-Fauré and Van Riet , paragraph 100, and the case-law cited therein).

18

Accordingly, the Court has ruled in particular that Article 49 EC¹ precludes the application of national rules making reimbursement of medical costs incurred in another Member State subject to a system of prior authorisation where it is apparent that such a system deters, or prevents, insured persons from approaching providers of medical services established in Member States other than the State of insurance, save where the barrier to the freedom to provide services to which it gives rise is justifiable under one of the derogations allowed by the EC Treaty (see, in particular, Case C-158/96 Kohll [1998] ECR I-1931, paragraphs 35 and 36, and Smits and Peerbooms , paragraphs 69 to 75, and Müller-Fauré and Van Riet , paragraphs 44, 67 and 68).

19

So far as concerns Article 22² of Regulation No 1408/71, it should nevertheless be borne in mind that that provision is in no way intended to regulate, and hence does not in any way prevent, the reimbursement by Member States, at the tariffs in force in the competent Member State, of costs incurred in connection with treatment provided in another Member State, even without prior authorisation (Kohll , paragraph 27, and Vanbraekel and Others , paragraph 36).

20

The purpose of Article 22(1)(c)(i) is to confer on the insured persons concerned an entitlement to benefits in kind provided on behalf of the competent institution by the institution of the place of stay, in accordance with the legislation of the Member State in which the benefits are provided, as though the covered person were insured in that State, the length of the period during which benefits are provided alone remaining to be governed by the legislation of the competent Member State (see, in particular, *Vanbraekel and Others* , paragraph 32). The competent institution is then required to reimburse, directly, the institution of the place of stay in compliance with the conditions laid down in Article 36 of Regulation No 1408/71.

21

It follows that, by guaranteeing in paragraph 1(c)(i) that insured persons covered by the legislation of one Member State and granted authorisation have access to treatment in the other Member States on conditions of reimbursement as favourable as those enjoyed by insured persons covered by the legislation of those other States and by stating, in the second subparagraph of paragraph 2, that the competent national institution may not refuse such authorisation where the two conditions laid down therein are satisfied, Article 22 of Regulation No 1408/71, as mentioned in particular by the Council and the Commission, helps to facilitate the free movement of insured persons (see, to that effect, *Vanbraekel and Others* , paragraph 32) and, to the same extent, the cross-border provision of medical services between Member States.

22

Insured persons are thus granted rights which they would not otherwise have since, as they involve reimbursement by the institution of the place of stay in accordance with the legislation administered by it, those rights cannot by definition be guaranteed to those persons under the legislation of the competent Member State alone (see, by analogy, Case C-62/91 *Gray* [1992] ECR I-2737, paragraph 10).

23

However, it should be borne in mind that, as the Court has previously held, Article 51¹⁹ of the EC Treaty (now, after amendment, Article 42 EC), does not prohibit the Community

legislature from attaching conditions to the rights and advantages which it accords in order to ensure freedom of movement for workers or from determining the limits thereto (Joined Cases 41/79, 121/79 and 796/79 Testa and Others [1980] ECR 1979, paragraph 14, and Gray , paragraph 11).

24

In those circumstances, it cannot be complained that the Community legislature made entitlement to the abovementioned rights subject to obtaining prior authorisation from the competent institution. It must furthermore be pointed out in that regard, first, that it is for that latter institution to bear, in accordance with the conditions laid down by Article 36 of Regulation No 1408/71, the cost of the services thus provided and, secondly, that the proper application of Article 22(1)(c)(i) and of Article 36⁹ of Regulation No 1408/71 is such as to require a level of administrative cooperation between the abovementioned institution and that of the place of stay.

25

It follows from all the foregoing that, contrary to the arguments put forward by the claimant in the main proceedings, Article 22(1)(c)(i) and (2) of Regulation No 1408/71² help to facilitate the free movement of patients and cross-border provision of medical services.

26

The answer to the first part of the question must therefore be that consideration thereof has disclosed no factor of such a kind as to affect the validity of Article 22(1)(c)(i) of Regulation No 1408/71.

The second part of the question

The purpose of the second part of the question

27

By the second part of its question the national court is essentially asking whether, in view of the answer given to the first part of the question, the CPAM was right to refuse to reimburse the cost of the treatment at issue in the main proceedings, in light of the adverse opinion issued by the National Medical Officer.

28

As the observations submitted to the Court show, the wording of this part of the question gives rise to a number of difficulties of interpretation.

29

The CPAM contends that this part of the question is inadmissible on the ground that it concerns exclusively the application of domestic law to the present case, which falls outwith the jurisdiction of the Court.

30

Ms Inizan, on the other hand, submits that the principle of procedural economy requires that the points of Community law which require interpretation be extracted from the order for reference, so that the Court should in this instance give a ruling not only on the validity of Article 22 of Regulation No 1408/71 but also on the interpretation of that provision having regard to the facts of the case in the main proceedings.

31

The Commission and a number of the governments which lodged observations before the Court submit that the answer to be given to the national court could involve an examination of whether Article R. 332-2 of the Social Security Code is consistent with Articles 49 EC and 50 EC.

32

In that regard, it is appropriate to recall, as a preliminary point, the consistent case-law regarding the division of functions provided for by Article 234 EC⁸, according to which it is for the national court to apply the rules of Community law, as interpreted by the Court, to the case before it (see, *inter alia*, Case C-320/88 *Shipping and Forwarding Enterprise Safe* [1990] ECR I-285, paragraph 11, Case C-342/97 *Lloyd Schuhfabrik Meyer* [1999] ECR I-3819, paragraph 11; and *Joined Cases C-223/99 and C-260/99 Agorà and Excelsior* [2001] ECR I-3605, paragraph 23).

33

It follows that it is for the national court to determine whether, by rejecting the request for reimbursement submitted by the claimant in the main proceedings, the CPAM has acted in conformity with the rules of Community law.

34

However, it is for the Court to extract from all the information provided to it by the national court, in particular the grounds of the order for reference, the points of Community law which require interpretation, having regard to the subject-matter of the proceedings (see, *inter alia*, Case 35/85 Tissier [1986] ECR 1207, paragraph 9, and *Agorà and Excelsior*, paragraph 24).

35

First, it must be noted that the opinion issued by the National Medical Officer to which the second part of the question refers concluded that the cost of the treatment at issue in the main proceedings should not be reimbursed on the ground that there was a wide choice of treatment available in France which could be considered to be equivalent and without involving undue delay.

36

It should be observed that the reasons thus relied upon by the National Medical Officer seem to be able to be covered by Article 22(2) of Regulation No 1408/71 as much as by Article R. 332-2 of the Social Security Code.

37

Article 22(2) of Regulation No 1408/71 lays down two conditions which, if satisfied, render mandatory the prior authorisation to which it refers. However, one of those conditions is that the treatment in question cannot be given to the person concerned within the time normally necessary for obtaining the treatment in question in the Member State of residence, taking account of his current state of health and the probable course of the disease. For its part, Article R. 332-2 of the Social Security Code provides that, in exceptional circumstances, sickness insurance funds may reimburse, at a flat rate, the cost of treatment given outside France where it is proved that the insured person could not receive the treatment appropriate to his condition in French territory.

38

Secondly, it must be noted that neither the order for reference nor the case-file before the national court makes it possible to determine with certainty the nature of the reimbursement which is at the heart of the dispute in the main proceedings and to which the second part of the question refers. In particular, it is difficult to determine whether that reimbursement is that provided for by Article 22(1)(c)(i) of Regulation No 1408/71, namely the provision of benefits in kind by the institution of the place of stay in accordance with the legislation which it administers, to be reimbursed subsequently by the competent institution, or whether it is a question of the claimant in the main proceedings obtaining directly from the CPAM the flat-rate reimbursement provided for in Article R. 332-2 of the Social Security Code, or one of those forms of reimbursement if the other cannot be obtained.

39

In those circumstances, it must be held that the second part of the question must be understood to be asking essentially, first, whether Article 22(2) of Regulation No 1408/71 is to be construed as precluding a sickness insurance fund from being able, in circumstances such as those of the main proceedings, to refuse to grant an insured person the prior authorisation referred to in Article 22(1)(c)(i) thereof and, secondly, whether Articles 49 EC and 50 EC must be interpreted as precluding national legislation such as Article R. 332-2 of the Social Security Code, which makes subject to a system of prior authorisation, granted on certain conditions, reimbursement of the cost of treatment such as that in issue in the main proceedings where it is provided in a Member State other than the State of residence of the insured person.

40

In order to give an answer to the second part of the question thus reformulated, it is therefore necessary to examine in turn Article 22 of Regulation No 1408/71 and the provisions of the Treaty relating to freedom to provide services.

Article 22(1)(c)(i) and (2) of Regulation No 1408/71

41

First of all, it should be borne in mind that the purpose of the second subparagraph of Article 22(2) of Regulation No 1408/71 is to identify two conditions which, where they are

cumulatively satisfied, mean that the competent national institution cannot refuse the authorisation sought on the basis of Article 22(1)(c)(i) thereof (Vanbraekel and Others , cited above, paragraph 31).

42

The first of those conditions is that the treatment in question be among the benefits provided for by the legislation of the Member State on whose territory the insured person resides. In that regard, it is none the less sufficient to note that there is nothing in the order for reference nor in the case-file relating to the main proceedings to show that the CPAM refused to reimburse the treatment in question on the ground that that condition had not been satisfied.

43

On the other hand, as is clear from the order for reference and from the wording of the opinion of the National Medical Officer, the second condition laid down in the second subparagraph of Article 22(2) of Regulation No 1408/71 is manifestly at issue in the context of the main proceedings, and thus it is appropriate to clarify its scope to the extent necessary for the resolution of the abovementioned dispute.

44

That second condition requires, as noted in paragraph 37 of the present judgment, that the treatment which the patient intends to undergo in a Member State other than that in which he resides cannot be given to the patient within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.

45

It follows that such a condition is not satisfied whenever it is apparent that treatment which is the same or equally effective for the patient can be obtained without undue delay in the Member State of residence (see, to similar effect, Smits and Peerbooms , paragraph 103, and Müller-Fauré and Van Riet , paragraph 89).

46

In that connection, in order to determine whether treatment which is equally effective for the patient can be obtained without undue delay in the Member State of residence, the competent

institution is required to have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history (see Smits and Peerbooms , paragraph 104, and Müller-Fauré and Van Riet , paragraph 90).

47

As follows from the case-law referred to in paragraph 32 of this judgment, it is for the national court to ascertain whether that second condition is satisfied in the case before it.

48

In that respect, it should also be made clear that the prior authorisation scheme which the Member States are called upon to implement pursuant to Article 22(1)(c)(i) and (2) of Regulation No 1408/71 must in particular be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings (see, to similar effect, Smits and Peerbooms , paragraph 90, and Müller-Fauré and Van Riet , paragraph 85).

49

It follows in particular that refusals to grant authorisation, or the opinions on which such refusals may be based, must refer to the specific provisions on which they are based and be properly reasoned in accordance with them. Likewise, courts or tribunals hearing and determining actions against such refusals must be able, if they consider it necessary for the purpose of carrying out the review which is incumbent on them, to gather the advice of fully objective and impartial independent experts.

50

It should moreover be borne in mind that Article 22(2) of Regulation No 1408/71 is not in any way intended to limit the situations in which authorisation to receive the benefits in kind may be obtained under the conditions laid down in Article 22(1)(c)(i) thereof (see Vanbraekel and Others , paragraph 31). It follows that the Member States are free to provide for such

authorisation to be granted also in situations where the two conditions laid down in the second subparagraph of Article 22(2) are not satisfied.

Articles 49 EC and 50 EC

51

As to whether Article R. 332-2 of the Social Security Code is consistent with the provisions of the Treaty relating to freedom to provide services, the first point to note is that, although the Court has no jurisdiction in proceedings brought under Article 234 EC to rule on the question whether a provision of national legislation is compatible with the Treaty, it may provide the national court with all such criteria for the interpretation of Community law as may enable it to answer that question (see, among others, Case 45/75 REWE Zentrale [1976] ECR 181, paragraph 11, and Case C-228/98 Dounias [2000] ECR I-577, paragraph 36).

52

As noted in paragraph 19 of the present judgment, national provisions whose purpose is to make reimbursement by the competent institutions of the Member State of residence subject to the conditions applied by them, in respect of health treatment received in another Member State, do not fall within the scope of Article 22 of Regulation No 1408/71.

53

On the other hand, such national provisions, which, as noted in paragraph 18 of the present judgment, may in certain circumstances constitute a barrier to freedom to provide medical services, must be examined, by the national court, in the light of their consistency with Articles 49 EC and 50 EC.

54

So far as concerns Article R. 332-2 of the Social Security Code, it must be stated that, by providing, in the third paragraph, that treatment provided outside France may give rise to flat-rate reimbursement by sickness insurance funds, subject to the favourable opinion of the medical supervisory body, where the insured person shows that he was not able to receive in France the treatment appropriate to his condition, the consequence of that provision is to deter or prevent insured persons from approaching providers of medical services established in Member States other than the State of residence. It follows that such a national provision

constitutes, as is apparent from the case-law referred to in paragraph 19 of this judgment, a restriction on freedom to provide services.

55

In the present case, account must however be taken of the fact that the multidisciplinary treatment of pain which the claimant in the main proceedings envisages undergoing involves her hospitalisation.

56

It should be borne in mind, in that regard, that the Court has previously acknowledged that a requirement that the assumption of costs, under a national social security system, of hospital treatment provided in a Member State other than that of affiliation must be subject to prior authorisation appears to be a measure which is both necessary and reasonable and which may be justified in the light of one of the derogations under the Treaty (see *Smits and Peerbooms* , paragraphs 76 to 80, and *Müller-Fauré and Van Riet* , paragraphs 76 to 81).

57

According to the case-law of the Court, in order for such a prior administrative authorisation scheme to be justified even though it derogates from a fundamental freedom such as that in issue in the main proceedings, it is none the less necessary that it be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily (see *Smits and Peerbooms* , paragraph 90, and *Müller-Fauré and Van Riet* , paragraph 85). As stated in paragraph 48 of this judgment, such a prior administrative authorisation scheme must, similarly, be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings.

58

In the present case, Article R. 332-2 of the Social Security Code provides that the reimbursement to which that provision refers may be granted where it is proved that the person covered by social insurance could not receive in French territory the treatment appropriate to his condition.

A condition of that type can be justified under Article 49 EC, provided that the condition is construed to the effect that authorisation to receive treatment in another Member State may be refused on that ground only if treatment which is the same or equally effective for the patient can be obtained without undue delay within the territory of the Member State in which the insured person's sickness fund is established (see, to that effect, *Smits and Peerbooms* , paragraph 103, and *Müller-Fauré and Van Riet* , paragraph 89).

In view of all the foregoing considerations, the answer to the second part of the question must be that:

—

the second subparagraph of Article 22(2) of Regulation No 1408/71 must be interpreted as meaning that the authorisation to which that provision refers may not be refused where it is apparent, first, that the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides and, secondly, that treatment which is the same or equally effective cannot be obtained without undue delay in that Member State;

—

Articles 49 EC and 50 EC must be interpreted as not precluding legislation of a Member State, such as that at issue in the main proceedings, which, first, makes reimbursement of the cost of hospital care provided in a Member State other than that in which the insured person's sickness fund is established conditional upon prior authorisation by that fund and, secondly, makes the grant of that authorisation subject to the condition that it be established that the insured person could not receive within the territory of the Member State where the fund is established the treatment appropriate to his condition. However, authorisation may be refused on that ground only if treatment which is the same or equally effective for the patient can be obtained without undue delay in the territory of the Member State in which he resides.

1.6.5. Costs

61

The costs incurred by the French, Belgian, Spanish, Irish, Luxembourg, Swedish and United Kingdom Governments and by the Council and the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

1.6.6. The Court's decision

On those grounds, THE COURT (Fifth Chamber), in answer to the question referred to it by the Tribunal des affaires de sécurité sociale de Nanterre by order of 23 November 2000, hereby rules:

1.

Consideration of the first part of the question has disclosed no factor of such a kind as to affect the validity of Article 22(1)(c)(i²) of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996.

2.

The second subparagraph of Article 22(2) ²of Regulation No 1408/71, as amended and updated by Regulation No 118/97, must be interpreted as meaning that the authorisation to which that provision refers may not be refused where it is apparent, first, that the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides and, secondly, that treatment which is the same or equally effective cannot be obtained without undue delay in that Member State.

3.

Articles 49 EC¹ and 50 EC¹⁸ must be interpreted as not precluding legislation of a Member State, such as that at issue in the main proceedings, which, first, makes reimbursement of the cost of hospital care provided in a Member State other than that in which the insured person's sickness fund is established conditional upon prior authorisation by that fund and, secondly, makes the grant of that authorisation subject to the condition that it be established that the insured person could not receive within the territory of the Member State where the fund is established the treatment appropriate to his condition. However, authorisation may be refused on that ground only if treatment which is the same or equally effective for the patient can be obtained without undue delay in the territory of the Member State in which he resides.

2. Reimbursement of cross-border healthcare, including but not limited to cases without the consent of the insurer.

2.1. European Commission v Kingdom of Spain⁶

Failure of a Member State to fulfil obligations – Article 49 EC¹ – Social security – Hospital care needed during a temporary stay in another Member State – Lack of right to assistance from the competent institution to supplement that of the institution of the Member State

2.1.1. Judgment

1 By its application, the Commission of the European Communities asks the Court to declare that the Kingdom of Spain has failed to fulfil its obligations under Article 49 EC¹ by refusing persons insured under the Spanish national health scheme reimbursement of medical

⁶ Judgment Of The Court (Grand Chamber) 15 June 2010, In Case C 211/08, European Commission v Kingdom of Spain

expenses which they have incurred in another Member State for hospital treatment received in accordance with Article 22(1)(a)(i)² of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996 (OJ 1997 L 28, p. 1), and as subsequently amended by Regulation (EC) No 1992/2006 of the European Parliament and of the Council of 18 December 2006 (OJ 2006 L 392, p. 1) ('Regulation No 1408/71'), in so far as the level of cover applicable in the Member State where the treatment is administered is lower than that provided for under the Spanish legislation.

2.1.2. Legal context

European Union legislation

2 Article 22² of Regulation No 1408/71, entitled 'Stay outside the competent State – Return to or transfer of residence to another Member State during sickness or maternity – Need to go to another Member State in order to receive appropriate treatment', provides:

'1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:

(a) whose condition requires benefits in kind which become necessary on medical grounds during a stay in the territory of another Member State, taking into account the nature of the benefits and the expected length of the stay;

or

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition,

shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay ... in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

2. ...

The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resided and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.’

3 Article 34a²⁰ of Regulation No 1408/71 provides:

‘... Articles 22(1)(a) and (c), ... 22(2), second subparagraph, ... shall apply by analogy to students and the members of their families as required.’

4 Article 36(1)⁹ of Regulation No 1408/71 provides:

‘Benefits in kind provided in accordance with the provisions of this chapter by the institution of one Member State on behalf of the institution of another Member State shall be fully refunded.’

5 Article 21(1) of Regulation (EEC) No 574/72 of the Council of 21 March 1972 laying down the procedure for implementing Regulation No 1408/71, as amended and updated by Regulation No 118/97, and as subsequently amended by Commission Regulation (EC) No 311/2007 of 19 March 2007 (OJ 2007 L 82, p. 6) (‘the Implementing Regulation’), provides:

‘In order to receive benefits in kind under Article 22(1)(a)(i)² of [Regulation No 1408/71], an employed or self-employed person shall submit to the care provider a document issued by the competent institution certifying that he is entitled to benefits in kind. That document shall be drawn up in accordance with Article 2. ...

...’

6 Article 34(1)⁴ of the Implementing Regulation states:

‘If it is not possible during an employed or self-employed person’s stay in a Member State other than the competent State to complete the formalities provided for in Articles 20 ... and ... 21 ... of the Implementing Regulation, his expenses shall, upon his application, be refunded by the competent institution in accordance with the refund rates administered by the institution of the place of stay.’

7 On the basis of Article 2(1) of the Implementing Regulation, the Administrative Commission on Social Security for Migrant Workers – set up pursuant to Article 80 of Regulation No 1408/71 – drew up a model for the certificate relating to the application of Article 22(1)(a)(i) of Regulation No 1408/71, namely, form ‘E 111’. Form E 111 was replaced, with effect from 1 June 2004, by the ‘European health insurance card’ pursuant to a number of decisions of the Administrative Commission of the European Communities on Social Security for Migrant Workers: Decision No 189 of 18 June 2003 aimed at introducing a European health insurance card to replace the forms necessary for the application of Council Regulations No 1408/71 and No 574/72 as regards access to health care during a temporary stay in a Member State other than the competent State or the State of residence (OJ 2003 L 276, p. 1); Decision No 190 of 18 June 2003 concerning the technical specifications of the European health insurance card (OJ 2003 L 276, p. 4); and Decision No 191 of 18 June 2003 concerning the replacement of forms E 111 and E 111 B by the European health insurance card (OJ 2003 L 276, p. 19).

8 The scope of Article 22(1)(a)(i) of Regulation No 1408/71 was defined by Decision No 194 of the Administrative Commission of the European Communities on Social Security for Migrant Workers of 17 December 2003 concerning the uniform application of Article 22(1)(a)(i) of Regulation No 1408/71 in the Member State of stay (OJ 2004 L 104, p. 127; ‘Decision No 194’).

9 The seventh recital in the preamble to Decision No 194 states:

‘The criteria set out in Article 22(1)(a)(i) ... cannot be interpreted in such a way that chronic or existing illnesses are excluded. The Court of Justice ruled [in Case C 326/00 IKA[2003] ECR I 1703] that the concept of “necessary treatment” cannot be interpreted “as meaning that [the benefit of that provision is] limited solely to cases where the treatment provided has become necessary because of a sudden illness. In particular, the circumstance that the treatment necessitated by developments in the insured person’s state of health during his temporary stay in another Member State may be linked to a pre-existent pathology of which he is aware, such as a chronic illness, does not mean that the conditions for the application of these provisions are not fulfilled”.’

10 The enacting terms of Decision No 194 provide:

‘1. Benefits in kind which become medically necessary and which are granted to a person staying temporarily in another Member State, are covered by the provisions of Article 22(1)(a)(i) ... with a view to preventing an insured person from being forced to return before the end of the planned duration of stay to the competent State to obtain the treatment he/she requires.

The purpose of benefits of this type is to enable the insured person to continue his/her stay under safe medical conditions, taking account of the planned length of the stay.

However, the situation where the aim of the temporary stay is to receive medical treatment is not covered by these provisions.

2. In order to determine whether a benefit in kind meets the requirements set out in Article 22(1)(a)(i), ... only medical factors within the context of a temporary stay, taking into account the medical condition and past history of the person considered, shall be considered.

...’

2.1.3. National legislation

11 Article 43 of the Spanish Constitution enshrines the right to the protection of health and confers upon the public authorities responsibility for organising the health system and protecting public health through the provision of the necessary benefits and services.

12 To that end, General Law on health No 14/1986 (Ley 14/1986, General de Sanidad) of 25 April 1986 (BOE No 102, 29 April 1986, p. 15207; ‘the General Law on Health’) lays the foundations for a national health service which is public, universal and free of charge.

13 The benefits provided by the national health service to persons covered by that system are entirely free of charge. However, under Article 17 of the General Law on Health, benefits provided outside that system are, as a general rule, to be paid for by the insured person and are not to be reimbursed by bodies within the national health system.

14 Article 5 of Royal Decree 63/1995 on the organisation of health benefits within the national health service (Real Decreto 63/1995, sobre ordenación de prestaciones sanitarias del

Sistema Nacional de Salud) of 20 January 1995 (BOE No 35, 10 February 1995, p. 4538), provided:

‘1. The means available within the national health service shall be used for the provision of benefits ...

2. The provision of benefits ... may be required only of the personnel and [facilities] of the national health service, whether internal or under contract, without prejudice to the provisions laid down in international agreements.

3. In cases where immediate, urgent, life-saving treatment has been administered outside the national health system, the related costs shall be reimbursed provided that it is shown that it was not possible to use the services of that system in good time and that the treatment does not amount to an inappropriate use or an abuse of this exception.’

15 Law 16/2003 on the consistency and quality of the national health service (Ley 16/2003, de cohesión y calidad del Sistema Nacional de Salud) of 28 May 2003 (BOE No 128, 29 May 2003, p. 20567) catalogues the benefits and services to be available under that system.

16 In accordance with Article 14 of the General Law on Health, Article 9 of Law 16/2003 provides:

‘Without prejudice to the provisions of international agreements to which Spain is party, medical benefits and services under the national health system shall be provided only by the staff lawfully authorised to do so, using the [facilities], whether in-house or under contract, of the national health service, except in life-threatening situations where it is shown that it was not possible to use the facilities of that system.’

17 Provisions for the implementation of Law 16/2003 have been laid down in Royal Decree 1030/2006 establishing the catalogue of common services available under the national health system and the procedure for its revision (Real Decreto 1030/2006, por el que se establece la cartera de servicios comunes del Sistema Nacional de Salud y el procedimiento para su actualización) of 15 September 2006 (BOE No 222, 16 September 2006, p. 32650). Royal Decree 1030/2006 repealed and replaced Royal Decree 63/1995.

18 Article 4(3) of Royal Decree 1030/2006 states:

‘All common services shall be provided solely by facilities belonging to the national health system or under contract thereto, except in life-threatening situations where it is shown that it was not possible to use the facilities of that system. In cases where immediate, urgent, life-saving treatment has been administered outside the national health system, the related costs shall be reimbursed provided that it is shown that it was not possible to use the facilities of that system in good time and that the treatment does not amount to an inappropriate use or an abuse of this exception. The present paragraph shall be without prejudice to the provisions of international agreements to which Spain is party or the provisions of domestic law governing treatment in the event of services being provided abroad.’

19 It follows from those provisions that, where a person insured under the Spanish national health system receives hospital treatment in another Member State, the necessity for which was brought about by changes in his state of health during a temporary stay in that Member State, the institution to which he is affiliated covers the costs of that treatment only within the limits of its obligation under the combined provisions of Articles 22(1)(a)(i) and 36 of Regulation No 1408/71, except in the circumstances described in the second sentence of Article 4(3) of Royal Decree 1030/2006 and subject to the conditions set out therein. That exception aside, therefore, such a person has no right to insurance cover at the expense of the Spanish institution in respect of that part of the cost of the treatment which is not covered by the institution of the Member State of stay.

2.1.4. Pre-litigation procedure

20 The Commission received a complaint from a French citizen resident at the material time in Spain and insured under the Spanish national health system. On returning to Spain after being admitted to hospital during a stay in France, under cover of form E 111, that person met with refusal on the part of the Spanish institution to reimburse the portion of the hospitalisation costs which, in accordance with the French legislation, the French institution had left him to pay.

21 After requesting the Kingdom of Spain, in vain, for information concerning its legislation on the refunding of costs incurred for healthcare received in another Member State,

the Commission asked that Member State by letter of 19 December 2005 to provide a satisfactory response within two months.

22 By letter of 13 February 2006, the Kingdom of Spain replied that its legislation did not provide for the possibility that a person insured under the Spanish national health system could obtain reimbursement from the competent institution for healthcare costs incurred outside that system, save in the exceptional circumstances envisaged, at that time, in Article 5 of Royal Decree 63/1995.

23 On 18 October 2006, the Commission sent the Kingdom of Spain a letter of formal notice in which it drew Spain's attention to the incompatibility of its domestic legislation with Article 49 EC in so far as that legislation precluded, with exceptions, the reimbursement pursuant to Article 22(1)(a)(i)² of Regulation No 1408/71 – by the competent institution to the person insured under the national health system – of costs incurred for hospital treatment received in another Member State, where there was a positive difference between the levels of cover respectively applicable in Spain and in that other Member State.

24 By letter of 29 December 2006, the Kingdom of Spain essentially stated in reply to that letter of formal notice that the position taken by its administrative authorities vis-à-vis the complainant referred to in paragraph 20 above was in conformity with Regulation No 1408/71; that the circumstances of the person concerned were different from those of the dispute which led to the judgment in Case C 368/98 Vanbraekel and Others [2001] ECR I 5363; and that the interpretation argued for by the Commission would affect the financial balance of its national health system.

25 Dissatisfied with that reply, the Commission sent the Kingdom of Spain a reasoned opinion on 19 July 2007, in which it stated that the Spanish legislation was contrary to Article 49 EC and requested that Member State to adopt the measures necessary to put an end to the infringement within two months of receiving the reasoned opinion.

26 Since, in its reply of 19 September 2007 to the reasoned opinion, the Kingdom of Spain maintained its position, the Commission decided to bring the present action.

Admissibility

27 The Kingdom of Spain contests the admissibility of the action.

28 It argues that the submissions made by the Commission are confused, as the Commission alleges infringement of Article 49 EC¹ while acknowledging that the practice of the Spanish administration is in conformity with Regulations No 1408/71 and No 574/72. Not only that, but the application contains a complaint alleging that the second sentence of Article 4(3) of Royal Decree 1030/2006 does not comply with Article 49 EC, whereas circumstances such as those of the complainant referred to in paragraph 20 above fall within the scope of the last sentence of Article 4(3) of the decree, which refers to European Union law ('EU law').

29 The Kingdom of Spain also argues that, in so far as the Commission complains that Spain is in breach of Article 34 of the Implementing Regulation because the Spanish administration refuses to pay persons insured under its national health system the difference between the total cost of hospital treatment received in another Member State and the costs covered by the competent Spanish institution in relation to that treatment, the fact that this complaint was put forward out of time renders it inadmissible.

30 In addition, the Kingdom of Spain contends that the application contains a complaint which was not put forward during the pre-litigation procedure, alleging that Article 4(3) of Royal Decree 1030/2006 is incompatible with Article 22(1)(a) of Regulation No 1408/71.

31 The Kingdom of Belgium contends that Article 49 EC was not mentioned at all in the reasoned opinion and, in consequence, the application may not contain an argument based on that provision.

32 In that regard, it should be borne in mind that it follows from Article 38(1)(c) of the Rules of Procedure of the Court of Justice and from the case-law relating to that provision that the application initiating proceedings must state the subject-matter of the dispute and a summary of the pleas in law on which the application is based and that that statement must be sufficiently clear and precise to enable the defendant to prepare its defence and the Court to rule on the application. It is therefore necessary for the essential points of law and of fact on which a case is based to be indicated coherently and intelligibly in the application itself and for the heads of claim to be set out unambiguously so that the Court does not rule *ultra petita* or indeed fail to rule on a claim (Case C 195/04 *Commission v Finland* [2007] ECR I 3351, paragraph 22 and the case-law cited, and Case C 343/08 *Commission v Czech Republic* [2010] ECR I 0000, paragraph 26).

33 Moreover, the subject-matter of an action brought under Article 226 EC is circumscribed by the pre-litigation procedure laid down in that provision. Consequently, the Commission's reasoned opinion and its application must be based on the same complaints (Commission v Finland, paragraph 18).

34 In the present case, the application and the submissions made by the Commission meet those various requirements.

35 Neither the reasoned opinion nor the application sets out a complaint alleging failure by the Kingdom of Spain to fulfil its obligations under Regulations No 1408/71 and No 574/72. In furtherance of the position consistently maintained by the Commission during the pre-litigation procedure, the application seeks only a declaration that Spain has failed to fulfil its obligations under Article 49 EC¹.

36 It is quite clear from the Commission's application and from its submissions that the shortcoming which the Commission alleges resides in the fact that, in the case of persons insured under the Spanish national health system whose state of health makes hospital treatment necessary during a temporary stay in another Member State, for the purposes of Article 22(1)(a)(i) of Regulation No 1408/71, the legislation at issue denies – except in the case of life-saving treatment, as referred to in the second sentence of Article 4(3) of Royal Decree 1030/2006 – the right, which derives from Article 49 EC, to receive complementary reimbursement from the Spanish institution where the level of cover applicable in the Member State of stay is lower than that which is applicable in Spain.

37 In that context, the reference which the Commission makes, *inter alia*, in its submissions to Article 22(1)(a)(i)² of Regulation No 1408/71 is not intended to form the basis for an autonomous complaint, but to define the group of insured persons to whose detriment the legislation at issue constitutes, in the view of the Commission, an infringement of Article 49 EC.

38 It follows that the action is admissible.

2.1.5. Substance

Arguments of the parties

39 The Commission submits that Article 49 EC applies to the healthcare services covered by the Spanish legislation, including where the need for such treatment arises during the insured person's temporary stay in another Member State.

40 After pointing out that Article 22² of Regulation No 1408/71 and Article 49 EC are complementary, the Commission asserts that, in the present case, the effect of the Spanish legislation is to restrict not only the provision of hospital care, but also the provision of tourist or educational services, the obtaining of which can be the reason for a temporary stay in another Member State.

41 Pointing out that the situation envisaged in Article 22(1)(a) of Regulation No 1408/71 covers all cases where treatment becomes necessary during a temporary stay in another Member State owing to a deterioration in the health of the insured person, the Commission submits that the legislation at issue is liable to induce a person insured under the Spanish national health system, who is faced with such a situation and has a choice between going to hospital in the Member State of stay and an early return to Spain to be treated there, to choose the second option whenever the level of cover applicable in the Member State of stay is less favourable than that applicable in Spain.

42 The Commission adds that the legislation at issue is such as to dissuade elderly insured persons or those suffering from a chronic illness – with the attendant risk of having to be admitted to hospital – from travelling, as tourists or students, to a Member State in which the conditions governing insurance cover for hospital treatment are less advantageous than in Spain.

43 The Commission argues that the restriction brought about by that legislation is not justified. In particular, it has not been shown that there is a need for such a restriction in the light of the objective of ensuring that the financial balance of the national health system is maintained, given that the costs supported by the Spanish national health service in respect of hospital care administered in another Member State to a person insured under the Spanish system cannot, in any case, exceed the cost of equivalent treatment in Spain.

44 The Spanish Government, supported by the Belgian, Finnish and United Kingdom Governments, challenges the view that the legislation at issue constitutes a restriction on the freedom to provide medical, tourist or educational services and contends that, in any event, the alleged restriction is justified by overriding reasons relating to the public interest in maintaining the financial balance of the national health system concerned.

Findings of the Court

45 First of all, it should be borne in mind that the applicability of Article 22 of Regulation No 1408/71 – and specifically, in the present case, of Article 22(1)(a)(i) – does not mean that Article 49 EC cannot apply at the same time. The fact that national legislation may be in conformity with Regulation No 1408/71 does not have the effect of removing that legislation from the scope of the provisions of the EC Treaty (see, to that effect, Case C 372/04 Watts [2006] ECR I 4325, paragraphs 46 and 47).

46 That said, it must first be determined whether, in the case of a person insured under the national health system whose state of health makes hospital care necessary during a temporary stay in another Member State, the services identified by the Commission in its action are cross-border services and, as such, within the scope of Article 49 EC (see, to that effect, Case 352/85 Bond van Adverteerders and Others [1988] ECR 2085, paragraph 13).

47 With regard, on the one hand, to healthcare services, it should be noted that, according to settled case-law, medical services provided for consideration fall within the scope of the provisions on the freedom to provide services, including situations where care is provided in a hospital environment (see, to that effect, Watts, paragraph 86 and the case-law cited, and Case C 444/05 Stamatelaki [2007] ECR I 3185, paragraph 19). Furthermore, the provision of medical services does not cease to be a provision of services for the purposes of Article 49 EC simply because, after paying the foreign provider for the care received, the insured person subsequently seeks reimbursement of the related costs through a social security system (see, to that effect, Watts, paragraph 89 and the case-law cited).

48 The Court has also held that Article 49 EC applies where the person providing the service and the recipient are established in different Member States (see Case C 55/98 Vestergaard [1999] ECR I 7641, paragraph 19). Services which the provider carries out without moving from the Member State in which he is established for recipients established in other Member States constitute the provision of cross-border services for the purposes of

Article 49 EC (see, *inter alia*, Case C-384/93 *Alpine Investments* [1995] ECR I-1141, paragraphs 21 and 22 and Case C 243/01 *Gambelli and Others* [2003] ECR I 13031, paragraph 53).

49 Furthermore, the Court has consistently held that the freedom to provide services involves not only the freedom of the provider to carry out services for recipients established in a Member State other than that in which the provider is established but also the freedom to receive or to benefit, as recipient, from the services carried out by a provider established in another Member State, without being hampered by restrictions (see, *inter alia*, *Gambelli and Others*, paragraph 55 and the case-law cited).

50 It follows that hospital services which are carried out in a Member State by a provider established there for a recipient established in another Member State are covered by the notion of the provision of services, for the purposes of Article 49 EC, including where – as in the present case – the reasons for which the recipient was staying temporarily in the Member State of establishment of the provider were not medical.

51 On the other hand, with regard to services other than medical services, such as tourist and educational services as specifically referred to by the Commission in its action, it is necessary to bear in mind, in addition to the case-law referred to in paragraph 48 above, that persons established in a Member State who travel to another Member State as tourists or on a study trip must be regarded as recipients of services for the purposes of Article 49 EC (Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, paragraph 16; Case 186/87 *Cowan* [1989] ECR 195, paragraph 15; and Case C 348/96 *Calfa* [1999] ECR I 11, paragraph 16).

52 It follows from the above considerations that the freedom to provide services encompasses the freedom of an insured person established in a Member State to travel – as a tourist or student, for example – to another Member State for a temporary stay and to receive hospital care there from a provider established in the latter Member State, where the need for such care during that stay arises because of his state of health.

53 Whilst it is established that EU law does not detract from the power of the Member States to organise their social security systems and that, in the absence of harmonisation at European Union level, it is for the legislation of each Member State to determine the conditions for the grant of social security benefits, the fact nevertheless remains that, when

exercising that power, Member States must comply with EU law and, in particular, with the provisions on the freedom to provide services (see, in particular, Watts, paragraph 92 and the case-law cited).

54 In those circumstances, it is appropriate, secondly, to consider whether the legislation at issue constitutes a failure to comply with those provisions.

55 It is settled law that Article 49 EC precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services entirely within a single Member State (see, *inter alia*, Stamatelaki, paragraph 25 and the case-law cited).

56 In that connection, the Court has held that the fact that national legislation does not guarantee an insured person who has been authorised to receive hospital care in another Member State, in accordance with Article 22(1)(c) of Regulation No 1408/71, a level of insurance cover equivalent to that to which he would have been entitled had he received hospital treatment in the Member State of affiliation is a restriction of the freedom to provide services, for the purposes of Article 49 EC¹, in that it may deter, or even prevent, that person from applying to providers of services established in other Member States (see, to that effect, *Vanbraekel and Others*, paragraph 45). The Court stated, with regard to national legislation under which hospital care was to be free of charge if provided within the national health service, that such a level of cover corresponds to the cost, in the system of the Member State of affiliation, of care equivalent to that provided to the insured person in the Member State of stay (see, to that effect, *Watts*, paragraphs 131 and 133).

57 The Court has held that, in so far as complementary reimbursement, which depends on the rules governing social insurance cover in the Member State of affiliation, does not by definition impose any additional financial burden on the sickness insurance scheme of that Member State as compared with the reimbursement to be made or the costs to be borne if hospital care had been provided in that State, it cannot be argued that making that sickness insurance scheme bear the costs of complementary reimbursement would be liable to have a significant effect on the financing of the social security system of that Member State (*Vanbraekel and Others*, paragraph 52).

58 However, with regard at least to hospital care, which is all that is at issue in the present case, cases of ‘unscheduled treatment’, as referred to in Article 22(1)(a²) of Regulation No

1408/71 – and at issue in the present case – must be distinguished, in the light of Article 49 EC, from cases of ‘scheduled treatment’, as referred to in Article 22(1)(c²) of that regulation, at issue both in *Vanbraekel and Others* and in *Watts*.

59 First of all, it should be noted that scheduled hospital treatment is received in another Member State under Article 22(1)(c) of Regulation No 1408/71 where – as is clear from the second subparagraph of Article 22(2) of that regulation – an objective finding has been made that the treatment in question, or treatment which is comparable in terms of effectiveness, is not available in the Member State of affiliation within a medically acceptable length of time (see, to that effect, *Watts*, paragraphs 57 and 59). In such circumstances, as the Court held in *Vanbraekel and Others*, the Member State of affiliation must, if it is not to find itself in breach of the rules on freedom to provide services, ensure – in addition to meeting its obligations under Articles 22(1)(c) of Regulation No 1408/71, read in conjunction with Article 36 thereof – that, should the case arise, the insured person has a level of cover which is equally as advantageous as the level of cover which would have been recognised if that treatment had been available under its own national health system within a medically acceptable length of time.

60 However, the situation is different in the case of unscheduled treatment, as referred to in Article 22(1)(a) of Regulation No 1408/71.

61 With regard to an insured person whose travel to another Member State is for reasons relating to tourism or education, for example, and not to any inadequacy in the health service to which he is affiliated, the rules of the Treaty on freedom of movement offer no guarantee that all hospital treatment services which may have to be provided to him unexpectedly in the Member State of stay will be neutral in terms of cost. Given the disparities between one Member State and another in matters of social security cover and the fact that the objective of Regulation No 1408/71 is to coordinate the national laws but not to harmonise them, the conditions attached to a hospital stay in another Member State may, according to the circumstances, be to the insured person’s advantage or disadvantage (see, by analogy, *Joined Cases C 393/99 and C 394/99 Hervein and Others* [2002] ECR I 2829, paragraphs 50 to 52; *Case C 387/01 Weigel* [2004] ECR I 4981, paragraph 55; and *Case C 392/05 Alevizos* [2007] ECR I 3505, paragraph 76).

62 Next, it should be pointed out that, in the case of scheduled hospital treatment in another Member State, the insured person is, as a general rule, able to obtain an overall

estimate of the cost of that treatment, in the form of a quote, enabling him to compare the levels of cover respectively applicable in the Member State of stay and the Member State of affiliation.

63 In those circumstances, the fact that the legislation of the Member State of affiliation does not guarantee the insured person the right to receive reimbursement from the competent institution of any positive difference between the level of cover applicable in that Member State and the level of cover applicable in the Member State in which the hospital treatment is scheduled to take place is likely to induce the insured person to cancel the treatment planned in that other Member State, which amounts to a restriction on the freedom to provide services, as the Court held in *Vanbraekel and Others* and in *Watts*.

64 However, as the Spanish Government has pointed out, the case of unscheduled treatment envisaged in Article 22(1)(a) of Regulation No 1408/71 covers, in particular, an indefinite number of cases in which the state of health of the insured person makes hospital treatment necessary, during a temporary stay in another Member State, because of circumstances – relating, *inter alia*, to the urgency of the situation, the seriousness of the illness or the accident, or even the fact that a return to the Member State of affiliation is ruled out for medical reasons – which, objectively, leave no alternative but to provide the insured person with hospital treatment in an establishment in the Member State of stay.

65 In all those cases, the legislation at issue cannot be regarded as having any restrictive effect on the provision of hospital treatment services by providers established in another Member State.

66 It is true that, as the Commission pointed out, the situation envisaged in Article 22(1)(a) of Regulation No 1408/71 also covers cases where the deterioration in the health of the insured person during a temporary stay in another Member State, while unexpected, is not such as to deprive him of the choice between going to hospital in that State and an early return to Spain to receive the necessary hospital treatment there.

67 Nevertheless, as paragraph 1 of the enacting terms of Decision No 194 makes clear, the system established under Article 22(1)(a)(i) of Regulation No 1408/71 is intended precisely to prevent the insured person from being constrained in such cases to return early to the Member State of affiliation to receive the necessary treatment there, by conferring on that person the right – which he would not otherwise have – of access to hospital treatment in the Member

State of stay on conditions of reimbursement as favourable as those enjoyed by insured persons covered by the legislation of that State (see, by analogy, Case C 56/01 Inizan [2003] ECR I 12403, paragraphs 21 and 22).

68 In addition, it should be noted that the potential effect of the legislation at issue on the situation of an insured person in that position depends on a factor which is uncertain at the time when that person is faced with such a choice, that is to say, the possibility that the level of cover applicable in the Member State of stay for hospital treatment there – the overall cost of which is, at that time, not known – is lower than the cost of equivalent treatment in Spain.

69 As regards services other than medical services, such as tourist or educational services, it should be pointed out that cases of unscheduled treatment for the purposes of Article 22(1)(a) of Regulation No 1408/71 imply by definition that, at the time when the insured person plans to travel to another Member State – as a tourist or a student, for example – there is uncertainty as to whether hospital treatment will be needed during his temporary stay in that other Member State.

70 The situation of elderly insured persons and the situation of those suffering from chronic or pre-existing illness, both of which – according to paragraph 1 of the enacting terms of Decision No 194 and the seventh recital in the preamble to that decision – fall within the scope of Article 22(1)(a) of Regulation No 1408/71, is similarly uncertain in that regard.

71 Although they may run a higher risk of deterioration in their state of health, those insured persons, in common with other insured persons, are likely to be affected by the legislation at issue only if their state of health actually necessitates hospital treatment, other than the treatment referred to in the second sentence of Article 4(3) of Royal Decree 1030/2006, during a temporary stay in another Member State or if the level of cover applicable in that Member State is lower than the cost of equivalent treatment in Spain.

72 It follows that the possibility that persons insured under the Spanish national health system might be induced to return early to Spain in order to receive hospital treatment there which has been made necessary by a deterioration in their health during a temporary stay in another Member State, or to cancel a trip to another Member State – for tourism or study, for example – because, if their case does not fall within the scope of the second sentence of Article 4(3) of Royal Decree 1030/2006, they cannot count on the competent institution making a complementary contribution if the cost of equivalent treatment in Spain exceeds the

level of cover applicable in that other Member State, appears too uncertain and indirect. Accordingly, the legislation at issue cannot, in general terms, be regarded as restricting the freedom to provide hospital treatment services, tourist services or educational services (see, by analogy, regarding the free movement of goods and freedom of movement for workers respectively, Case C 69/88 Krantz [1990] ECR I 583, paragraph 11, and Case C 190/98 Graf [2000] ECR I 493, paragraphs 24 and 25).

73 The case of the complainant referred to in paragraph 20 above confirms that conclusion. It shows that the effect of the legislation at issue is hypothetical, inasmuch as the application for complementary reimbursement submitted by the person concerned proved to be unfounded, as is apparent from the documents before the Court, because the cost of equivalent treatment in Spain is lower than the level of cover applied in the Member State of stay.

74 Lastly, it should be pointed out that, in contrast with the cases covered by point (c) of Article 22(1) of Regulation No 1408/71, those covered by point (a) of that provision are, for the Member States and the institutions responsible for social security in those States, unforeseeable.

75 In its capacity as the Member State of affiliation, every Member State is free, within the framework of its powers under Articles 153 TFEU and 168 TFEU to organise its public health and social security system (see to that effect, Watts, paragraphs 92 and 146, and Joined Cases C 570/07 and C 571/07 Blanco Pérez and Chao Gómez [2010] ECR I 0000, paragraph 43), to adopt measures affecting the extent and the conditions – especially regarding time-limits – of the offer of hospital treatment in its own territory, so as to be able to control the number of authorisations to be issued, under Article 22(1)(c) of Regulation No 1408/71, for treatment in another Member State which has been scheduled by persons insured under its own system.

76 However, as the Danish and Finnish Governments have pointed out, the ever-increasing mobility of citizens within the European Union, particularly for reasons of tourism or education, is likely to mean an ever greater number of cases of unscheduled hospital treatment, for the purposes of Article 22(1)(a) of Regulation No 1408/71, which the Member States can in no way control.

77 In that context, where every Member State relies, as Member State of affiliation, on the application of the legislation of the Member State of stay as regards the level of cover, for which the competent institution is ultimately responsible, in respect of hospital treatment

which becomes necessary owing to the state of health of the insured person during his temporary stay in the latter Member State, the combined application of Article 22(1)(a) of Regulation No 1408/71 and of Article 36 thereof, concerning the mechanism for reimbursement between the institutions concerned, is based on the principle of overall compensation of risk.

78 Thus, cases in which unscheduled hospital treatment provided to an insured person during a temporary stay in another Member State bring about – as a consequence of the application of the legislation of the Member State of stay – a heavier financial burden for the Member State of affiliation than if that treatment had been provided in one of its own establishments, are deemed to be counterbalanced overall by cases in which, on the contrary, application of the legislation of the Member State of stay leads the Member State of affiliation to incur lower costs for the hospital treatment in question than those which would have resulted from the application of its own legislation.

79 Consequently, the fact of imposing on a Member State the obligation to guarantee to persons insured under the national system that the competent institution will provide complementary reimbursement whenever the level of cover applicable in the Member State of stay in respect of the unscheduled hospital treatment in question proves to be lower than that applicable under its own legislation would ultimately undermine the very fabric of the system which Regulation No 1408/71 sought to establish. In every case concerning such treatment, the competent institution of the Member State of affiliation would be systematically exposed to the highest financial burden, whether through the application, in accordance with Article 22(1)(a) of that regulation, of the legislation of a Member State of stay under which the level of cover is higher than that provided for under its own or through the application of its own legislation in the contrary situation.

80 In the light of all the above considerations, the Commission has failed to show that, viewed globally, the legislation at issue constitutes a failure by the Kingdom of Spain to fulfil its obligations under Article 49 EC.

81 The action must therefore be dismissed.

2.1.6. Costs

82 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Kingdom of Spain has applied for costs to be awarded against the Commission and the latter has been unsuccessful, the Commission must be ordered to pay the costs. Pursuant to the first subparagraph of Article 69(4) of the Rules of Procedure, the Kingdom of Belgium, the Kingdom of Denmark, the Republic of Finland and the United Kingdom, which have intervened in the proceedings, must bear their own costs.

2.1.7. The Court's decision

On those grounds, the Court (Grand Chamber) hereby:

1. Dismisses the action;
2. Orders the European Commission to pay the costs;
3. Orders the Kingdom of Belgium, the Kingdom of Denmark, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland to bear their own costs.

2.2. *Abdon Vanbraekel and Others v Alliance nationale des mutualités chrétiennes (ANMC)*⁷

Social security - Sickness insurance - Articles 22² and 36⁹ of Regulation (EEC) No 1408/71 - Freedom to provide services - Article 59¹¹ of the EC Treaty (now, after amendment, Article 49 EC) - Hospital treatment costs incurred in another Member State - Refusal of authorisation subsequently declared unfounded

⁷ Judgment Of The Court 12 July 2001, In Case C-368/98, *Abdon Vanbraekel and Others v Alliance nationale des mutualités chrétiennes (ANMC)*

2.2.1. Judgment

1.

By judgment of 9 October 1998, received at the Court on 16 October 1998, the Cour de travail de Mons (Higher Labour Court, Mons) referred to the Court for a preliminary ruling under Article 177¹⁶ of the EC Treaty (now Articles 234 EC) a question on the interpretation of Articles 22² and 36⁹ of Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, in the version amended and updated by Council Regulation (EEC) No 2001/83 of 2 June 1983 (OJ 1983 L 230, p. 6, 'Regulation No 1408/71'), and of Article 59 of the EC Treaty (now, after amendment, Article 49 EC).

2.

That question has been raised in proceedings between Abdon Vanbraekel and his six children, as heirs of Ms Jeanne Descamps, and the Alliance nationale des mutualités chrétiennes ('the ANMC') concerning the latter's refusal to reimburse the costs of hospital treatment incurred by Ms Descamps in connection with orthopaedic surgery which she underwent in a hospital in France.

2.2.2. Community law

3.

Article 22(1)² of Regulation No 1408/71 provides:

'An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:

(a) whose condition necessitates immediate benefits during a stay in the territory of another Member State; or

(b) ... or

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition,

shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

(ii) to cash benefits provided by the competent institution in accordance with the provisions of the legislation which it administers. However, by agreement between the competent institution and the institution of the place of stay or residence, such benefits may be provided by the latter institution on behalf of the former, in accordance with the provisions of the legislation of the competent State.'

4.

The second subparagraph of Article 22(2)² of Regulation No 1408/71 provides:

'The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.'

5.

Section 7 of Chapter 1 in Title III of Regulation No 1408/71, headed 'Reimbursement between institutions', contains a single provision, Article 36, which is worded as follows:

'1. Without prejudice to the provisions of Article 32, benefits in kind provided in accordance with the provisions of this chapter by the institution of one Member State on behalf of the institution of another Member State shall be fully refunded.

2. The refunds referred to in paragraph 1 shall be determined and made in accordance with the procedure provided for by the implementing Regulation referred to in Article 98, either on production of proof of actual expenditure or on the basis of lump-sum payments.

In the latter case, the lump-sum payments shall be such as to ensure that the refund is as close as possible to actual expenditure.

3. Two or more Member States, or the competent authorities of those States, may provide for other methods of reimbursement or may waive all reimbursement between institutions under their jurisdiction.'

2.2.3. National legal framework

6.

Article 76 quater(1) of the Law of 9 August 1963 introducing and organising a compulsory sickness and invalidity insurance scheme ('the Law of 9 August 1963') provided at the material time:

'Unless the King provides otherwise, the benefits provided for in this Law shall not be granted where the recipient is not actually present on Belgian territory at the time of making the claim for benefits or where health benefits have been provided outside the national territory.

7.

Article 221(1) of the Royal Decree of 4 November 1963 implementing the Law of 9 August 1963 provides:

'Authorisation to receive health benefits provided outside the national territory shall be granted:

(2) for the recipient, where the restoration of his health requires hospital treatment which can be given under better medical conditions abroad provided that the medical expert has first determined such treatment to be essential.'

8.

However, the Belgian Government states in its written observations that requests for authorisation to receive treatment in another Member State are now considered under Article 22 of Regulation No 1408/71 rather than the Belgian legislation cited above.

9.

Thus it follows from ministerial instructions set out in Circular No 83/54-80/54 of the Institut national d'assurance maladie-invalidité (INAMI) of 4 February 1983 that the Belgian legislation no longer applies where the situation in question is governed by Community rules.

10.

As regards the issue of Form E 112, referred to in Regulation (EEC) No 574/72 of the Council of 21 March 1972 fixing the procedure for implementing Regulation No 1408/71 (OJ, English Special Edition 1972 (I), p. 159) and, accordingly, the reimbursement of medical benefits provided in another Member State, Ministerial Circular O.A. No 81/215-80/51 of 18 June 1971 provides as follows:

I. As regards the application of Article 22² of Regulation No 1408/71, the following principles shall apply:

1 Authorisation to receive treatment abroad shall not be given where the medical and technical facilities for providing such treatment are also available in Belgium;

2 Where authorisation to receive treatment abroad is given in very exceptional cases, that is to say where the treatment cannot be given in Belgium, the medical expert must clearly specify the establishment which is to provide the treatment and/or the medical specialist and also the proposed period of treatment;

2 Subject to paragraph 2, benefits not covered by Belgian insurance cannot be provided abroad, that is to say Form E 112 cannot be issued for benefits which are not reimbursable in Belgium under the compulsory sickness-invalidity insurance scheme (absolute bar).

The main proceedings and the question referred to the Court

11.

Ms Descamps, a Belgian national residing in Belgium and insured under the ANMC, suffered from bilateral gonarthrosis. In February 1990, she sought authorisation from the ANMC to undergo orthopaedic surgery in France, to be paid for by the ANMC.

12.

Authorisation was refused on the ground that the request was not adequately supported, since Ms Descamps had not produced the opinion of a doctor practising in a national university institution.

13.

Despite being refused authorisation, Ms Descamps went ahead with the operation in France in April 1990. She then brought an action against the ANMC before the Tribunal du travail de Tournai (Belgium) for reimbursement of the cost of that treatment.

14.

By judgment of 10 December 1991, the Tribunal du travail de Tournai dismissed her action. It held that the ANMC's decision refusing authorisation was well founded, notably on the ground that Ms Descamps '[had] not shown, by at the least producing the opinion of a Belgian university professor, that the operative treatment in France [had been] performed under better medical conditions than would have been the case in Belgium'.

15.

Ms Descamps appealed against that decision to the Cour du travail de Mons, which, by interlocutory judgment of 8 October 1993, held that the requirement, upheld by the Tribunal du travail de Tournai, that the opinion of a Belgian university professor was necessary before authorisation could be granted was excessive. In the same judgment, the Cour du travail de Mons designated an expert to assess whether the restoration of Ms Descamps's health in March 1990 necessitated hospital treatment which could be provided in better medical conditions abroad than in Belgium.

16.

The expert's report submitted on 29 December 1994 concluded that 'in March 1990 Mrs Jeanne Descamps's recovery required hospital treatment which could be provided in better medical conditions abroad (an operation performed by Dr Cartier in Paris, Article 221(1) of the Royal Decree of 4 November 1963)'.

17.

According to the pleadings exchanged before the Cour du travail de Mons after submission of the expert's report, reimbursement of the medical costs incurred by Ms Descamps came to a total of FRF 38 608.99 using the formula for calculating reimbursement laid down in the French legislation and to a total of FRF 49 935.44 using the formula laid down in the Belgian legislation.

18.

Ms Descamps died in the course of the proceedings, on 10 August 1996. Her heirs, namely her husband, Mr Vanbraekel, and her six children, are pursuing this action.

19.

In view of the report of the designated expert, the Cour du travail de Mons held that the ANMC would be ordered to pay the costs connected with Ms Descamps's hospital treatment 'in accordance with Article 22 of Regulation [No] 1408/71 and Articles 59 and 60 of the Treaty'. It held that the only question still to be resolved was the amount of the costs assumed and decided to stay proceedings and to refer the following question to the Court for a preliminary ruling:

'Where, in the context of proceedings before it, a national court has acknowledged that hospital treatment in a Member State other than that of the competent institution was necessary, although the prior authorisation provided for in Article 22 of Regulation No 1408/71 was refused:

(a) Must the costs of hospital treatment be reimbursed in accordance with the scheme of the State of the competent institution or in accordance with that organised by the State on whose territory the hospital treatment has taken place?

(b) Is a limitation of the amount reimbursed under the legislation of the State of the competent institution permitted, having regard to Article 36 of Regulation No 1408/71 which refers to reimbursement in full?'

2.2.4. Admissibility

20.

The Irish, Netherlands and United Kingdom Governments argue that the judgment asking for a preliminary ruling does not state precisely why the national court needs an interpretation of Community law to decide the case and that it does not contain sufficient information about the relevant points of law and facts to enable the Member States effectively to exercise their right to lodge written observations before the Court.

21.

In regard to that argument, it should be observed that the Court has consistently ruled that the need to provide an interpretation of Community law which will be of use to the national court makes it necessary that the national court define the factual and legislative context of the questions it is asking or, at the very least, explain the factual circumstances on which those questions are based (see, in particular, judgment in Joined Cases C-320/90 to 322/90 *Telemarsicabruzzo and Others* [1993] ECR I-393, paragraph 6; orders in Case C-152/92 *Banchero* [1993] ECR I-1085, paragraph 4, Joined Cases C-128/97 and C-137/97 *Testa and Modesti* [1998] ECR I-2181, paragraph 5, and Case C-116/00 *Laguillaumie* [2000] ECR I-4979, paragraph 15). The Court has also repeatedly emphasised the importance for the referring court to state the precise reasons which prompted it to question the interpretation of Community law and to consider it necessary to refer questions to the Court of Justice for a preliminary ruling (see, in particular, orders in Case C-101/96 *Italia Testa* [1996] ECR I-3081, paragraph 6, *Testa and Modesti*, paragraph 15, and *Laguillaumie*, paragraph 16).

22.

In the present case, however, the national court has not failed to comply with those requirements.

23.

The referring court's judgment indicates the applicable national provisions and gives a description of the facts which, although concise, is sufficient to enable the Court to adjudicate on the matter.

24.

Furthermore, as previously observed, the national court has already held that, in the circumstances of the case before it, the conditions to which Community law subjects the existence of a right to reimbursement of the costs of treatment received in a Member State other than the State in which the person concerned is insured were satisfied. As the judgment makes clear, the request for a preliminary ruling addressed to the Court seeks only to ascertain the amount of the reimbursement to be made and, in particular, whether it is the scheme of the Member State in which the person concerned is insured or the scheme governed by the legislation of the Member State on whose territory the treatment was provided that must be applied in this regard.

25.

In those circumstances, the question referred by the national court does indeed call for examination.

2.2.5. The questions referred

26.

By the first part of its question, the national court is asking essentially whether, when a person who has requested authorisation on the basis of Article 22(1)(c) of Regulation No 1408/71 has been refused by the competent institution and it is subsequently established that that refusal was unfounded, the reimbursement by the competent institution of the costs of the treatment should be made according to the relevant rules in force in the Member State in

which the person concerned is insured or according to those laid down in the legislation of the Member State on whose territory the treatment was provided.

27.

In answering that question, it should be noted at the outset that, although the national court does not say so, the Community provisions whose interpretation appears to be relevant for the purpose of answering the question are, first, Article 22(1)(c) and (i) of Regulation No 1408/71 and, second, Article 59¹¹ of the Treaty.

28.

As already observed, the national court states that it has held that the medical costs at issue in the main proceedings must be paid by the ANMC 'in accordance with Article 22 of Regulation No 1408/71 and Articles 59 and 60¹² of the Treaty'.

Article 22² of Regulation No 1408/71

29.

As regards the applicability of Article 22 of Regulation No 1408/71 to the case before the national court, it must be borne in mind first of all that Ms Descamps did request prior authorisation on the basis of that provision and that the national court decided to declare the refusal of authorisation inoperative.

30.

The fact that the refusal of authorisation was held unfounded in the main proceedings, on the basis of the criteria for authorisation laid down in the national legislation and not according to the criteria set out in the second paragraph of Article 22(2)² of Regulation No 1408/71, does not mean that there was no ground to apply that regulation, as the Belgian Government maintains.

31.

It follows from the second subparagraph of Article 22(2) of Regulation No 1408/71 that the sole purpose of that provision is to identify the circumstances in which the competent national institution is precluded from refusing authorisation sought on the basis of Article 22(1)(c). That provision is not designed to limit the circumstances in which such authorisation

may be granted pursuant to Article 22(1)(c). It follows that, where permission is granted on the basis of a national rule which, like the legislation at issue in the main proceedings, provides that authorisation is to be granted where it is established that hospital treatment can be provided under better medical conditions abroad, such permission constitutes an authorisation within the meaning of Article 22(1)(c) of Regulation No 1408/71.

32.

As regards the extent of the rights conferred by Article 22(1)(c) on an insured person who has been granted such authorisation, it follows from paragraph 1(i) that the insured person must in principle be entitled to the benefits in kind provided on behalf of the competent institution by the institution of the place where the insured person is staying, in accordance with the provisions of the legislation of the State in which the benefits are provided, as if the covered person were insured in that State. Only the length of the period during which benefits are provided remains to be governed by the legislation of the competent State. By guaranteeing that insured persons covered by the legislation of one Member State and granted authorisation have access to treatment in the other Member States on conditions as favourable as those enjoyed by persons covered by the legislation of those other States, that provision helps to facilitate the free movement of persons covered by social insurance.

33.

It follows from the foregoing that, as regards the basis on which costs are borne, the legislation of the Member State in which the treatment is given is to be applied, while the competent institution remains responsible for subsequently reimbursing the institution of the place of stay, as provided for in Article 36⁹ of Regulation No 1408/71.

34.

Both the practical effect and the spirit of those provisions require, moreover, that the request of an insured person for authorisation on the basis of Article 22(1)(c) of Regulation No 1408/71 has been refused by the competent institution and it is subsequently established, either by the competent institution itself or by a court decision, that that refusal was unfounded, that person is entitled to be reimbursed directly by the competent institution by an amount equivalent to that which it would ordinarily have borne if authorisation had been properly granted in the first place.

35.

The national court states that the amount reimbursable under the Belgian system is higher than the amount payable under the French system and is uncertain about the amount of the reimbursement to which the plaintiffs, in their capacity as Ms Descamps's heirs, are actually entitled under Community law. The question therefore arises whether the plaintiffs can also claim extra reimbursement to cover the difference between the two systems.

36.

It should be noted that Article 22² of Regulation No 1408/71 is not intended to regulate, and therefore does not in any way prevent, reimbursement by Member States at the tariffs in force in the competent State, of costs incurred in connection with treatment provided in another Member State (see Case C-158/96 Kohll [1998] ECR I-1931, paragraph 27) where the legislation of the Member State in which the person concerned is insured makes provision for such reimbursement and the tariffs applied under that legislation are more beneficial than those applied by the Member State in which the treatment was provided.

37.

Although Article 22 of Regulation No 1408/71 does not have the effect of preventing extra reimbursement, additional to that resulting from the application of the system of the Member State where the treatment was provided, when the system applied in the Member State in which the person concerned is insured is more beneficial, that provision does not have the further effect of requiring such additional reimbursement. Consequently, it is necessary to consider whether such an obligation might arise under Article 59 of the Treaty.

The rules on freedom to provide services

38.

It must be determined first of all whether the situation at issue in the main proceedings falls within the scope of freedom to provide services within the meaning of Article 59 of the Treaty.

39.

A number of the Governments which have submitted written observations to the Court have argued that hospital services cannot constitute an economic activity for the purposes of Article 60 of the EC Treaty (now Article 50 EC).

40.

It should be borne in mind first of all that, under Article 60 of the Treaty, services for the purposes of the Treaty are services normally provided for remuneration in so far as they are not governed by the provisions relating to freedom of movement for goods, capital and persons.

41.

It is settled case-law that medical activities fall within the scope of Article 60 of the Treaty, there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment (see Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, paragraph 16, Case C-159/90 *Society for the Protection of Unborn Children Ireland* [1991] ECR I-4685, paragraph 18, and *Kohll*, paragraphs 29 and 51).

42.

It is also settled case-law that the special nature of certain services does not remove them from the ambit of the fundamental principle of freedom of movement (Case 279/80 *Webb* [1981] ECR 3305, paragraph 10, and *Kohll* paragraph 20), so that the fact that the national rules at issue in the main proceedings are social security rules cannot exclude application of Articles 59¹¹ and 60¹² of the Treaty (*Kohll*, paragraph 21).

43.

Since the hospital services at issue in the main proceedings fall within the scope of freedom to provide services, it is necessary to go on to consider whether the fact that national legislation does not guarantee a person covered by its social insurance scheme who has been authorised to receive hospital treatment in another Member State in accordance with Article 22(1)(c) of Regulation No 1408/71 a level of payment equivalent to that to which he would

have been entitled if he had received hospital treatment in the Member State in which he was insured entails a restriction of freedom to provide services within the meaning of Article 59 of the Treaty.

44.

In that regard, it is settled case-law that Article 59¹¹ of the Treaty precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within one Member State (Case C-381/93 *Commission v France* [1994] ECR I-5145, paragraph 17, and *Kohll*, paragraph 33).

45.

In the present case, there is no doubt that the fact that a person has a lower level of cover when he receives hospital treatment in another Member State than when he undergoes the same treatment in the Member State in which he is insured may deter, or even prevent, that person from applying to providers of medical services established in other Member States and constitutes, both for insured persons and for service providers, a barrier to freedom to provide services (see, by analogy, *Luisi and Carbone*, paragraph 16, Case C-204/90 *Bachmann v Belgium* [1992] ECR I-249, paragraph 31, and *Kohll*, paragraph 35).

46.

Consequently, it is necessary to examine whether the fact that the national legislation of a Member State does not guarantee a person insured in that State at least an equally advantageous level of cover when hospital services are provided in another Member State could be objectively justified.

47.

It should be remembered that the Court has held that it cannot be excluded that the risk of seriously undermining the financial balance of a social security system might constitute an overriding reason in the general interest capable of justifying a barrier to the principle of freedom to provide services (*Kohll*, paragraph 41).

48.

The Court has likewise recognised, as regards the objective of maintaining a balanced medical and hospital service open to all, that even if that objective is intrinsically linked to the method of financing the social security system, it may also fall within the derogations on grounds of public health under Article 56¹³ of the EC Treaty (now, after amendment, Article 46 EC) in so far as it contributes to the attainment of a high level of health protection (Kohll, paragraph 50).

49.

The Court has also stated that Article 56 of the Treaty allows Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for the public health, and even the survival, of the population (Kohll, paragraph 51).

50.

In the situation at issue in the main proceedings, however, none of the overriding reasons referred to in paragraphs 47 to 49 above can justify the barrier in question.

51.

In the present case, the national court held that Ms Descamps was in fact entitled to obtain the authorisation provided for by the national legislation under which she was covered and by Article 22(1)(c) of Regulation No 1408/71. In such circumstances, it cannot be claimed that payment of additional reimbursement, covering the difference between the system of cover laid down by the legislation of the Member State in which she was insured and that applied by the Member State in which the treatment was provided, when the former is more advantageous than the latter, would be liable to jeopardise the maintenance, in the Member State of registration, of a balanced medical and hospital service open to all or the maintenance of treatment capacity or medical competence on national territory.

52.

Furthermore, since such additional reimbursement, which is a function of the system of cover applying in the State of registration, does not in theory impose any additional financial

burden on the sickness insurance scheme of that State by comparison with the reimbursement to be made if hospital treatment had been provided in that latter State, it cannot be argued that making that sickness insurance fund bear such additional reimbursement would be liable to have a significant effect on the financing of the social security system (Kohll, paragraph 42).

53.

In view of all the foregoing considerations, the answer to be given to the first part of the question referred to the Court must be that Article 22(1)(c) and (i) of Regulation No 1408/71 is to be interpreted as meaning that, when an insured person has been authorised by the competent institution to go to another Member State for treatment, the institution of the place where the treatment is provided is required to provide him with benefits in kind in accordance with the rules on assumption of the costs of health care which the latter administers, as if the person concerned were registered with it.

Where the request of an insured person for authorisation on the basis of Article 22(1)(c) of that regulation has been refused by the competent institution and it is subsequently established that such refusal was unfounded, the person concerned is entitled to be reimbursed directly by the competent institution by an amount equivalent to that which would have been borne by the institution of the place of treatment under the rules laid down by the legislation applied by the latter institution if authorisation had been properly granted in the first place.

As Article 22 of that regulation is not intended to regulate any reimbursement at the tariffs in force in the Member State of registration, it does not have the effect of preventing or prescribing payment by that State of additional reimbursement covering the difference between the system of cover laid down by the legislation of that State and the system applied by the Member State of treatment, where the former is more advantageous than the latter and such reimbursement is provided for by the legislation of the Member State of registration.

Article 59 of the EC Treaty is to be interpreted as meaning that, if the reimbursement of costs incurred on hospital services provided in a Member State of stay, calculated under the rules in force in that State, is less than the amount which application of the legislation in force

in the Member State of registration would afford to a person receiving hospital treatment in that State, additional reimbursement covering that difference must be granted to the insured person by the competent institution.

Second part of the question referred to the Court

54.

By the second part of its question, the national court asks essentially whether Article 36⁹ of Regulation No 1408/71 is to be interpreted as meaning that an insured person who has requested authorisation on the basis of Article 22(1)(c)² of Regulation No 1408/71 and been refused by the competent institution is entitled to reimbursement of all the medical costs which he incurred in the Member State in which he received treatment once it is established that the rejection of his request for authorisation was unfounded.

55.

In order to answer that reformulated question, it is sufficient to state that it follows from the actual wording of Article 36 of Regulation No 1408/71 that the full refund between institutions to which that provision refers concerns only benefits in kind provided by the institution of a Member State of stay on behalf of the competent institution, pursuant to the provisions of Title III, Chapter 1, of that regulation. Consequently, as observed in paragraphs 32 and 33 above, that refund applies only to benefits in kind for which the assumption of costs by the institution of the place of stay is provided for by the legislation applied by that institution, and in precise proportion to which that assumption of costs is stipulated.

56.

The answer to be given to the second part of the question referred to the Court must therefore be that Article 36 of Regulation No 1408/71 cannot be interpreted as meaning that it follows from that provision that a covered person who has requested authorisation on the basis of Article 22(1)(c) of that regulation and been refused by the competent institution is entitled to reimbursement of all the medical costs which he incurred in the Member State in which he received treatment once it is established that the rejection of his request for authorisation was unfounded.

2.2.6. Costs

57.

The costs incurred by the Belgian, Danish, German, Spanish, French, Irish, Netherlands, Austrian, Finish, Swedish and United Kingdom Governments and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court.

2.2.7. The Court's decision

On those grounds,

THE COURT

in answer to the question referred to it by the Cour du travail de Mons by judgment of 9 October 1998, hereby rules:

1. Article 22(1)(c) and (i)² of Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, in the version amended and updated by Council Regulation (EEC) No 2001/83 of 2 June 1983, is to be interpreted as meaning that, when an insured person has been authorised by the competent institution to go to another Member State for treatment, the institution of the place where the treatment is provided is required to provide him with benefits in kind in accordance with the rules on assumption of the costs of health care which the latter administers, as if the person concerned were registered with it.

Where the request of an insured person for authorisation on the basis of Article 22(1)(c) of that regulation has been refused by the competent institution and it is subsequently established that such refusal was unfounded, the person concerned is entitled to be reimbursed directly by the competent institution by an amount equivalent to that which would have been

borne by the institution of the place of stay under the rules laid down by the legislation applied by the latter institution if authorisation had been properly granted in the first place.

As Article 22² of that regulation is not intended to regulate any reimbursement at the tariffs in force in the Member State of registration, it does not have the effect of preventing or prescribing payment by that State of additional reimbursement covering the difference between the system of cover laid down by the legislation of that State and the system applied by the Member State of stay, where the former is more advantageous than the latter and such reimbursement is provided for by the legislation of the Member State of registration.

Article 59¹¹ of the EC Treaty (now, after amendment, Article 49 EC) is to be interpreted as meaning that, if the reimbursement of costs incurred on hospital services provided in a Member State of stay, calculated under the rules in force in that State, is less than the amount which application of the legislation in force in the Member State of registration would afford to a person receiving hospital treatment in that State, additional reimbursement covering that difference must be granted to the insured person by the competent institution.

2. Article 36⁹ of Regulation No 1408/71, in the version amended and updated by Regulation No 2001/83, cannot be interpreted as meaning that it follows from that provision that a covered person who has requested authorisation on the basis of Article 22(1)(c) of that regulation and been refused by the competent institution is entitled to reimbursement of all the medical costs which he incurred in the Member State in which he received treatment once it is established that the rejection of his request for authorisation was unfounded.

2.3. The Queen, on the application of: Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health⁸

2.3.1. Judgment

1 This reference for a preliminary ruling concerns the interpretation of Articles 48 EC to 50 EC and Article 152(5) EC, as well as Article 22 of Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996 (OJ 1997 L 28, p. 1; ‘Regulation No 1408/71’).

2 The reference was made in the course of proceedings arising from the refusal of Bedford Primary Care Trust (‘Bedford PCT’) to reimburse the cost of hospital treatment received in France by Mrs Watts, who resides in the United Kingdom.

2.3.2. Legal context

Community law

3 Article 22² of Regulation No 1408/71, entitled ‘Stay outside the competent State – Return to or transfer of residence to another Member State during sickness or maternity – Need to go to another Member State in order to receive appropriate treatment’, states:

‘1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and

⁸ Judgment Of The Court (Grand Chamber) 16 May 2006; Case C-372/04; The Queen, on the application of: Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition,

shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay ... in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

2. ...

The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of his disease.

4 As is apparent from Decision No 153 (94/604/EC) of the Administrative Commission of the European Communities on Social Security for Migrant Workers of 7 October 1993 on the model forms necessary for the application of Council Regulations (EEC) No 1408/71 and (EEC) No 574/72 (E 001, E 103 to E 127) (OJ 1994 L 244, p. 22), Form E 112 is the certificate necessary for the application of Article 22(1)(c)(i) of Regulation No 1408/71.

2.3.3..National law

5 The National Health Service Act 1977 ('the NHS Act') states that the Secretary of State for Health is required to provide a National Health Service in England and Wales.

6 That duty is laid down in sections 1 and 3 of the NHS Act, which are worded as follows:

'Section 1

1. (1) It is the Secretary of State's duty to continue the promotion in England and Wales of a comprehensive health service designed to secure improvement

(a) in the physical and mental health of the people of those countries, and

(b) in the prevention, diagnosis and treatment of illness, and for that purpose to provide or secure the effective provision of services in accordance with this Act.

(2) The services so provided shall be free of charge except in so far as the making and recovery of charges is expressly provided for under any enactment, whenever passed.

Section 3

3. (1) It is the Secretary of State's duty to provide throughout England and Wales, to such extent as he considers necessary to meet all reasonable requirements,

(a) hospital accommodation;

(b) other accommodation for the purpose of any service provided under this Act;

(c) medical, dental, nursing and ambulance services;

(d) such other facilities for the care of expectant and nursing mothers and young children as he considers are appropriate as part of the health service;

(e) such facilities for the prevention of illness, the care of persons suffering from illness and the aftercare of persons who have suffered from illness as he considers are appropriate as part of the health service;

(f) such other services as are required for the diagnosis and treatment of illness.'

7 According to the information provided by the order for reference, the National Health Service ('NHS') has the following principal characteristics.

8 Hospital care is provided free of charge by the relevant NHS bodies to all persons ordinarily resident in the United Kingdom, on a non-profit-making basis.

9 Treatment is funded directly by the State, essentially from general taxation revenue which is apportioned by central government between the various Primary Care Trusts

(‘PCTs’) according to the relative needs of the populations of the geographical area covered by them.

10 No employee or employer contributions are payable. No patient co-payments are charged.

11 There are no national lists of medical benefits to be provided.

12 Access to hospital treatment is generally dependent on referral by a general practitioner.

13 As the budget allocated by the government to the NHS is not sufficient to allow for the swift provision of treatment to all patients, regardless of urgency, the NHS makes use of the available resources by setting priorities, which results in some quite lengthy waiting lists for less urgent treatment. NHS bodies determine, within the limits of the budgetary provision made available to them, the weighting of clinical priorities within national guidelines.

14 The waiting lists are intended to ensure the provision of hospital care in accordance with priorities and decisions made by the NHS bodies as to the use of available resources and to maintain fairness between patients who require hospital treatment for differing conditions and with different degrees of urgency.

15 NHS patients are not entitled to receive a specific treatment at a specific time. The type, location and timing of hospital treatment are determined on the basis of clinical priority and the resources of the relevant NHS body, and not the choice of the patient. Decisions of the NHS bodies can be challenged by judicial review, but such challenges usually fail.

16 Given that NHS treatment is provided free of charge, the question of its reimbursement does not arise and is not regulated. Therefore there is no set tariff for reimbursement in United Kingdom legislation.

17 NHS patients are not entitled to obtain hospital treatment in the private sector in England and Wales at the expense of the NHS.

18 PCTs are statutory bodies established under section 16A of the NHS Act, as inserted by section 2 of the Health Act 1999 and amended by the National Health Service Reform and Health Care Professions Act 2002. Their membership is determined in accordance with regulations. Some of their members are appointed by the Secretary of State for Health. The role of PCTs is to manage and deliver healthcare locally, including general medical services.

All areas of England are covered by a PCT. In each financial year, the Secretary of State pays the different PCTs an amount, which is subject to a cash limit, designed to cover expenditure on hospital treatment and administration costs.

19 'NHS trusts' are separate legal bodies, which were set up under the National Health Service and Community Care Act 1990. Section 5(1) of that Act, as amended by section 13 of the Health Act 1999, provides that the purpose of the NHS trusts is to provide goods and services within the framework of the NHS. The functions of the trusts are conferred by ministerial order. Nearly all UK hospitals are run by an NHS trust. NHS trusts receive their funding through payments made by PCTs in respect of the treatments and medical services commissioned by them.

20 The relationship between PCTs and NHS trusts is based, by virtue of section 4 of the 1990 Act, on a system of 'NHS contracts', which are not contracts enforceable at law, but which have attached to them a special form of internal arbitration by the Secretary of State. NHS contracts generally record agreement as to the amount of services anticipated and their relative funding.

21 PCTs and NHS trusts are not profit-making bodies. Any budget which is allocated, but not spent, can in some circumstances be carried forward. Otherwise, it must be returned to central government.

22 Patients not ordinarily resident in the United Kingdom may receive medical treatment under the NHS, though in principle not free of charge. The NHS (Charges to Overseas Visitors) Regulations 1989 provide for the making and recovery of charges for NHS treatment provided to overseas visitors. The PCTs are required to provide such treatment unless the patient satisfies any of the exemption criteria in those regulations. Those regulations provide exceptions inter alia for treatment within hospital accident and emergency departments, and to reflect the rights of persons insured in other Member States.

23 The order for reference states that since Regulation No 1408/71 is directly applicable in all Member States there is no legislation implementing it in the United Kingdom. An NHS patient ordinarily resident in the United Kingdom may receive hospital treatment in another Member State pursuant to Article 22(1)(c) of that regulation, in which case reimbursement of the costs associated with that treatment is made in accordance with that regulation directly to

the competent institution in the Member State in which the treatment was obtained at the rate of reimbursement applicable in that Member State.

2.3.4. The main proceedings

24 Suffering from arthritis of the hips, Mrs Watts made enquiries of Bedford PCT as to the possibility of her undergoing surgery abroad under the E 112 scheme.

25 On 1 October 2002, she was seen by a UK consultant who informed Bedford PCT by letter of 28 October 2002 that Mrs Watts was as deserving as any of his other patients with severe arthritis, that her mobility was severely hampered and that she was in constant pain. He classified her case as ‘routine’, which meant a wait of approximately one year for surgery in a local hospital.

26 On 21 November 2002, Bedford PCT informed Mrs Watts of its refusal to issue her with an E 112 form on the ground that the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 was not satisfied. It considered that she could receive treatment in a local hospital ‘within the government’s NHS Plan targets’ and therefore ‘without undue delay’.

27 On 12 December 2002, Mrs Watts issued proceedings seeking permission to apply for judicial review of that refusal decision.

28 On 22 January 2003, the High Court of Justice of England and Wales, Queen’s Bench Division (Administrative Court), heard the application for permission. The court heard that, at the beginning of January 2003, Mrs Watts went to see a consultant in France who told her that her need for surgery was becoming more urgent because of a deterioration in her state of health. The Secretary of State for Health and Bedford PCT therefore suggested that Mrs Watts should be re-examined so that the decision of 21 November 2002 could be reconsidered.

29 On 31 January 2003, Mrs Watts was re-examined by the UK consultant who had examined her in October 2002. He wrote to Bedford PCT on the same day stating that Mrs Watts should now be categorised as a patient requiring surgery ‘soon’, in an intermediate category between the most urgent cases and the routine cases. That meant that she would be operated on within three or four months, in April or May 2003.

30 On 4 February 2003, Bedford PCT repeated its refusal to issue an E 112 form on the ground that the waiting period for treatment locally had been reduced to three or four months. It repeated its reliance on the NHS Plan targets in concluding that there was no undue delay in Mrs Watts's case.

31 On 7 March 2003, Mrs Watts underwent a hip replacement operation in Abbeville (France). She paid the fees for that surgery, equivalent to GBP 3 900.

32 She continued with her application for permission to apply for judicial review of Bedford PCT's refusal decision, claiming in addition reimbursement of the medical fees incurred in France.

33 On 1 October 2003, the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), which had reserved judgment until the delivery of the judgment of the Court of Justice of 13 May 2003 in Case C-385/99 Müller-Fauré and van Riet [2003] ECR I-4509, held that the medical services which Mrs Watts received in France fall within the scope of Article 49 EC notwithstanding the fact that the reimbursement of the costs of the treatment received is applied for under the NHS.

34 It nevertheless dismissed Mrs Watts's application. Although it found that 'any national authority properly directing itself in accordance with the principles laid down by the [Court], in particular [in Case C-157/99 Smits and Peerbooms [2001] ECR I-5473] and Muller-Fauré and van Riet, would have been bound to conclude in October-November 2002 that the anticipated delay of approximately one year was, on any view, "undue", and thus such as to trigger the claimant's right under Article 49 [EC] to reimbursement of the costs of obtaining more timely treatment in another Member State', it nevertheless held that Mrs Watts had not had to face undue delay after her case was reassessed at the end of January 2003. The court held that a waiting time of between three and four months did not entitle Mrs Watts to have treatment abroad and claim reimbursement of the cost of that treatment from the NHS.

35 Mrs Watts and the Secretary of State for Health appealed against that judgment to the Court of Appeal (England and Wales) (Civil Division). Mrs Watts's appeal was based primarily on the dismissal of her application for reimbursement and on the considerations set out in the judgment at first instance that the waiting time applicable in national law is a relevant factor in applying Article 49 EC and a factor of fundamental importance in the context of Article 22 of Regulation No 1408/71. The Secretary of State for Health's appeal

was based essentially on the argument that NHS patients are not entitled to rely on Article 49 EC, so that Mrs Watts's case should be governed exclusively by Article 22² of Regulation No 1408/71.

36 In a decision of 20 February 2004, the referring court states that, given the judgments in *Smits and Peerbooms* and *Müller-Fauré and van Riet*, national health services financed by the State, such as the NHS, fall within the scope of Article 49 EC. It adds, however, that it appears from paragraph 98 of the judgment in *Müller-Fauré and van Riet* that the right, based on that article, to receive treatment abroad is subject to there being a right to obtain treatment in the relevant Member State, which UK patients do not have under the NHS.

37 It is of the view that, since medical treatment is a supply of services within the meaning of Article 49 EC, the national authorities responsible for financing health services may not, in principle, prevent residents from receiving treatment in another Member State unless such a restriction is justified by the need to maintain a balanced medical and hospital service which is available to everyone; such a justification may not, however, be invoked where it would result in undue delay in the provision of treatment to the patient in his Member State of residence.

38 It states that, by virtue of the judgment in Case C-56/01 *Inizan* [2003] ECR I-12403, the concept of undue delay must be interpreted, in line with the second condition in the second subparagraph of Article 22(2) of Regulation No 1408/71, on the basis of clinical considerations arising in each individual case and not by having regard to normal waiting times and lists based on economic considerations. It asserts, however, that the Court has not yet given a clear answer as to how that concept should be interpreted.

39 It also raises the question, in the light of the *Inizan* judgment, of the relevance of budgetary considerations in the context of a case such as the present dispute in the main proceedings. It asks whether it must be found that a Member State is under an obligation to set aside resources to enable its nationals to receive treatment abroad within a shorter period, at the risk, first, of extending the waiting times for treatment in that Member State of more urgent cases and, second, of affecting the management of resources and the planning of the healthcare system in question.

40 Assuming such an obligation exists, the referring court asks whether the Member State concerned is required to reimburse the cost of treatment received abroad according to the legislation of the host Member State, pursuant to Article 22² of Regulation No 1408/71, or according to its own legislation, pursuant to Article 49 EC. It also asks whether travel and accommodation expenses must be taken into account in such a case.

41 The referring court stresses that a duty to reimburse according to the legislation of the competent Member State would mean, for a system such as the NHS in which healthcare is provided free of charge, a duty to reimburse in full. It considers therefore that if the concept of undue delay is to be assessed without regard to budgetary considerations, the application of Article 49 EC would involve the interference of Community law in the budgetary policy of the Member States in relation to public health, such as to raise questions with regard to Article 152(5) EC.

2.3.5. The questions referred

42 In those circumstances the Court of Appeal (England and Wales) (Civil Division) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘(1) Having regard to the nature of the NHS and its position under national law, is Article 49 EC, read in the light of *Geraets-Smits* [and *Peerbooms*], *Muller-Fauré* [and *van Riet*] and *Inizan*, to be interpreted as meaning that in principle persons ordinarily resident in the United Kingdom enjoy an entitlement in EU law to receive hospital treatment in other Member States at the expense of the United Kingdom National Health Service (“the NHS”)?

In particular, on the true interpretation of Article 49 EC¹:

(a) Is there any distinction between a State-funded national health service such as the NHS and insurance funds such as the Netherlands ZFW scheme, in particular having regard to the fact that the NHS has no fund out of which payment must be made?

(b) Is the NHS obliged to authorise and pay for such treatment in another Member State, notwithstanding that it is not obliged to authorise and pay for such treatment to be carried out privately by a United Kingdom service provider?

(c) Is it relevant if the patient secures the treatment independently of the relevant NHS body, and without prior authorisation or notification?

(2) In answering Question 1, is it material whether hospital treatment provided by the NHS is itself the provision of services within Article 49 EC?

If so, and in the circumstances set out in the statement of facts above, are Articles 48 EC, 49 EC and 50 EC to be interpreted as meaning that in principle:

(a) the provision of hospital treatment by NHS bodies constitutes the provision of services within Article 49 EC¹;

(b) a patient receiving hospital treatment under the NHS as such exercises a freedom to receive services within Article 49 EC; and

(c) NHS bodies providing hospital treatment are services providers within Articles 48 EC and 50 EC?

(3) If Article 49 EC applies to the NHS, may it or the Secretary of State rely as objective justification for refusing prior authorisation for hospital treatment in another Member State on:

(a) the fact that authorisation would seriously undermine the NHS system of administering medical priorities through waiting lists;

(b) the fact that authorisation would permit patients with less urgent medical needs to gain priority over patients with more urgent medical needs;

(c) the fact that authorisation would have the effect of diverting resources to pay for less urgent treatment for those who are willing to travel abroad, thus adversely affecting others who do not wish or are not able to travel abroad or increasing costs of NHS bodies;

(d) the fact that authorisation may require the United Kingdom to provide additional funding for the NHS budget or to restrict the range of treatments available under the NHS;

(e) the comparative costs of the treatment and the incidental costs thereof in the other Member State?

(4) In determining whether treatment is available “without undue delay” for the purposes of Article 49 EC, to what extent is it necessary or permissible to have regard in particular to the following:

(a) waiting times;

(b) the clinical priority accorded to the treatment by the relevant NHS body;

(c) the management of the provision of hospital care in accordance with priorities aimed at giving best effect to finite resources;

(d) the fact that treatment under the NHS is provided free at the point of delivery;

(e) the individual medical condition of the patient, and the history and probable course of the disease in respect of which that patient seeks treatment?

(5) On the proper interpretation of Article 22(1)(c)² of Regulation No 1408/71 and in particular the words “within the time normally necessary for obtaining the treatment in question”:

(a) Are the applicable criteria identical with those applicable in determining questions of “undue delay” for the purposes of Article 49 EC¹?

(b) If not, to what extent is it necessary or permissible to have regard to the matters set out in Question 4?

(6) In circumstances where a Member State is obliged in EU law to fund the hospital treatment in other Member States of persons ordinarily resident in the first Member State, is the cost of such treatment to be calculated under Article 22² of Regulation No 1408/71 by reference to the legislation of the Member State where the treatment is provided or under Article 49 EC by reference to the legislation of the Member State of residence?

In each case:

- (a) What is the precise extent of the obligation to pay or reimburse the cost, in particular where, as in the case of the United Kingdom, hospital treatment is provided to patients free at the point of delivery and there is no nationally set tariff for reimbursement of patients for the cost of treatment?
 - (b) Is the obligation limited to the actual cost of providing the same or equivalent treatment in the first Member State?
 - (c) Does it include an obligation to meet travel and accommodation costs?
- (7) Are Article 49 EC¹ and Article 22² of Regulation No 1408/71 to be interpreted as imposing an obligation on Member States to fund hospital treatment in other Member States without reference to budgetary constraints and, if so, are these requirements compatible with the Member States' responsibility for the organisation and delivery of health services and medical care, as recognised under Article 152(5) EC?'

The questions

Preliminary considerations

43 By its questions, the referring court seeks clarification of the scope both of the EC Treaty provisions on the freedom to provide services and of Article 22² of Regulation No 1408/71.

44 As the Commission of the European Communities suggested in its written observations, it is necessary to rule first on the request for interpretation of Article 22 of Regulation No 1408/71.

45 It is not in dispute, according to the order for reference, that Mrs Watts sought authorisation under an E 112 form to go to another Member State to receive treatment there

appropriate to her condition at the expense of the NHS, pursuant to Article 22(1)(c)(i) of Regulation No 1408/71. It is also clear from that order that Bedford PCT, with which Mrs Watts was registered, refused her that authorisation on the ground that she did not satisfy the conditions laid down by Article 22(2) of that regulation.

46 The applicability of Article 22² to the present case does not, however, preclude it from also falling within the scope of Article 49 EC¹.

47 The fact that a national measure may be consistent with a provision of secondary legislation, in this case Article 22 of Regulation No 1408/71, does not have the effect of removing that measure from the scope of the provisions of the Treaty (Case C-158/96 Kohll [1998] ECR I-1931, paragraph 25).

48 It should further be noted that the purpose of Article 22(1)(c)(i) of Regulation No 1408/71 is to confer a right to the services in kind provided, on behalf of the competent institution, by the institution of the place where the treatment is provided, in accordance with the provisions of the legislation of the Member State in which the services are provided as if the person concerned were registered with that institution (see *Inizan*, paragraph 20). The applicability of Article 22 of Regulation No 1408/71 to the situation in question does not mean that the person concerned may not simultaneously have the right under Article 49 EC to have access to healthcare in another Member State under rules on the assumption of costs different from those laid down by Article 22 (see to that effect Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraphs 37 to 53).

49 In the light of the foregoing, an answer should be given first of all to the request for interpretation of Article 22 of Regulation No 1408/71, which is the subject of the fifth question, then to the requests for interpretation of the provisions on the freedom to supply services set out in the first four questions, and lastly to the sixth and seventh questions, which jointly relate to Article 49 EC and Article 22 of Regulation No 1408/71.

50 It should be noted, as the Commission points out, that the present case exclusively concerns medical services supplied by hospitals and requiring the admission of the person concerned as an inpatient to the hospital in which those services are supplied.

The fifth question

51 By this question, the referring court asks essentially whether the criteria for the interpretation of the phrase ‘within the time normally necessary for obtaining the treatment in question’ in the second subparagraph of Article 22(2)² of Regulation No 1408/71 are the same as those used to define the term ‘without undue delay’ in the context of Article 49 EC.

52 Referring at this stage to the fourth question, the referring court also asks whether, in interpreting the time referred to in the second subparagraph of Article 22(2) of Regulation No 1408/71, it is necessary or permissible to take account of the factors set out in the fourth question, namely the existence of waiting times, the clinical priorities defined by the competent NHS body, the management of the supply of hospital care in accordance with priorities intended to give best effect to finite resources, the fact that treatment under the NHS is provided free of charge and the individual medical condition of the patient and the history and probable course of his illness.

53 It should be noted as a preliminary point that, in the context of the general objectives of the Treaty, Article 22 of Regulation No 1408/71 is one of a number of measures designed to allow a patient covered by the legislation of one Member State to enjoy, under the conditions which it specifies, benefits in kind in the other Member States, whatever the national institution with which he is registered and whatever the place of his residence (see to that effect Case C-156/01 Van der Duin and ANOZ Zorgverzekeringen [2003] ECR I-7045, paragraph 50, and Case C-145/03 Keller [2005] ECR I-2529, paragraph 45).

54 By guaranteeing in paragraph (1)(c)(i) that a patient covered by the legislation of one Member State who has been authorised may have access to treatment in the other Member States on reimbursement conditions as favourable as those enjoyed by persons covered by the legislation of those States, and by stating in the second subparagraph of paragraph (2) that the competent national institution may not refuse such authorisation where the two conditions referred to in that provision are satisfied, Article 22 of Regulation No 1408/71 helps to facilitate the free movement of patients and, to the same extent, the provision of cross-border medical services between Member States (see to that effect Vanbraekel, paragraph 32; Inizan, paragraph 21; and Keller, paragraph 46).

55 The second subparagraph of Article 22(2)² of Regulation No 1408/71 lays down two conditions which, if both satisfied, render mandatory grant by the competent institution,

regardless of the Member State to which it belongs, of the prior authorisation to which that provision refers (see *Inizan*, paragraph 37).

56 To satisfy the first condition the treatment in question must be among the benefits provided for by the legislation of the Member State on whose territory the person resides. It does not appear that in the main proceedings the refusal to assume the costs of the treatment was based on the failure to comply with that first condition.

57 The second condition is satisfied only where the treatment which the patient plans to undergo in a Member State other than that in the territory of which he resides cannot be given within the time normally necessary for obtaining the treatment in question in the Member State of residence, taking account of his current state of health and the probable course of his disease.

58 That second condition is clearly in issue in the dispute in the main proceedings, as is shown by both the wording of the fifth question and the terms in which the competent body informed Mrs Watts of its refusal to issue an E 112 form (see paragraphs 26 and 30 of the present judgment).

59 As Mrs Watts, the French and Belgian Governments and the Commission pointed out in their written observations, the Court gave an interpretation in paragraphs 45 and 46 of the judgment in *Inizan* of the time referred to in the second subparagraph of Article 22(2) of Regulation No 1408/71, adopting the interpretation it had given for the term ‘undue delay’ in *Smits and Peerbooms* (paragraphs 103 and 104) and *Müller-Fauré and van Riet* (paragraphs 89 and 90) concerning the assessment of the compatibility with Article 49 EC of a national provision making the assumption of the cost of hospital treatment planned in another Member State subject to a requirement that that treatment be necessary.

60 Indeed, as Advocate General Geelhoed observed in point 101 of his Opinion, there is no reason which seriously justifies different interpretations depending on whether the context is Article 22 of Regulation No 1408/71 or Article 49 EC, since in both cases the question is, as the Belgian Government pointed out in its written observations, whether the hospital treatment required by the patient’s medical condition can be provided on the territory of his Member State of residence within an acceptable time which ensures its usefulness and efficacy.

61 In paragraph 45 of *Inizan* the Court thus held, referring by analogy to paragraph 103 of *Smits and Peerbooms* and paragraph 89 of *Müller-Fauré and van Riet*, that the second condition set out in the second subparagraph of Article 22(2)² of Regulation No 1408/71 is not satisfied whenever it is apparent that treatment which is the same or equally effective for the patient can be obtained without undue delay in his Member State of residence.

62 Basing its decision on paragraph 104 of *Smits and Peerbooms* and paragraph 90 of *Müller-Fauré and van Riet*, the Court held that, in order to determine whether treatment which is equally effective for the patient can be obtained without undue delay in the Member State of residence, the competent institution is required to have regard to all the circumstances of each specific case, taking due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history (*Inizan*, paragraph 46).

63 In paragraph 92 of *Müller-Fauré and van Riet* the Court also pointed out that, in determining whether a treatment which is the same or equally effective for the patient is available without undue delay from an establishment on the territory of the Member State of residence, the competent institution cannot base its decision exclusively on the existence of waiting lists on that territory without taking account of the specific circumstances of the patient's medical condition.

64 That point made in relation to Article 49 EC¹ may be extended to Article 22 of Regulation No 1408/71, given the matters set out in paragraphs 59¹¹ and 60¹² of the present judgment.

65 It should be noted in this connection that Article 20 of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (OJ 2004 L 166, p. 1), which is intended to replace Article 22 of Regulation No 1408/71, lays down a duty to grant the authorisation in question in particular where the treatment cannot be given in the Member State of residence 'within a time-limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness'.

66 It is in the light of those points that the factors should be set out to which the referring court should have regard amongst those identified in the fourth question in order to determine

whether the second condition set out in the second subparagraph of Article 22(2)² of Regulation No 1408/71 is satisfied or not.

67 Where the demand for hospital treatment is constantly rising, primarily as a consequence of medical progress and increased life expectancy, and the supply is necessarily limited by budgetary constraints, it cannot be denied that the national authorities responsible for managing the supply of such treatment are entitled, if they consider it necessary, to institute a system of waiting lists in order to manage the supply of that treatment and to set priorities on the basis of the available resources and capacities.

68 As is clear from the wording of the second subparagraph of Article 22(2) of Regulation No 1408/71, and pursuant to the case-law set out in paragraphs 62 and 63 of the present judgment, in order to be entitled to refuse the authorisation referred to in Article 22(1)(c) of that regulation on the ground of waiting time, the competent institution must however establish that the waiting time, arising from objectives relating to the planning and management of the supply of hospital care pursued by the national authorities on the basis of generally predetermined clinical priorities, within which the hospital treatment required by the patient's state of health may be obtained in an establishment forming part of the national system in question, does not exceed the period which is acceptable in the light of an objective medical assessment of the clinical needs of the person concerned in the light of his medical condition and the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the authorisation is sought.

69 Furthermore, as the Commission points out and as Advocate General Geelhoed observed in point 86 of his Opinion, the setting of waiting times should be done flexibly and dynamically, so that the period initially notified to the person concerned may be reconsidered in the light of any deterioration in his state of health occurring after the first request for authorisation.

70 If the waiting time arising from the general planning objectives does not exceed a medically acceptable waiting time within the meaning of paragraph 68 of the present judgment, the competent institution is entitled to find that the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 is not satisfied and to refuse to grant the authorisation sought by the person concerned under Article 22(1)(c)(i)² of that regulation.

71 That is because if patients covered by a national health service such as that in issue in the main proceedings had to be authorised to go to another Member State to receive there, at the expense of the competent institution, hospital treatment which the hospitals covered by that service are able to supply within a medically acceptable period within the meaning of paragraph 68 of the present judgment merely because treatment which is the same or equally effective is available more quickly in that other Member State, the resulting patient migration would be liable to put at risk the competent Member State's planning and rationalisation efforts in the vital healthcare sector so as to avoid the problems of hospital overcapacity, imbalance in the supply of hospital medical care and logistical and financial wastage (see to that effect Smits and Peerbooms, paragraph 106, and Müller-Fauré and van Riet, paragraph 91).

72 In the situation opposite to that referred to in paragraph 70 of the present judgment, however, the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 must be regarded as satisfied.

73 The fact that the cost of the hospital treatment envisaged in another Member State may be higher than it would have been had it been provided in a hospital covered by the national system in question cannot in such a case be a legitimate ground for refusing authorisation.

74 In such a situation, the fact that the grant of the authorisation sought would oblige a national health service such as that in issue in the main proceedings, which is characterised by free hospital treatment provided within its own establishments, to establish a financial mechanism so as to enable that service to satisfy the request for reimbursement from the institution of the host Member State and relating to the benefits in kind provided by that institution to the patient in question is also not a legitimate ground for refusing authorisation (see to that effect Müller-Fauré and van Riet, paragraph 105).

75 Contrary to the fears expressed by the United Kingdom Government in its written observations, the interpretation of the time referred to in the second subparagraph of Article 22(2) of Regulation No 1408/71, set out in paragraphs 59 to 72 of the present judgment, is not liable to undermine the national competent authorities' power to manage the available hospital capacity in their territory by the use of waiting lists, provided that the existence of such lists does not prevent the taking account in each individual case of the medical circumstances and the clinical needs of the person concerned when he requests authorisation

to receive hospital treatment in another Member State at the expense of the system with which he is registered.

76 Furthermore, the effect of such an interpretation is to preclude the national competent authorities from refusing to grant the authorisation sought by a patient whose case, in the light of an objective medical assessment, was sufficiently urgent to justify obtaining treatment in another Member State within a shorter period than that which would result from waiting lists reflecting general planning and management objectives, and within which the person concerned may hope to obtain the treatment in question in a local hospital covered by the national health service. It does not undermine, by contrast, the right of those authorities to withhold authorisation where there is no urgency arising from the clinical condition of the patient in question such as to make the waiting time arising from such objectives appear unreasonable in the light of that condition.

77 That interpretation is also not liable to lead to an exodus of patients who, having sufficient resources for that purpose, might seek to go to another Member State to obtain the hospital treatment at the subsequent expense of the national health service with which they are registered, regardless of medical need, within a shorter time than that within which that treatment can be provided to them in a national establishment covered by that service. It preserves the right of the competent institution to refuse the authorisation necessary for the assumption of the cost of the hospital treatment to be obtained in another Member State in the absence of particular circumstances justifying the view that the waiting time imposed on the person concerned exceeds the medically acceptable period in his particular case.

78 In the main proceedings, it is for the referring court to determine whether the waiting time invoked by the competent body of the NHS, and based on the planning objectives pursued by the United Kingdom authorities, in order to refuse the initial application for authorisation and the renewed request exceeded a medically acceptable period in the light of the patient's particular condition and clinical needs at those respective times.

79 In the light of the foregoing, the answer to the fifth question must be that the second subparagraph of Article 22(2)² of Regulation No 1408/71 must be interpreted as meaning that, in order to be entitled to refuse to grant the authorisation referred to in Article 22(1)(c)(i) of that regulation on the ground that there is a waiting time for hospital treatment, the competent institution is required to establish that that time does not exceed the period which is acceptable on the basis of an objective medical assessment of the clinical needs of the person

concerned in the light of all of the factors characterising his medical condition at the time when the request for authorisation is made or renewed, as the case may be.

The first four questions

80 By the first four questions, which it is convenient to consider together, the referring court asks essentially whether and in what circumstances an NHS patient is entitled under Article 49 EC to receive hospital treatment in another Member State at the expense of that national service.

81 The first question asks whether, given the particular characteristics of the NHS, a person residing in the United Kingdom is entitled under that article to receive hospital treatment in a Member State other than the United Kingdom at the expense of the NHS. As part of that question, the referring court asks in particular whether, in interpreting Article 49 EC in such a context, account should be taken, first, of the fact that there is no fund available to NHS bodies out of which such treatment may be paid for, and, second, of the fact that there is no duty on the NHS to pay for hospital treatment received by an NHS patient in a private hospital in England or Wales. It also asks whether the failure to request authorisation or notify the competent NHS body in advance has a bearing on the interpretation of Article 49 EC.

82 By the second question, the referring court asks whether, in order to answer the first question, it is necessary to determine whether hospital treatment provided by the NHS constitutes services within the meaning of Article 49 EC¹.

83 By the third question, it asks, on the assumption that that provision is applicable, whether a series of factors which it lists may validly be relied upon by the national competent authorities in refusing to grant the prior authorisation necessary in order for the NHS to assume the costs of hospital treatment to be obtained in another Member State.

84 The fourth question, which coincides with the third, asks which factors may or must be taken into account in determining whether the hospital treatment required by the patient's state of health may be provided without undue delay in an NHS establishment and whether, consequently, the authorisation sought by that patient for reimbursement of the cost of

treatment to be obtained in another Member State may be refused by the competent institution.

85 In order to answer those questions, it is first necessary to determine whether Article 49¹EC applies to facts such as those in issue in the main proceedings.

86 It should be noted in that regard that, according to settled case-law, medical services provided for consideration fall within the scope of the provisions on the freedom to provide services (see, *inter alia*, Case C-159/90 *Society for the Protection of Unborn Children Ireland* [1991] ECR I-4685, paragraph 18, and *Kohll*, paragraph 29), there being no need to distinguish between care provided in a hospital environment and care provided outside such an environment (*Vanbraekel*, paragraph 41; *Smits and Peerbooms*, paragraph 53; *Müller-Fauré and van Riet*, paragraph 38; and *Inizan*, paragraph 16).

87 It has also been held that the freedom to provide services includes the freedom for the recipients of services, including persons in need of medical treatment, to go to another Member State in order to receive those services there (see *Joined Cases 286/82 and 26/83 Luisi and Carbone* [1984] ECR 377, paragraph 16).

88 It should be noted as regards the main proceedings that the establishment in another Member State in which Mrs Watts received treatment was paid by her directly.

89 The fact that reimbursement of the hospital treatment in question is subsequently sought from a national health service such as that in question in the main proceedings does not mean that the rules on the freedom to provide services guaranteed by the Treaty do not apply (see to that effect *Smits and Peerbooms*, paragraph 55, and *Müller-Fauré and van Riet*, paragraph 39). It has already been held that a supply of medical services does not cease to be a supply of services within the meaning of Article 49 EC on the ground that the patient, after paying the foreign supplier for the treatment received, subsequently seeks the reimbursement of that treatment from a national health service (see *Müller-Fauré and van Riet*, paragraph 103).

90 It must therefore be found that Article 49 EC applies where a patient such as Mrs Watts receives medical services in a hospital environment for consideration in a Member State other than her State of residence, regardless of the way in which the national system with which that

person is registered and from which reimbursement of the cost of those services is subsequently sought operates.

91 It must therefore be found that a situation such as that which gave rise to the dispute in the main proceedings, in which a person whose state of health necessitates hospital treatment goes to another Member State and there receives the treatment in question for consideration, falls within the scope of the Treaty provisions on the freedom to provide services, there being no need in the present case to determine whether the provision of hospital treatment in the context of a national health service such as the NHS is in itself a service within the meaning of those provisions.

92 Whilst it is not in dispute that Community law does not detract from the power of the Member States to organise their social security systems, and that, in the absence of harmonisation at Community level, it is for the legislation of each Member State to determine the conditions in which social security benefits are granted, when exercising that power Member States must comply with Community law, in particular the provisions on the freedom to provide services (see, *inter alia*, *Smits and Peerbooms*, paragraphs 44 to 46; *Müller-Fauré and van Riet*, paragraph 100; and *Inizan*, paragraph 17). Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector.

93 It is therefore necessary to ascertain whether there is any such restriction in a case such as that in issue in the main proceedings.

94 It should be noted in this connection that according to well-established case-law, Article 49 EC precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within a Member State (*Case C-381/93 Commission v France* [1994] ECR I-5145, paragraph 17; *Kohll*, paragraph 33; and *Smits and Peerbooms*, paragraph 61).

95 In the present case it is clear from the decision of 20 February 2004 of the referring court and from the order for reference, in particular the third question, that, whilst NHS patients are free to go to a hospital in another Member State, they cannot have treatment in such an establishment at the NHS's expense without prior authorisation.

96 It is true, as the United Kingdom, Spanish, Maltese and Finnish Governments and Ireland submit, that an NHS patient cannot choose when and where the hospital treatment required by his state of health will be provided under the NHS. However, it is not in dispute that the corollary of the Secretary of State's duty under sections 1 and 3 of the NHS Act (see paragraph 6 of the present judgment) is the right to obtain treatment available under the NHS free of charge in NHS hospitals without having to seek prior authorisation.

97 Thus whereas according to the decision of 20 February 2004 and the order for reference prior authorisation is a prerequisite for the NHS to assume the costs of hospital treatment available in another Member State, the receipt of free NHS treatment does not depend on such authorisation, only the means of receiving that treatment being subject to a prior decision by the national competent authorities.

98 It must therefore be found that the system of prior authorisation referred to in paragraph 95 of the present judgment deters, or even prevents, the patients concerned from applying to providers of hospital services established in another Member State and constitutes, both for those patients and for service providers, an obstacle to the freedom to provide services (see to that effect *Smits and Peerbooms*, paragraph 69, and *Müller-Fauré and van Riet*, paragraph 44).

99 That conclusion is not undermined by the fact, referred to in Question 1(b), that the NHS is not obliged to authorise and assume the cost of hospital treatment provided to patients in private non-NHS hospitals in England and Wales.

100 In applying the case-law set out in paragraph 94 of the present judgment, the conditions for the NHS's assuming the cost of hospital treatment to be obtained in another Member State should not be compared to the situation in national law of hospital treatment received by patients in private local hospitals. On the contrary, the comparison should be made with the conditions in which the NHS provides such services in its hospitals.

101 Since the existence of a restriction on the freedom to provide services has been established, and before ruling on whether an NHS patient is entitled under Article 49 EC to receive hospital medical treatment in another Member State at the expense of the national service concerned without such a restriction, it is necessary to examine whether that restriction can be objectively justified.

102 As was done in a large number of the observations submitted to the Court, it is necessary to recall in this regard the overriding considerations capable of justifying obstacles to the freedom to provide hospital medical services.

103 The Court has already held that it is possible for the risk of seriously undermining the financial balance of a social security system to constitute an overriding reason in the general interest capable of justifying an obstacle to the freedom to provide services (Kohll, paragraph 41; Smits and Peerbooms, paragraph 72; and Müller-Fauré and van Riet, paragraph 73).

104 The Court has likewise acknowledged that the objective of maintaining a balanced medical and hospital service open to all may also fall within the derogations on grounds of public health under Article 46 EC in so far as it contributes to the attainment of a high level of health protection (Kohll, paragraph 50; Smits and Peerbooms, paragraph 73; and Müller-Fauré and van Riet, paragraph 67).

105 The Court has also held that Article 46 EC²¹ permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for the public health, and even the survival, of the population (Kohll, paragraph 51; Smits and Peerbooms, paragraph 74; and Müller-Fauré and van Riet, paragraph 67).

106 It is therefore necessary to determine whether the restriction at issue can in fact be justified in the light of such overriding reasons, and if such is the case to make sure, in accordance with settled case-law, that it does not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules (see Smits and Peerbooms, paragraph 75, and the case-law cited).

107 As regards hospital medical services, the Court has already made the following observations in paragraphs 76 to 80 of Smits and Peerbooms.

108 It is well known that the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning, generally designed to satisfy various needs, must be possible.

109 For one thing, such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the State concerned. For

another thing, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. Such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied.

110 From those two points of view, the requirement that the assumption of costs by the national system of hospital treatment provided in another Member State be subject to prior authorisation appears to be a measure which is both necessary and reasonable.

111 As regards specifically the Netherlands system of health insurance, in issue in the cases giving rise to the *Smits and Peerbooms* judgment, the Court acknowledged in paragraph 81 thereof that, if patients were at liberty, regardless of the circumstances, to use the services of hospitals with which their health insurance fund had no agreement, whether those hospitals were situated in the Netherlands or in another Member State, all the planning which goes into the system of agreements in an effort to guarantee a rationalised, stable, balanced and accessible supply of hospital services would be jeopardised at a stroke.

112 Those observations, expressed in relation to a system of social security based on a system of agreements between the public health insurance funds and the suppliers of hospital services, which permit, in the name of overriding planning objectives, limits to be placed on the right of patients to resort at the expense of the national system with which they are registered to hospital treatment not provided by that system, may be adopted in respect of a national health system such as the NHS.

113 In the light of the foregoing, and in answer to Question 1(c), Community law, in particular Article 49 EC, does not therefore preclude the right of a patient to receive hospital treatment in another Member State at the expense of the system with which he is registered from being subject to prior authorisation.

114 Nevertheless, the conditions attached to the grant of such authorisation must be justified in the light of the overriding considerations mentioned above and must satisfy the requirement of proportionality referred to in paragraph 106 of the present judgment (see to that effect *Smits and Peerbooms*, paragraph 82, and *Müller-Fauré and van Riet*, paragraph 83).

115 It is settled case-law that a system of prior authorisation cannot legitimise discretionary decisions taken by the national authorities which are liable to negate the effectiveness of provisions of Community law, in particular those relating to a fundamental freedom such as that at issue in the main proceedings (see Smits and Peerbooms, paragraph 90, and Müller-Fauré and van Riet, paragraph 84, and the case-law cited in those paragraphs).

116 Thus, in order for a system of prior authorisation to be justified even though it derogates from a fundamental freedom of that kind, it must in any event be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily. Such a system must furthermore be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings (Smits and Peerbooms, paragraph 90, and Müller-Fauré and van Riet, paragraph 85).

117 To that end, refusals to grant authorisation, or the advice on which such refusals may be based, must refer to the specific provisions on which they are based and be properly reasoned in accordance with them. Likewise, courts or tribunals hearing actions against such refusals must be able, if they consider it necessary for the purpose of carrying out the review which it is incumbent on them to make, to seek the advice of wholly objective and impartial independent experts (see to that effect Inizan, paragraph 49).

118 In relation to the dispute in the main proceedings, it should be noted, as does the Commission, that the regulations on the NHS do not set out the criteria for the grant or refusal of the prior authorisation necessary for reimbursement of the cost of hospital treatment provided in another Member State, and therefore do not circumscribe the exercise of the national competent authorities' discretionary power in that context. The lack of a legal framework in that regard also makes it difficult to exercise judicial review of decisions refusing to grant authorisation.

119 It should be noted with regard to the circumstances and factors referred to in the third and fourth questions that, given the findings set out in paragraphs 59 to 77 of the present judgment, a refusal to grant prior authorisation cannot be based merely on the existence of waiting lists enabling the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out in the individual case in

question an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.

120 It follows that, where the delay arising from such waiting lists appears to exceed in the individual case concerned an acceptable period having regard to an objective medical assessment of all the circumstances of the situation and the clinical needs of the person concerned, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the duty to make available specific funds to reimburse the cost of treatment provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State.

121 As regards the factors mentioned in Questions 1(a) and 3(d), to the findings set out in paragraphs 59 to 77 of the present judgment should be added the point that, although Community law does not detract from the power of the Member States to organise their social security systems and decide the level of resources to be allocated to their operation, the achievement of the fundamental freedoms guaranteed by the Treaty nevertheless inevitably requires Member States to make adjustments to those systems. It does not follow that this undermines their sovereign powers in the field (see Müller-Fauré and van Riet, paragraphs 100 and 102).

122 As Advocate General Geelhoed observed in point 88 of his Opinion, it must therefore be found that the need for the Member States to reconcile the principles and broad scheme of their healthcare system with the requirements arising from the Community freedoms entails, on the same basis as the requirements arising from Article 22 of Regulation No 1408/71, a duty on the part of the competent authorities of a national health service, such as the NHS, to provide mechanisms for the reimbursement of the cost of hospital treatment in another Member State to patients to whom that service is not able to provide the treatment required within a medically acceptable period as defined in paragraph 68 of the present judgment.

123 In the light of the foregoing, the answer to the first four questions must be as follows:

- Article 49 EC applies where a person whose state of health necessitates hospital treatment goes to another Member State and there receives such treatment for consideration, there being no need to determine whether the provision of hospital treatment within the national health service with which that person is registered is in itself a service within the meaning of the Treaty provisions on the freedom to provide services.
- Article 49 EC must be interpreted as meaning that it does not preclude reimbursement of the cost of hospital treatment to be provided in another Member State from being made subject to the grant of prior authorisation by the competent institution.
- A refusal to grant prior authorisation cannot be based merely on the existence of waiting lists intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.

Where the delay arising from such waiting lists appears to exceed an acceptable time having regard to an objective medical assessment of the abovementioned circumstances, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the obligation to make available specific funds to reimburse the cost of treatment to be provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State.

The sixth question

124 By this question, the referring court asks essentially whether the reimbursement which a Member State is required by Community law to provide of the cost of hospital treatment in another Member State should be calculated under Article 22 of Regulation No 1408/71 by reference to the legislation of the Member State in which that treatment was provided (the host Member State), or under Article 49 EC by reference to the legislation of the Member State of residence of the patient (the competent Member State). It also wishes to know whether the fact that the hospital treatment is provided free of charge by the national health service in question and the fact that there is therefore no tariff for reimbursement in the legislation of the competent Member State have any bearing on that question. It also asks whether the obligation to fund hospital treatment provided in the host Member State includes the travel and accommodation costs.

125 It should, first of all, be noted in this regard that the patient who, having requested authorisation under Article 22(1)(c)(i) of Regulation No 1408/71, was granted that authorisation or received a refusal to authorise subsequently held to be unfounded must, according to the express terms of that provision, be entitled to the benefits in kind provided on behalf of the competent institution by the institution of the host Member State, in accordance with the provisions of the legislation of that State, as if he were registered with that institution (see *Vanbraekel*, paragraph 32; *Inizan*, paragraph 20; and *Keller*, paragraph 65).

126 It follows that, in such a case, the rules for reimbursement laid down by the legislation of the host Member State are to be applied, while the competent institution remains responsible for subsequently reimbursing the institution of that State, as provided for in Article 36 of Regulation No 1408/71 (see *Vanbraekel*, paragraph 33).

127 The fact that, because the hospital treatment in the national health service in question is free of charge, the legislation of the competent Member State does not include a tariff for reimbursement does not preclude the application of the provisions of Articles 22(1)(c)(i) and 36 of Regulation No 1408/71. The competent institution's obligation under the system set up by those provisions is to reimburse the institution of the host Member State the costs of the benefits provided by that institution in accordance with the provisions of that State, without

there being any need in that regard to refer to any tariff for reimbursement set by the legislation of the competent Member State.

128 Next, it is necessary to consider whether an NHS patient is entitled under Article 49 EC to receive from the competent institution a greater proportion of the cost of hospital treatment received in the host Member State than would be the case under the provisions of the legislation of that State.

129 It should be noted in that connection that the Court has already held that the fact that the legislation of the competent Member State does not guarantee a patient covered by that legislation, who has been authorised to receive hospital treatment in another Member State in accordance with Article 22(1)(c) of Regulation No 1408/71, a level of payment equivalent to that to which he would have been entitled if he had received hospital treatment in the competent Member State is an unjustified restriction of the freedom to provide services within the meaning of Article 49 EC (see *Vanbraekel*, paragraphs 43 to 52).

130 In the light of that case-law, in the context of national rules which, like those in issue in the main proceedings, provide that hospital treatment in establishments belonging to the national health service instituted by those rules is to be free of charge, it must be found that there is no restriction of the freedom to provide services where the patient registered with that service, who was authorised to receive hospital treatment in another Member State pursuant to Article 22(1)(c)(i) of Regulation No 1408/71 or who received a refusal to authorise subsequently held to be unfounded, is entitled to have the cost of that treatment reimbursed in full pursuant to the provisions of the legislation of the host Member State. That patient is not required in such a case to make any financial contribution to the cost of that treatment.

131 By contrast, where the legislation of the host Member State does not provide for the reimbursement in full of the cost of hospital treatment in that State, in order to place the patient in the position he would have been in had the national health service with which he was registered been able to provide him free of charge, within a medically acceptable period, with treatment equivalent to that which he received in the host Member State, the competent institution must in addition reimburse him the difference between the cost, objectively quantified, of that equivalent treatment up to the total amount invoiced for the treatment

received in the host Member State and the amount reimbursed by the institution of that State pursuant to the legislation of that State, where the first amount is greater than the second.

132 Contrary to the view taken by Mrs Watts in her written observations, the obligation of the competent institution in all circumstances to cover the full amount of the difference between the cost of the hospital treatment provided in the host Member State and that of the reimbursement by the institution of that Member State under that State's provisions, including where the cost of that treatment is greater than the cost of equivalent treatment in the competent Member State, would afford that patient cover in excess of that to which he is entitled under the national health service with which he is registered.

133 It should further be noted that in the context of legislation which, like that in the main proceedings, contains, according to the order for reference (see paragraph 22 of the present judgment), rules for calculating the amount of the costs which must in principle be invoiced to particular foreign patients, and recovered from them, for treatment in a hospital covered by the national health service, those rules may be useful reference tools in determining, for the purposes of the calculation referred to in paragraph 131 of the present judgment, the cost in the competent Member State of treatment in a hospital covered by that service, equivalent to that provided to the patient in the host Member State.

134 As regards the travel and accommodation costs, it should be noted in the case of the system of authorisation established by Article 22(1)(c)(i) of Regulation No 1408/71 that that provision confers on the patient the right to receive 'benefits in kind' provided, on behalf of the competent institution, by the institution of the host Member State according to the provisions implemented by that institution.

135 As is confirmed by the second subparagraph of Article 22(2) of Regulation No 1408/71, the sole purpose of Article 22(1)(c)(i) of that regulation is to confer on patients covered by the legislation of one Member State and granted authorisation by the competent institution the right to have access to 'treatment' in another Member State on conditions for reimbursement as favourable as those enjoyed by patients covered by the legislation of that other State (see Vanbraekel, paragraph 32, and Inizan, paragraph 21).

136 The obligation imposed on the competent institution by Articles 22² and 36⁹ of Regulation No 1408/71 therefore relates exclusively to the expenditure connected with the healthcare received by the patient in the host Member State, namely, in the case of hospital

treatment, the cost of medical services strictly defined and the inextricably linked costs relating to the patient's stay in the hospital for the purposes of his treatment.

137 The essential characteristic of 'benefits in kind' within the meaning of Regulation No 1408/71 is that they are 'designed to cover care received by the person concerned' by the direct payment or reimbursement of 'medical expenses' incurred by that patient's state (see, in the context of a statutory scheme of social insurance against the risk of reliance on care, Case C-160/96 *Molenaar* [1998] ECR I-843, paragraphs 32 and 34).

138 Since its purpose is thus not to settle the question of ancillary costs, such as the cost of travel and any accommodation other than in the hospital itself, incurred by a patient authorised by the competent institution to go to another Member State to receive there treatment appropriate to his state of health, Article 22 of Regulation No 1408/71 does not make provision for, but also does not prohibit, the reimbursement of such costs. In those circumstances, it is necessary to consider whether an obligation to reimburse such costs might arise under Article 49 EC¹ (see, by analogy, *Vanbraekel*, paragraph 37).

139 It follows from the case-law cited in paragraph 94 of the present judgment that the legislation of a Member State cannot, without infringing Article 49 EC, exclude reimbursement of the ancillary costs incurred by a patient authorised to go to another Member State to receive there hospital treatment whilst providing for the reimbursement of those costs where the treatment is provided in a hospital covered by the national system in question.

140 By contrast, a Member State is not required under Article 49 EC to lay down a duty on its competent institutions to reimburse the ancillary costs associated with a cross-border movement authorised for medical purposes where there is no such duty in respect of such costs where these arise from movement within the Member State.

141 In those circumstances, it is for the referring court to determine whether the United Kingdom rules provide for the assumption of ancillary costs associated with such movement within the United Kingdom.

142 If that is the case, the patient who was authorised to go to another Member State to receive there hospital treatment or who received a refusal to authorise subsequently held to be unfounded is entitled, as the Belgian Government stated in its written observations and as

Advocate General Geelhoed stated in point 118 of his Opinion, to seek reimbursement of the ancillary costs associated with that cross-border movement for medical purposes subject to the same objective and transparent limits as those set by the competent legislation for the reimbursement of the ancillary costs associated with medical treatment provided in the competent Member State (see to that effect Case C-8/02 Leichtle [2004] ECR I-2641, particularly paragraphs 41 to 48).

143 In the light of the foregoing, the answer to the sixth question must be that:

– Article 49 EC must be interpreted as meaning that where the legislation of the competent Member State provides that hospital treatment provided under the national health service is to be free of charge, and where the legislation of the Member State in which a patient registered with that service was or should have been authorised to receive hospital treatment at the expense of that service does not provide for the reimbursement in full of the cost of that treatment, the competent institution must reimburse that patient the difference (if any) between the cost, objectively quantified, of equivalent treatment in a hospital covered by the service in question up to the total amount invoiced for the treatment provided in the host Member State and the amount which the institution of the latter Member State is required to reimburse under Article 22(1)(c)(i) of Regulation No 1408/71 on behalf of the competent institution pursuant to the legislation of that Member State.

– Article 22(1)(c)(i)² of Regulation No 1408/71 must be interpreted as meaning that the right which it confers on the patient concerned relates exclusively to the expenditure connected with the healthcare received by that patient in the host Member State, namely, in the case of hospital treatment, the cost of medical services strictly defined and the inextricably linked costs relating to his stay in the hospital.

– Article 49 EC must be interpreted as meaning that a patient who was authorised to go to another Member State to receive there hospital treatment or who received a refusal to authorise subsequently held to be unfounded is entitled to seek from the competent institution reimbursement of the ancillary costs associated with that cross-border movement for medical purposes provided that the legislation of the competent Member State imposes a

corresponding obligation on the national system to reimburse in respect of treatment provided in a local hospital covered by that system.

The seventh question

144 By this question, the referring court asks whether Article 49 EC and Article 22 of Regulation No 1408/71 must be interpreted as imposing an obligation on Member States to fund hospital treatment in other Member States without reference to budgetary constraints and, if so, whether such an obligation is compatible with Article 152(5) EC²².

145 It should, first of all, be noted in this regard that, as is clear from the findings set out in relation to the answers to the first six questions, the requirements arising from Article 49 EC¹ and Article 22 of Regulation No 1408/71 are not to be interpreted as imposing on the Member States an obligation to reimburse the cost of hospital treatment in other Member States without reference to any budgetary consideration but, on the contrary, are based on the need to balance the objective of the free movement of patients against overriding national objectives relating to management of the available hospital capacity, control of health expenditure and financial balance of social security systems.

146 Next, it should be noted that, according to Article 152(5)²² EC, Community action in the field of public health is to fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

147 That provision does not, however, exclude the possibility that the Member States may be required under other Treaty provisions, such as Article 49 EC, or Community measures adopted on the basis of other Treaty provisions, such as Article 22 of Regulation No 1408/71, to make adjustments to their national systems of social security. It does not follow that this undermines their sovereign powers in the field (see to that effect *Müller-Fauré and van Riet*, paragraph 102, and, by analogy, *Case C-376/98 Germany v Parliament and Council* [2000] ECR I-8419, paragraph 78).

148 In the light of the foregoing, the answer to the seventh question must be that the obligation of the competent institution under both Article 22 of Regulation No 1408/71 and Article 49 EC to authorise a patient registered with a national health service to obtain, at that

institution's expense, hospital treatment in another Member State where the waiting time exceeds an acceptable period having regard to an objective medical assessment of the condition and clinical requirements of the patient concerned does not contravene Article 152(5) EC.

2.3.6. Costs

149 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

2.3.7. The Court's decision

On those grounds, the Court (Grand Chamber) hereby rules:

1. The second subparagraph of Article 22(2)² of Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996, must be interpreted as meaning that, in order to be entitled to refuse to grant the authorisation referred to in Article 22(1)(c)(i)² of that regulation on the ground that there is a waiting time for hospital treatment, the competent institution is required to establish that that time does not exceed the period which is acceptable on the basis of an objective medical assessment of the clinical needs of the person concerned in the light of all of the factors characterising his medical condition at the time when the request for authorisation is made or renewed, as the case may be.

2. Article 49 EC¹ applies where a person whose state of health necessitates hospital treatment goes to another Member State and there receives such treatment for consideration, there being no need to determine whether the provision of hospital treatment within the

national health service with which that person is registered is in itself a service within the meaning of the Treaty provisions on the freedom to provide services.

Article 49 EC¹ must be interpreted as meaning that it does not preclude reimbursement of the cost of hospital treatment to be provided in another Member State from being made subject to the grant of prior authorisation by the competent institution.

A refusal to grant prior authorisation cannot be based merely on the existence of waiting lists intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.

Where the delay arising from such waiting lists appears to exceed an acceptable time having regard to an objective medical assessment of the abovementioned circumstances, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the obligation to make available specific funds to reimburse the cost of treatment to be provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State.

3. Article 49 EC¹ must be interpreted as meaning that where the legislation of the competent Member State provides that hospital treatment provided under the national health service is to be free of charge, and where the legislation of the Member State in which a patient registered with that service was or should have been authorised to receive hospital treatment at the expense of that service does not provide for the reimbursement in full of the cost of that treatment, the competent institution must reimburse that patient the difference (if

any) between the cost, objectively quantified, of equivalent treatment in a hospital covered by the service in question up to the total amount invoiced for the treatment provided in the host Member State and the amount which the institution of the latter Member State is required to reimburse under Article 22(1)(c)(i)² of Regulation No 1408/71, as amended and updated by Regulation No 118/97, on behalf of the competent institution pursuant to the legislation of that Member State.

Article 22(1)(c)(i)² of Regulation No 1408/71 must be interpreted as meaning that the right which it confers on the patient concerned relates exclusively to the expenditure connected with the healthcare received by that patient in the host Member State, namely, in the case of hospital treatment, the cost of medical services strictly defined and the inextricably linked costs relating to his stay in the hospital.

Article 49 EC must be interpreted as meaning that a patient who was authorised to go to another Member State to receive there hospital treatment or who received a refusal to authorise subsequently held to be unfounded is entitled to seek from the competent institution reimbursement of the ancillary costs associated with that cross-border movement for medical purposes provided that the legislation of the competent Member State imposes a corresponding obligation on the national system to reimburse in respect of treatment provided in a local hospital covered by that system.

4. The obligation of the competent institution under both Article 22² of Regulation No 1408/71, as amended and updated by Regulation No 118/97, and Article 49 EC¹ to authorise a patient registered with a national health service to obtain, at that institution's expense, hospital treatment in another Member State where the waiting time exceeds an acceptable period having regard to an objective medical assessment of the condition and clinical requirements of the patient concerned does not contravene Article 152(5) EC²².

2.4. V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen⁹

2.4.1. Judgment

1

By order of 6 October 1999, received at the Court on 11 October 1999, the Centrale Raad van Beroep (Higher Social Security Court) referred to the Court for a preliminary ruling under Article 234 EC three questions on the interpretation of Article 59¹¹ of the EC Treaty (now, after amendment, Article 49 EC) and Article 60¹² of the EC Treaty (now Article 50 EC).

2

Those questions have been raised in two sets of proceedings between Ms Müller-Fauré and Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA (mutual sickness insurance fund; the Zwijndrecht Fund), established in Zwijndrecht (Netherlands), and between Ms Van Riet and Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen (the Amsterdam Fund), established in Amsterdam (Netherlands), concerning the reimbursement of medical costs incurred in Germany and Belgium respectively.

National legal framework

3

In the Netherlands, the sickness insurance scheme is based inter alia on the Ziekenfondswet (Law on Sickness Funds) of 15 October 1964 (Staatsblad 1964, No 392), which has been subsequently amended (the ZFW), and on the Algemene Wet Bijzondere Ziektekosten (Law on general insurance for special sickness costs) of 14 December 1967 (Staatsblad 1967, No

⁹ Judgment Of The Court 13 May 2003; Case C-385/99; V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen

617), which has also been subsequently amended, (the AWBZ). Both the ZFW and the AWBZ establish a system of benefits in kind under which an insured person is entitled not to reimbursement of costs incurred for medical treatment but to free treatment. Both laws are based on a system of agreements between sickness funds and providers of health care.

4

Under Articles 2 to 4 of the ZFW, workers whose annual income does not exceed an amount determined by that law, persons treated as such and persons in receipt of social benefits, as well as dependent members of their families living with them in the same household, are compulsorily and automatically insured under that law.

5

Article 5(1) of the ZFW provides that any person coming within its scope who wishes to claim entitlement under that law must be affiliated to a sickness fund operating in the municipality in which he resides.

6

Article 8 of the ZFW provides:

1.

An insured person shall be entitled to benefits in the form of necessary medical care, provided that he is not entitled to such care under the Algemene Wet Bijzondere Ziektekosten ... Sickness funds shall ensure that any insured person registered with them is able to rely on that right.

2.

The nature, content and extent of the benefits shall be defined by or pursuant to a Royal Decree, it being understood that they shall in any event include medical assistance, the extent of which remains to be defined, and also the care and treatment provided in categories of institutions to be defined. Furthermore, the grant of a benefit may be conditional on a financial contribution by the insured person; this contribution need not be the same for all insured persons.

...

7

The Verstrekkingsbesluit Ziekenfondsverzekering (Decree on sickness insurance benefits in kind) of 4 January 1966, (Staatsblad 1966, No 3), which has been subsequently amended (the Verstrekkingsbesluit), implements Article 8(2) of the ZFW.

8

The Verstrekkingsbesluit thus determines entitlement to benefits and the extent of such benefits for various categories of care, including in particular the categories medical and surgical assistance and in-patient hospital care.

9

The principal features of the system of agreements put in place by the ZFW are as follows.

10

Article 44(1) of the ZFW provides that the sickness funds are to enter into agreements with persons and establishments offering one or more forms of care, as referred to in the Royal Decree adopted to implement Article 8.

11

Article 44(3) of the ZFW provides that such agreements are to include as a minimum provisions concerning the nature and extent of the parties' mutual obligations and rights, the categories of care to be provided, the quality and effectiveness of the care provided, supervision of compliance with the terms of the agreement, including supervision of the benefits provided or to be provided and the accuracy of the amounts charged for those benefits, and also an obligation to communicate the information necessary for that supervision.

12

The sickness funds are free to enter into agreements with any care provider, subject to a twofold reservation. First, under Article 47 of the ZFW, every sickness fund is required to enter into an agreement ... with any establishment in the region in which it operates or which the population of that region regularly attends. Second, agreements can be entered into only

with establishments which are duly authorised to provide the care in question or with persons lawfully authorised to do so.

13

Article 8a of the ZFW provides:

1.

An establishment providing services such as those referred to in Article 8 must be authorised to do so.

2.

A Royal Decree may provide that an establishment belonging to a category to be defined by Royal Decree is to be regarded as authorised for the purposes of this Law. ...

14

Under Article 8c(a) of the ZFW approval of an establishment operating a hospital facility must be refused if that establishment does not meet the requirements of the *Wet ziekenhuisvoorzieningen* (Law on hospital facilities) on distribution and needs. That law, its implementing directives (in particular the directive based on Article 3 of the law, *Nederlandse Staatscourant* 1987, No 248) and also the district plans determine in greater detail national needs in relation to various categories of hospitals and their distribution between the various health regions within the Netherlands.

15

As regards the specific exercise of the right to benefits, Article 9 of the ZFW provides:

1.

Save as provided for in the Royal Decree referred to in Article 8, an insured person wishing to claim entitlement to a benefit shall apply to a person or an establishment with whom or with which the sickness fund with which he is registered has entered into an agreement for that purpose, subject to the provisions of paragraph 4.

2.

The insured person may choose from among the persons and establishments mentioned in paragraph 1, subject to the provisions of paragraph 5 and the provisions regarding conveyance by ambulance, as laid down in the Wet ambulancevervoer ((Law on conveyance by ambulance), Staatsblad 1971, No 369).

3.

[repealed]

4.

A sickness fund may, by way of derogation from paragraphs 1 and 2 hereof, authorise an insured person, for the purpose of claiming entitlement to a benefit, to apply to another person or establishment in the Netherlands where this is necessary for his health care. The Minister may determine the cases and circumstances in which an insured person may be granted authorisation, in claiming entitlement to a benefit, to apply to a person or an establishment outside the Netherlands.

16

The Minister exercised the powers conferred on him by the final sentence of Article 9(4) of the ZFW in adopting the Regeling hulp in het buitenland ziekenfondsverzekering (Regulation on care provided abroad under the sickness insurance rules) of 30 June 1988, (Nederlandse Staatscourant 1988, No 123; the Rhbz). Article 1 of the Rhbz provides: A sickness fund may authorise an insured person claiming entitlement to a benefit to apply to a person or establishment outside the Netherlands in those cases in which the sickness fund has determined that such action is necessary for the health care of the insured person.

17

In the event of an insured person obtaining authorisation to apply to a provider established outside the Netherlands, the cost of any treatment is wholly assumed by the sickness fund to which the person is affiliated.

18

The Centrale Raad van Beroep explains that, according to its established case-law, applications for authorisation to undergo medical treatment abroad funded under the ZFW must be submitted to the insured person's sickness fund and the latter must, except in exceptional circumstances such as an emergency, have given its prior agreement to the provision of treatment, failing which it will not be possible to obtain reimbursement of the cost of the treatment.

19

Furthermore, as regards the condition laid down in Article 9(4) of the ZFW and Article 1 of the Rhbz that the insured's treatment abroad must be medically necessary, it appears from the documents before the Court that the fund takes account, in practice, of the methods of treatment available in the Netherlands and ascertains whether appropriate treatment can be provided there without undue delay.

2.4.2. The main proceedings

The Müller-Fauré case

20

While on holiday in Germany, Ms Müller-Fauré underwent dental treatment involving the fitting of six crowns and a fixed prosthesis on the upper jaw. The treatment was provided between 20 October and 18 November 1994 without recourse to any hospital facilities.

21

When she returned from her holiday, she applied to the Zwijndrecht Fund for reimbursement of the costs of the treatment, which amounted to a total of DEM 7 444.59. By letter of 12 May 1995 the Fund refused reimbursement on the basis of the opinion of its advisory dental officer.

22

Ms Müller-Fauré sought the opinion of the Ziekenfondsraad, which is responsible for supervising the management and administration of sickness funds and which, on 16 February 1996, confirmed the Zwijndrecht Fund's decision on the ground that insured persons are entitled only to treatment itself and not to reimbursement of any related costs, except in exceptional circumstances which did not exist in this case.

23

Ms Müller-Fauré then brought an action before the Arrondissementsrechtbank te Rotterdam (District Court, Rotterdam) (Netherlands). By judgment of 21 August 1997, that court upheld the Fund's decision, having also found that the case entailed no exceptional circumstances such as to justify reimbursement of the costs, given, in particular, the scale of the treatment and the fact that it extended over several weeks.

24

The Centrale Raad van Beroep points out that in any event only a limited part of the treatment received by Ms Müller-Fauré is covered by the Verstrekkingsbesluit and is therefore eligible for reimbursement. Furthermore, it finds that Ms Müller-Fauré voluntarily sought treatment from a dentist established in Germany while she was on holiday there because she lacked confidence in dental practitioners in the Netherlands. Such circumstances cannot, according to the case-law of the court concerned, provide grounds under the national legislation for reimbursement in respect of medical treatment undergone abroad without authorisation from the insured person's fund.

The Van Riet case

25

Ms Van Riet had been suffering from pain in her right wrist since 1985. On 5 April 1993, the doctor treating her requested that the Amsterdam Fund's medical adviser should grant authorisation for his patient to have an arthroscopy performed in Deurne hospital (Belgium) where that examination could be carried out much sooner than in the Netherlands. The Fund rejected that request by letters of 24 June and 5 July 1993 on the ground that the test could also be performed in the Netherlands.

In the meantime, Ms Van Riet had already had the arthroscopy carried out at Deurne hospital in May 1993 and, following that examination, the decision was taken to carry out an ulnar reduction to relieve the patient's pain. Care before and after the treatment, and the treatment itself, were provided in Belgium, partly in hospital and partly elsewhere. The Amsterdam Fund refused to reimburse the cost of the care, which amounted to a total of BEF 93 782. That decision was confirmed by the Ziekenfondsraad on the ground that there was no emergency nor any medical necessity such as to justify Ms Van Riet receiving treatment in Belgium, since appropriate treatment was available in the Netherlands within a reasonable period. The competent Arrondissementsrechtbank rejected as unfounded Ms Van Riet's action against the decision for the same reasons as the Amsterdam Fund.

The Centrale Raad van Beroep, before which the applicant in the main proceedings brought an appeal, states that, although it is not disputed that most of the treatment given to Ms Van Riet is indeed covered by the Verstrekkingsbesluit, the treatment was provided in Belgium without prior authorisation and without it being established that Ms Van Riet could not reasonably wait, for medical or other reasons, until the Amsterdam Fund had taken a decision on her application. Furthermore, in that court's view, the time which Ms Van Riet would have had to wait for the arthroscopy in the Netherlands was not unreasonable. The documents before the Court show that the waiting time was about six months.

The referring court submits that, in this instance, the conditions for application of Article 22(1)(a) of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996 (OJ 1997 L 28, p. 1; Regulation No 1408/71), were not met, since neither Ms Müller-Fauré's nor Ms Van Riet's state of health necessitated immediate treatment during a stay in the territory of another Member State. Furthermore, nor has it been established, in conformity with Article 22(1)(c) and (2), second paragraph, of that regulation that the treatment concerned could not, account being taken of the state of health of the applicants in the main actions, be given in the Netherlands within the time normally

necessary, a fact which would have obliged the sickness funds to authorise treatment in another Member State.

29

The national court none the less raises a question as to the compatibility of the decisions refusing reimbursement with Articles 59 and 60 of the Treaty in the light of the judgment in Case C-158/96 Kohll [1998] ECR I-1931. It notes that the national provisions at issue do not of themselves prevent insured persons from applying to a service provider established in another Member State but impose a precondition that the sickness insurance fund of which the insured persons are members must have entered into an agreement with that provider, something which, as a rule, is not the case. In the absence of such an agreement, reimbursement of costs incurred in another Member State is subject to prior authorisation, which is not granted unless it is necessary for [the insured person's] health care, which in general is the case only where the contracted care providers cannot offer all the appropriate care. The obligation to obtain prior authorisation therefore works to the advantage of contracted medical care providers — which are virtually always from the Netherlands — and to the detriment of care providers from other Member States. The referring court adds that the administrative powers of the Netherlands authorities do not extend to care providers established in other Member States, which may hinder the conclusion of agreements with those providers.

30

If it were found that the authorisation required by Article 9(4) of the ZFW impedes the freedom to provide services, the Centrale Raad van Beroep seeks to ascertain whether the requirement is justified.

31

In that connection, the referring court draws attention to the characteristics of the Netherlands sickness insurance scheme. In essence, unlike reimbursement schemes, the scheme guarantees that benefits in kind will be provided. In the submission of the defendants in the main actions, the financial balance of the scheme could be jeopardised if it were possible for insured persons to obtain reimbursement, without prior authorisation, of the costs of care provided in another Member State. The national court refers in that regard to national measures taken to control the costs of hospital care, in particular the rules laid down in the Wet

ziekenhuisvoorzieningen concerning the planning and geographical distribution of care, and those in the ZFW limiting reimbursement to care provided by authorised hospitals.

The questions referred for a preliminary ruling

32

Those were the circumstances in which the Centrale Raad van Beroep decided to stay proceedings and refer the following questions to the Court for a preliminary ruling:

1.

Are Articles 59¹¹ and 60¹² of the EC Treaty ... to be interpreted as meaning that in principle a provision such as Article 9(4) of the Ziekenfondswet, read in conjunction with Article 1 of the Regeling hulp in het buitenland ziekenfondsverzekering, is incompatible therewith in so far as it stipulates that in order to assert his entitlement to benefits a person insured with a sickness insurance fund requires the prior authorisation of that fund to seek treatment from a person or establishment outside the Netherlands with whom or which the sickness insurance fund has not concluded an agreement?

2.

If so, do the objectives of the Netherlands system of benefits in kind referred to above constitute an overriding reason in the general interest capable of justifying a restriction on the fundamental principle of freedom to provide services?

3.

Does the question whether the treatment as a whole or only a proportion thereof involved hospital care affect the answers to these questions?

33

By letter of 12 July 2001, the Court Registry asked the referring court whether it wished to maintain its reference for a preliminary ruling in the light of the judgment delivered on that date in Case C-157/99 Smits and Peerbooms [2001] ECR I-5473.

34

By letter of 25 October 2001, the referring court informed the Court that it was maintaining the reference since Smits and Peerbooms did not specifically deal with the attributes of the Netherlands sickness insurance scheme, which is a benefits-in-kind scheme based on agreements. It also asked the Court to explain the import of paragraph 103 of the judgment, which states: ... the condition concerning the necessity of the treatment, laid down by the rules at issue in the main proceedings, can be justified under Article 59¹¹ of the Treaty, provided that the condition is construed to the effect that authorisation to receive treatment in another Member State may be refused on that ground only if the same or equally effective treatment [for the patient] can be obtained without undue delay from an establishment with which the insured person's sickness insurance fund has contractual arrangements.

35

More specifically, the referring court asks the Court what is meant by without undue delay and, in particular, whether that condition must be assessed on a strictly medical basis, regardless of the waiting time for the treatment sought.

36

By letter of 6 March 2002, the Court Registry requested the parties to the main actions, the Member States and the Commission to submit any observations which they might have on the conclusions to be drawn from the judgment in Smits and Peerbooms in the light of the questions raised by the Centrale Raad van Beroep.

The first question

37

By its first question, the national court is essentially asking whether Articles 59 and 60 of the Treaty are to be interpreted as precluding legislation of a Member State, such as the legislation at issue in the main proceedings, which makes assumption of the costs of care provided in another Member State, by a person or an establishment with whom or which the insured person's sickness fund has not concluded an agreement, conditional upon prior authorisation by the fund.

38

It should be borne in mind, as a preliminary point, that it is settled case-law that medical activities fall within the scope of Article 60 of the Treaty, there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment (see, most recently, *Smits and Peerbooms* , paragraph 53).

39

The Court also found, in paragraphs 54 and 55 of *Smits and Peerbooms* , that the fact that the applicable rules are social security rules and, more specifically, provide, as regards sickness insurance, for benefits in kind rather than reimbursement does not mean that the medical treatment in question falls outside the scope of the freedom to provide services guaranteed by the EC Treaty. Indeed, in the disputes before the national court, the treatment provided in a Member State other than that in which the persons concerned were insured resulted in direct payment by the patient to the doctor providing the service or the establishment in which the care was provided.

40

Since medical services fall within the ambit of freedom to provide services for the purposes of Articles 59 and 60 of the Treaty, it is necessary to determine whether the legislation at issue in the main actions introduces restrictions on that freedom in making assumption of the costs of care provided in a Member State other than that in which the insured person's sickness fund is established, by a person or establishment which has not concluded an agreement with that fund, conditional upon prior authorisation by the fund.

41

In that regard the Court has already held, in paragraph 62 of the judgment in *Smits and Peerbooms* , that while the ZFW does not deprive insured persons of the possibility of using a service provider established in a Member State other than that in which the sickness fund covering the insured is situated, it does nevertheless make reimbursement of the costs thus incurred subject to prior authorisation, which may be given, as the referring court points out, only where provision of the care at issue, irrespective of whether it involves a hospital, is a medical necessity.

42

Since the requirement of medical necessity is in practice satisfied only where adequate treatment cannot be obtained without undue delay from a contracted doctor or hospital in the Member State in which the person is insured, this requirement by its very nature is liable severely to limit the circumstances in which such authorisation will be issued (Smits and Peerbooms , paragraph 64).

43

Admittedly, it is open to the Netherlands sickness insurance funds to enter into agreements with hospital establishments outside the Netherlands. In such a case no prior authorisation would be required in order for the cost of treatment provided by such establishments to be assumed under the ZFW. However, with the exception of hospitals situated in regions adjoining the Netherlands, it seems unlikely that a significant number of hospitals in other Member States would ever enter into agreements with those sickness insurance funds, given that their prospects of admitting patients insured by those funds remain uncertain and limited (Smits and Peerbooms , paragraphs 65 and 66).

44

The Court has therefore already held that rules such as those at issue in the main proceedings deter, or even prevent, insured persons from applying to providers of medical services established in Member States other than that of the insurance fund and constitute, both for insured persons and service providers, a barrier to freedom to provide services (Smits and Peerbooms , paragraph 69).

45

However, before coming to a decision on whether Articles 59 and 60 of the Treaty preclude rules such as those at issue in the main actions, it is appropriate to determine whether those rules can be objectively justified, which is the subject of the second question.

The second and third questions

46

By its second and third questions, which it is appropriate to examine together, the referring court is asking whether legislation such as that at issue in the main proceedings, which has

restrictive effects on freedom to provide services, can be justified by the actual particular features of the national sickness insurance scheme, which provides not for reimbursement of costs incurred but essentially for benefits in kind and is based on a system of agreements intended both to ensure the quality of the care and to control the costs thereof. It also wishes to know whether the fact that the treatment at issue is provided in whole or in part in a hospital environment has any effect in that regard.

The arguments submitted to the Court

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In the submission of the Netherlands Government and the Zwijsdrecht Fund, the authorisation required by Article 9(4) of the ZFW is an integral part of the Netherlands sickness insurance scheme. Sickness cover by way of benefits in kind, as provided by that scheme, necessitates the prior conclusion, between the fund and care providers, of agreements dealing with the volume, quality, effectiveness and costs of health care in order, first, to allow for needs-based planning and expenditure control and, second, to ensure that a high-quality medical service is provided, that benefits are comparable and thus that insured persons are treated equally. A system of agreements of that kind is in the main advantageous to the insured.

48

In those circumstances, insured persons must apply to contracted care providers alone or, if they none the less wish to be treated by a non-contracted doctor or establishment established in the Netherlands or abroad, obtain prior authorisation from the sickness insurance scheme to which they belong.

49

The Netherlands Government and the Zwijsdrecht Fund add that, if there were no requirement for prior authorisation, it would never be in the interest of care providers to participate in the system of agreements by becoming subject to contractual clauses dealing with the availability, volume, quality, effectiveness and cost of services, with the result that the authorities managing the sickness insurance scheme would be unable to make any needs-related plans by adjusting expenditure to needs and to ensure that a high-quality medical service was open to all. The system of agreements would thus lose its *raison d'être* as a means of managing health care, which would prejudice the sovereign power of the Member States,

recognised by the Court's case-law, to organise their social security systems. The Netherlands Government explains in that connection that there are waiting lists because of the limited financial resources available for health-care cover and that this gives rise to a need to quantify the benefits to be provided and to make them subject to priorities which must be strictly observed.

50

Furthermore, the Netherlands sickness funds cannot be forced to conclude agreements with a greater number of care providers than is necessary to meet the needs of people living in the Netherlands. The Netherlands Government points out that it is specifically to meet those needs that most of the agreements are entered into with care providers established in the Netherlands since demand from the insured is clearly greatest within the national territory.

51

Finally, as regards the way in which it is appropriate to determine whether the same or equally effective treatment can be obtained without undue delay, in the words of paragraph 103 of *Smits and Peerbooms*, the *Zwijndrecht Fund* submits that the mere fact of a person being on a waiting list does not mean that such treatment is not available. If it were to adopt a different interpretation, the Court would significantly extend the conditions in which benefits are awarded, which are a matter of national competence. Moreover, it would cast uncertainty over all attempted planning and rationalisation in the health-care sector aimed at avoiding over-capacity, supply-side imbalance, wastage and loss.

52

The Netherlands Government argues, in that regard, that it is quite apparent from paragraph 103 of *Smits and Peerbooms* that the period within which medical treatment is necessary is to be determined by reference to the patient's medical condition and history. It is the national court's responsibility to ascertain whether the treatment is available within that period, which amounts to a factual assessment.

53

The Danish, German, Spanish, Irish, Italian, Swedish and United Kingdom Governments, together with the Icelandic and Norwegian Governments, generally endorse the foregoing observations.

54

In particular, the Spanish Government maintains that any distinction between treatment provided by a practitioner and treatment provided in a hospital is unnecessary where a sickness insurance scheme provides exclusively benefits in kind. If an insured person is given health care or purchases a medicinal product in a Member State other than that in which his insurance fund is established, the duties and taxes paid by providers or suppliers are not paid into the budget of the Member State of affiliation, which adversely affects one of the sources of financing of social security in that State.

55

The Irish and United Kingdom Governments submit that if insured persons were entitled to go to a Member State other than that in which they are insured in order to receive treatment there, there would be adverse consequences for the setting of priorities for medical treatment and the management of waiting lists, which are significant aspects of the organisation of sickness insurance. In that regard, the United Kingdom Government points out that the finite financial resources allocated to the National Health Service (the NHS) are managed by local health authorities which establish timetables based on clinical judgments and medically determined priorities for different treatments. Patients do not have the right to demand a certain timetable for their hospital treatment. It follows that if patients could shorten their waiting time by obtaining, without prior authorisation, medical treatment in other Member States for which the competent fund was none the less obliged to assume the cost, the financial balance of the system would be threatened and the resources available for more urgent treatment would be severely depleted, thereby placing at risk its ability to provide adequate levels of health care.

56

The United Kingdom Government adds that if hospital services were to be liberalised, its own hospitals would be unable to predict either the loss of demand that would follow from recourse being had to hospital treatment in other Member States or the increase in demand that would follow from persons insured in those other States being able to seek hospital treatment in the United Kingdom. Those effects of liberalisation would not necessarily offset each other and the impact would be different for every hospital in the United Kingdom.

As regards the criteria by which it should be ascertained whether treatment which is the same or equally effective for the patient could be obtained without undue delay in the Member State in which the person is insured, the United Kingdom Government, like the Swedish Government, refers to Article 22(2), second paragraph, of Regulation No 1408/71, in conjunction with Article 22(1)(c), from which it is apparent that the person concerned may not be refused the authorisation required to go to the territory of another Member State to receive there the treatment where, taking account of his current state of health and the probable course of the disease, he cannot be given the treatment within the time normally necessary in the Member State of residence. There is also a reference to the way in which those provisions were interpreted in paragraph 10 of the judgment in Case 182/78 Pierik [1979] ECR 1977.

In that regard the United Kingdom Government draws attention to the fact that in practice authorisation for treatment in another Member State is generally given in the United Kingdom when there is a delay for treatment beyond the maximum waiting times. National waiting lists take account of the different needs of different categories of patients and permit the best possible allocation of hospital resources. The lists are flexible so that if a patient's condition suddenly deteriorates, he can be moved up the waiting list and treated more quickly. To compel the competent authorities to authorise treatment abroad in circumstances other than where there is a delay beyond the normal waiting time and to pass the cost on to the NHS would have damaging consequences for its management and financial viability.

In any event, the United Kingdom Government points to the specific characteristics of the NHS and asks the Court to uphold the principle that health care provided under such a national sickness insurance scheme does not fall within the scope of Article 60 of the Treaty and that the NHS, which is a non-profit-making body, is not a service provider for the purposes of the Treaty.

60

The Danish Government argues that there would be a risk of excessive consumption of medical services if patients had unrestricted access to free medical care in Member States other than that in which the insured's sickness insurance fund is established and also a risk, in the event of numerous journeys abroad for medical purposes, of it not being possible to maintain the competence of doctors established in national territories at an adequate level as regards unusual and complex diseases.

61

The Belgian Government submits that the specific nature of the Netherlands scheme, in providing not for reimbursement of costs incurred but for benefits in kind, does not amount per se to a general-interest reason justifying a restriction on freedom to provide services. It submits that it is appropriate to draw a distinction between services supplied elsewhere than in a hospital and those supplied in a hospital.

62

In the first case, there is no justification for any restriction on freedom to provide services, as can be seen from the judgment in *Kohll*. However, in the second case, there are sound reasons, linked to protecting the financial balance of the social security system and to maintaining a balanced medical and hospital service open to all, which justify requiring prior authorisation when services are to be provided in a hospital environment in a Member State other than that in which the insured's sickness insurance fund is established. Furthermore, in the absence of prior authorisation, the Member States with waiting lists for hospital treatment might have a tendency to send their nationals abroad for treatment instead of investing in their own infrastructure, thereby thwarting the other Member States' attempted hospital-related planning.

63

The Commission distinguishes between care provided in a surgery, which it places on the same footing as out-patient treatment within a hospital environment, and hospital treatment as such. As regards the first category, the analysis in the judgments in Case C-120/95 *Decker* [1998] ECR I-1831 and *Kohll* should be upheld, by regarding the requirement for prior authorisation as incompatible with Community law, except in the case of certain services,

dental work in particular, which are extremely costly and specialised. As to the second category of care, provided in a hospital environment, reference should be made to the analysis in the judgment in *Smits and Peerbooms* , and whilst it should be recognised that the requirement for prior authorisation is justified by planning needs, refusal of authorisation should none the less be subject to the limits set by the Court in that judgment.

64

As to the interpretation of the words without undue delay employed in paragraph 103 of the judgment in *Smits and Peerbooms* , the Commission submits that only the patient's medical condition should be taken into account, as is clear from paragraph 104 of the judgment.

65

Finally, the Norwegian Government argues that the conditions on which benefits are granted and the periods within which they can be given are a matter solely for national legislation. Community law cannot confer on patients the right to receive, in a Member State other than that in which the persons concerned are insured, health care to which they are not entitled in their own Member State. Nor can it entitle them to receive treatment within a shorter time-limit than that provided for by national legislation. If it did so, it would prejudice the Member State's power to organise their social security systems and would go beyond the scope of the Treaty provisions on freedom to provide services.

Findings of the Court

66

It is clear from the documents before the Court that the reasons put forward to justify the requirement for prior authorisation where sickness insurance is to cover benefits provided in a Member State other than that in which the person concerned is insured, whether within a hospital environment or not, are linked (i) to the protection of public health inasmuch as the system of agreements is intended to ensure that there is a high-quality, balanced medical and hospital service open to all, (ii) to the financial balance of the social security system in that a system of that kind also permits the managing authorities to control expenditure by adjusting it to projected requirements, according to preestablished priorities, and (iii) to the essential characteristics of the sickness insurance scheme in the Netherlands, which provides benefits in kind.

The risk that the protection of public health may be adversely affected

67

It is apparent from the Court's case-law that the objective of maintaining a high-quality, balanced medical and hospital service open to all, may fall within one of the derogations provided for in Article 56 of the EC Treaty (now, after amendment, Article 46 EC), in so far as it contributes to the attainment of a high level of health protection (Kohll , paragraph 50, and Smits and Peerbooms , paragraph 73). In particular, that Treaty provision permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for public health, and even the survival of the population (Kohll , paragraph 51, and Smits and Peerbooms , paragraph 74).

68

However, it is settled case-law that it is necessary, where justification is based on an exception laid down by the Treaty or indeed on an overriding general-interest reason, to ensure that the measures taken in that respect do not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules (see Case 205/84 Commission v Germany [1986] ECR 3755, paragraphs 27 and 29; Case C-180/89 Commission v Italy [1991] ECR I-709, paragraphs 17 and 18; Case C-106/91 Ramrath [1992] ECR I-3351, paragraphs 30 and 31, and Smits and Peerbooms , paragraph 75).

69

In this instance the arguments put forward to justify the requirement for prior authorisation seek to establish that, if it were open to patients to get treatment in a Member State other than that in which they are insured, without prior authorisation to that effect, the competent State could no longer guarantee that in its territory there would be a high-quality, balanced medical and hospital service open to all and hence a high level of public health protection.

70

As to the Danish Government's argument that the actual competence of practitioners, working in surgeries or in a hospital environment, would be undermined because of numerous journeys abroad for medical purposes, the Court finds that no specific evidence has been adduced in support of this argument.

71

The objective of maintaining a balanced medical and hospital service open to all is inextricably linked to the way in which the social security system is financed and to the control of expenditure, which are dealt with below.

The risk of seriously undermining the financial balance of the social security system

72

It must be recalled, at the outset, that, according to the Court's case-law, aims of a purely economic nature cannot justify a barrier to the fundamental principle of freedom to provide services (see, to that effect, Case C-398/95 SETTG [1997] ECR I-3091, paragraph 23, and Kohll , paragraph 41).

73

However, in so far as, in particular, it could have consequences for the overall level of public-health protection, the risk of seriously undermining the financial balance of the social security system may also constitute per se an overriding general-interest reason capable of justifying a barrier of that kind (Kohll , paragraph 41, and Smits and Peerbooms , paragraph 72).

74

It is self-evident that assuming the cost of one isolated case of treatment, carried out in a Member State other than that in which a particular person is insured with a sickness fund, can never make any significant impact on the financing of the social security system. Thus an overall approach must necessarily be adopted in relation to the consequences of freedom to provide health-related services.

75

In that regard, the distinction between hospital services and non-hospital services may sometimes prove difficult to draw. In particular, certain services provided in a hospital environment but also capable of being provided by a practitioner in his surgery or in a health centre could for that reason be placed on the same footing as non-hospital services. However, in the main actions, the fact that the care at issue is partly hospital treatment and partly non-hospital treatment has not given rise to disagreement between the parties to the main

proceedings or on the part of the Member States which have submitted observations under Article 23 of the EC Statute of the Court of Justice or the Commission.

Hospital services

76

As regards hospital services, such as those provided to Ms Van Riet in Deurne hospital, the Court, in paragraphs 76 to 80 of the judgment in *Smits and Peerbooms* , made the following findings.

77

It is well known that the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible.

78

As may be seen, in particular, from the system of agreements involved in the main actions, this kind of planning generally meets a variety of concerns.

79

For one thing, it seeks to achieve the aim of ensuring that there is sufficient and permanent accessibility to a balanced range of high-quality hospital treatment in the State concerned.

80

For another thing, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. Such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for health care are not unlimited, whatever the mode of funding applied.

81

In those circumstances, a requirement that the assumption of costs, under a national social security system, of hospital treatment provided in a Member State other than that of affiliation

must be subject to prior authorisation appears to be a measure which is both necessary and reasonable.

82

As regards specifically the system set up by the ZFW, the Court clearly acknowledged that, if insured persons were at liberty, regardless of the circumstances, to use the services of hospitals with which their sickness insurance fund had no agreement, whether those hospitals were situated in the Netherlands or in another Member State, all the planning which goes into the system of agreements in an effort to guarantee a rationalised, stable, balanced and accessible supply of hospital services would be jeopardised at a stroke (Smits and Peerbooms , paragraph 81).

83

Although Community law does not therefore in principle preclude a system of prior authorisation for this category of services, the conditions attached to the grant of such authorisation must none the less be justified in the light of the overriding considerations mentioned above and must satisfy the requirement of proportionality referred to in paragraph 68 above.

84

It likewise follows from settled case-law that a scheme of prior administrative authorisation cannot legitimise discretionary decisions taken by the national authorities, which are liable to negate the effectiveness of provisions of Community law, in particular those relating to a fundamental freedom such as that at issue in the main proceedings (see Joined Cases C-358/93 and C-416/93 *Bordessa and Others* [1995] ECR I-361, paragraph 25; Joined Cases C-163/94, C-165/94 and C-250/94 *Sanz de Lera and Others* [1995] ECR I-4821, paragraphs 23 to 28, and Case C-205/99 *Analir and Others* [2001] ECR I-1271, paragraph 37).

85

Thus, in order for a prior administrative authorisation scheme to be justified even though it derogates from a fundamental freedom of that kind, it must be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily (*Analir and Others* , paragraph 38). Such a prior administrative authorisation scheme must likewise be

based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings (Smits and Peerbooms , paragraph 90).

86

In the main actions, the disputes do not concern the actual cover provided by the Netherlands sickness insurance scheme for the medical and hospital treatment with which Ms Müller-Fauré and Ms Van Riet were provided. In those actions, what is disputed is whether it was a medical necessity for them to have the treatment at issue in Germany and Belgium respectively, rather than in the Netherlands. In that regard, in paragraphs 99 to 107 of Smits and Peerbooms , the Court also ruled on that condition concerning the necessity of the proposed treatment, to which the grant of authorisation is subject.

87

As the national court states, it follows from the wording of Article 9(4) of the ZFW and Article 1 of the Rhbz that in principle that condition applies irrespective of whether the request for authorisation relates to treatment in an establishment located in the Netherlands with which the insured person's sickness insurance fund has no agreement or in an establishment located in another Member State.

88

As regards hospital treatment carried out outside the Netherlands, the national court states that the condition concerning the necessity of the treatment is in practice interpreted as meaning that such treatment is not to be authorised unless it appears that appropriate treatment cannot be provided without undue delay in the Netherlands. The Netherlands Government explains that if Article 9(4) of the ZFW is read in conjunction with Article 1 of the Rhbz, authorisation must be refused solely where the care required by the insured person's state of health is available from contracted care providers.

89

The condition concerning the necessity of the treatment, laid down by the legislation at issue in the main proceedings, can be justified under Article 59 of the Treaty, provided that the condition is construed to the effect that authorisation to receive treatment in another Member

State may be refused on that ground only if treatment which is the same or equally effective for the patient can be obtained without undue delay from an establishment with which the insured person's sickness insurance fund has an agreement (Smits and Peerbooms , paragraph 103).

90

In order to determine whether treatment which is equally effective for the patient can be obtained without undue delay in an establishment having an agreement with the insured person's fund, the national authorities are required to have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history (see, to that effect, Smits and Peerbooms , paragraph 104).

91

The Court also stated, at paragraphs 105 and 106 of Smits and Peerbooms , that:

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thus construed, the condition concerning the necessity of treatment can allow an adequate, balanced and permanent supply of high-quality hospital treatment to be maintained on the national territory and the financial stability of the sickness insurance system to be assured;

—

were large numbers of insured persons to decide to be treated in other Member States even when the hospitals having agreements with their sickness insurance funds offer adequate identical or equivalent treatment, the consequent outflow of patients would be liable to put at risk the very principle of having agreements with hospitals and, consequently, undermine all the planning and rationalisation carried out in this vital sector in an effort to avoid the phenomena of hospital overcapacity, imbalance in the supply of hospital medical care and logistical and financial wastage.

However, a refusal to grant prior authorisation which is based not on fear of wastage resulting from hospital overcapacity but solely on the ground that there are waiting lists on national territory for the hospital treatment concerned, without account being taken of the specific circumstances attaching to the patient's medical condition, cannot amount to a properly justified restriction on freedom to provide services. It is not clear from the arguments submitted to the Court that such waiting times are necessary, apart from considerations of a purely economic nature which cannot as such justify a restriction on the fundamental principle of freedom to provide services, for the purpose of safeguarding the protection of public health. On the contrary, a waiting time which is too long or abnormal would be more likely to restrict access to balanced, high-quality hospital care.

Non-hospital services

As regards non-hospital medical services such as those supplied to Ms Müller-Fauré and, in part, to Ms Van Riet, no specific evidence has been produced to the Court, not even by the Zwijndrecht and Amsterdam Funds or the Netherlands Government, to support the assertion that, were insured persons at liberty to go without prior authorisation to Member States other than those in which their sickness funds are established in order to obtain those services from a non-contracted provider, that would be likely seriously to undermine the financial balance of the Netherlands social security system.

It is true that removal of the condition that there should be a system of agreements in respect of services supplied abroad adversely affects the ways in which health-care expenditure may be controlled in the Member State of affiliation.

However, the documents before the Court do not indicate that removal of the requirement for prior authorisation for that type of care would give rise to patients travelling to other countries in such large numbers, despite linguistic barriers, geographic distance, the cost of staying abroad and lack of information about the kind of care provided there, that the financial balance of the Netherlands social security system would be seriously upset and that, as a

result, the overall level of public-health protection would be jeopardised — which might constitute proper justification for a barrier to the fundamental principle of freedom to provide services.

96

Furthermore, care is generally provided near to the place where the patient resides, in a cultural environment which is familiar to him and which allows him to build up a relationship of trust with the doctor treating him. If emergencies are disregarded, the most obvious cases of patients travelling abroad are in border areas or where specific conditions are to be treated. Furthermore, it is specifically in those areas or in respect of those conditions that the Netherlands sickness funds tend to set up a system of agreements with foreign doctors, as the observations submitted to the Court reveal.

97

Those various factors seem likely to limit any financial impact on the Netherlands social security system of removal of the requirement for prior authorisation in respect of care provided in foreign practitioners' surgeries.

98

In any event, it should be borne in mind that it is for the Member States alone to determine the extent of the sickness cover available to insured persons, so that, when the insured go without prior authorisation to a Member State other than that in which their sickness fund is established to receive treatment there, they can claim reimbursement of the cost of the treatment given to them only within the limits of the cover provided by the sickness insurance scheme in the Member State of affiliation.

The argument based on the essential characteristics of the Netherlands sickness insurance scheme

99

The Zwijndrecht Fund and the Netherlands, Spanish and Norwegian Governments have drawn attention to the fact that Member States are free to set up the social security system of their choice. In this instance, in the absence of prior authorisation, insured persons could apply freely to non-contracted care providers with the result that the existence of the

Netherlands system of benefits in kind, the operation of which is in essence dependent upon the system of agreements, would be jeopardised. Furthermore, the Netherlands authorities would be obliged to introduce mechanisms for reimbursement into their method of organising access to health care since, instead of receiving free health services on national territory, the insured would have to advance the sums needed to pay for the services received and wait for some time before being reimbursed. Thus, Member States would be obliged to abandon the principles and underlying logic of their sickness insurance schemes.

100

In that regard it follows from settled case-law that Community law does not detract from the power of the Member States to organise their social security systems (see, in particular, Case 238/82 Duphar and Others [1984] ECR 523, paragraph 16, and Case C-70/95 Sodemare and Others [1997] ECR I-3395, paragraph 27). Therefore, in the absence of harmonisation at Community level, it is for the legislation of each Member State to determine the conditions on which social security benefits are granted (see, in particular, Case 110/79 Coonan [1980] ECR 1445, paragraph 12; Case C-349/87 Paraschi [1991] ECR I-4501, paragraph 15, and Joined Cases C-4/95 and C-5/95 Stöber and Piosa Pereira [1997] ECR I-511, paragraph 36). However, it is nevertheless the case that the Member States must comply with Community law when exercising that power (Decker , paragraph 23, and Kohll , paragraph 19).

101

Two preliminary observations must be made on this point.

102

First, achievement of the fundamental freedoms guaranteed by the Treaty inevitably requires Member States to make some adjustments to their national systems of social security. It does not follow that this would undermine their sovereign powers in this field. It is sufficient in this regard to look to the adjustments which they have had to make to their social security legislation in order to comply with Regulation No 1408/71, in particular with the conditions laid down in Article 69 thereof regarding the payment of unemployment benefit to workers residing in the territory of other Member States when no national system provided for the grant of such benefits to unemployed persons registered with an employment agency in another Member State.

Second, as has already been made clear in paragraph 39 above, a medical service does not cease to be a provision of services because it is paid for by a national health service or by a system providing benefits in kind. The Court has, in particular, held that a medical service provided in one Member State and paid for by the patient cannot cease to fall within the scope of the freedom to provide services guaranteed by the Treaty merely because reimbursement of the costs of the treatment involved is applied for under another Member State's sickness insurance legislation which is essentially of the type which provides for benefits in kind (*Smits and Peerbooms* , paragraph 55). The requirement for prior authorisation where a person is subsequently to be reimbursed for the costs of that treatment is precisely what constitutes, as has already been stated in paragraph 44 above, the barrier to freedom to provide services, that is to say, to a patient's ability to go to the medical service provider of his choice in a Member State other than that of affiliation. There is thus no need, from the perspective of freedom to provide services, to draw a distinction by reference to whether the patient pays the costs incurred and subsequently applies for reimbursement thereof or whether the sickness fund or the national budget pays the provider directly.

It is in the light of those observations that it is appropriate to determine whether removal of the requirement for sickness insurance funds to grant prior authorisation for non-hospital health care provided in a Member State other than that of affiliation, is such as to call in question the essential characteristics of the system of access to health care in the Netherlands.

First, when applying Regulation No 1408/71, those Member States which have established a system providing benefits in kind, or even a national health service, must provide mechanisms for ex post facto reimbursement in respect of care provided in a Member State other than the competent State. That is the case, for example, where it has not been possible to complete the formalities during the relevant person's stay in that State (see Article 34 of Regulation (EEC) No 574/72 of the Council of 21 March 1972 fixing the procedure for implementing Regulation No 1408/71) or where the competent State has authorised access to treatment abroad in accordance with Article 22(1)(c) of Regulation No 1408/71.

106

Second, as has already been stated in paragraph 98 above, insured persons who go without prior authorisation to a Member State other than the one in which their sickness fund is established to receive treatment there can claim reimbursement of the cost of the treatment received only within the limits of the cover provided by the sickness insurance scheme of the Member State of affiliation. Thus, in the present case, it is apparent from the documents before the Court that, in relation to the EUR 3 806.35 paid by Ms Müller-Fauré to a provider established in Germany, the Zwijsendrecht Fund would in any event, given the extent of the insurance cover provided by the Fund, contribute only up to a maximum amount of EUR 221.03. Likewise, the conditions on which benefits are granted, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons, remain enforceable where treatment is provided in a Member State other than that of affiliation. That is particularly so in the case of the requirement that a general practitioner should be consulted prior to consulting a specialist.

107

Third, nothing precludes a competent Member State with a benefits in kind system from fixing the amounts of reimbursement which patients who have received care in another Member State can claim, provided that those amounts are based on objective, non-discriminatory and transparent criteria.

108

Consequently, the evidence and arguments submitted to the Court do not show that removal of the requirement that sickness insurance funds grant prior authorisation to their insured to enable them to receive health care, in particular other than in a hospital, provided in a Member State other than that of affiliation would undermine the essential characteristics of the Netherlands sickness insurance scheme.

109

In the light of all the foregoing considerations, the answer to the questions must be that:

—

Articles 59 and 60 of the Treaty must be interpreted as not precluding legislation of a Member State, such as that at issue in the main proceedings, which (i) makes the assumption of the costs of hospital care provided in a Member State other than that in which the insured person's sickness fund is established, by a provider with which that fund has not concluded an agreement, conditional upon prior authorisation by the fund and (ii) makes the grant of that authorisation subject to the condition that such action is necessary for the insured person's health care. However, authorisation may be refused on that ground only if treatment which is the same or equally effective for the patient can be obtained without undue delay in an establishment which has concluded an agreement with the fund;

—

by contrast, Articles 59 and 60 of the Treaty do preclude the same legislation in so far as it makes the assumption of the costs of non-hospital care provided in another Member State by a person or establishment with whom or which the insured person's sickness fund has not concluded an agreement conditional upon prior authorisation by the fund, even when the national legislation concerned sets up a system of benefits in kind under which insured persons are entitled not to reimbursement of costs incurred for medical treatment, but to the treatment itself which is provided free of charge.

2.4.3. Costs

110

The costs incurred by the Netherlands, Belgian, Danish, German, Spanish, Irish, Italian, Finnish, Swedish, United Kingdom, Icelandic and Norwegian Governments and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the actions pending before the national court, the decision on costs is a matter for that court.

2.4.4. The Court's decision

On those grounds, THE COURT, in answer to the questions referred to it by the Centrale Raad van Beroep by order of 6 October 1999, hereby rules:

—

Article 59¹¹ of the EC Treaty (now, after amendment, Article 49 EC) and Article 60¹² of the EC Treaty (now Article 50 EC) must be interpreted as not precluding legislation of a Member State, such as that at issue in the main proceedings, which (i) makes the assumption of the costs of hospital care provided in a Member State other than that in which the insured person's sickness fund is established, by a provider with which that fund has not concluded an agreement, conditional upon prior authorisation by the fund and (ii) makes the grant of that authorisation subject to the condition that such action is necessary for the insured person's health care. However, authorisation may be refused on that ground only if treatment which is the same or equally effective for the patient can be obtained without undue delay in an establishment which has concluded an agreement with the fund;

—

by contrast, Articles 59¹¹ and 60¹² of the Treaty do preclude the same legislation in so far as it makes the assumption of the costs of non-hospital care provided in another Member State by a person or establishment with whom or which the insured person's sickness fund has not concluded an agreement conditional upon prior authorisation by the fund, even when the national legislation concerned sets up a system of benefits in kind under which insured persons are entitled not to reimbursement of costs incurred for medical treatment, but to the treatment itself which is provided free of charge.

2.5. European Commission v French Republic¹⁰

Failure of a Member State to fulfil obligations – Article 49 EC – Social security – Medical treatment proposed in another Member State and requiring the use of major medical equipment – Requirement of prior authorisation – Planned treatment provided in another Member State – Difference in the levels of cover in force in the Member State of affiliation and in the Member State of stay, respectively – Insured person’s right to assistance by the competent institution to supplement that of the institution of the Member State of stay

2.5.1. Judgment

1 By its application, the European Commission of the European Communities asks the Court to declare that, by making, pursuant to Article R. 332-4 of the Social Security Code, subject to the grant of prior authorisation reimbursement for medical services available at a general practitioner’s surgery and requiring the use of major medical equipment listed in Article R. 712-2-II of the Public Health Code (now Article R. 6122-26 of that code); on the one hand, and on the other by failing to provide, in Article R. 332-4, or in any other provision of French law, for it to be possible for a patient, insured under the French social security system, to be granted additional reimbursement in the circumstances set out in paragraph 53 of the judgment of 12 July 2001 in Case C 368/98 Vanbraekel and Others [2001] ECR I 5363, the French Republic has failed to fulfil its obligations under Article 49 EC¹.

2.5.2. Legal context

The relevant provisions of European Union law

2 Under Article 22(1)² of Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their

¹⁰ Judgment Of The Court (Grand Chamber) 5 October 2010 In Case C 512/08, European Commission v French Republic

families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996 (OJ 1997 L 28, p. 1), as most recently amended by Regulation (EC) No 1992/2006 of the European Parliament and of the Council of 18 December 2006 (OJ 2006 L 392, p. 1, 'Regulation No 1408/71'):

'An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:

(a) whose condition requires benefits in kind which become necessary on medical grounds during a stay in the territory of another Member State, taking into account the nature of the benefits and the expected length of the stay; or

...

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition,

shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay ... in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

...'

Relevant provisions of national law

The Social Security Code

3 Responsibility for payment of medical treatment for persons insured under the French system provided outside France is governed, in particular, by Articles R. 332 3 and R. 332 4 of the Social Security Code, which were introduced into that code by Decree No 2005-386 of 19 April 2005 on responsibility for payment for treatment received outside France and amending the Social Security Code (second part: decrees in the Council of State) (JORF of 27 April 2005, p. 7321).

4 Those articles of the Social Security Code provide:

‘Article R. 332-3

Health insurance funds shall reimburse the cost of treatment given to insured persons and to those entitled under them in a Member State of the European Union or party to the Agreement on the European Economic Area, on the same conditions as if the treatment had been received in France, subject to the proviso that the amount reimbursed may not exceed the total sum paid out by the insured person and subject to the adjustments provided by Articles R. 332-4 to R. 332-6.

Article R. 332-4

Except in the case of unforeseen treatment, only on prior authorisation may health insurance funds reimburse the cost of hospital treatment or treatment requiring the use of major medical equipment referred to at section II of Article R. 712-2 of the public health code given to insured persons and to those entitled under them in another Member State of the European Union or State party to the Agreement on the European Economic Area and appropriate to their condition.

That authorisation referred to may be refused only if one of the following conditions applies:

- 1 The proposed treatment is not one of those in respect of which the French rules provide for responsibility for its payment;
- 2 Treatment that is identical or equally effective can be obtained in good time in France, taking into account the patient’s condition and the likely development of his illness.

The insured person shall send his request for authorisation to the fund to which he is affiliated. The decision shall be taken by the medical examination board. It must be notified within a period compatible with the degree of urgency and availability of the treatment proposed and at the latest two weeks after receipt of the request. If no reply has been given at the end of that period, authorisation shall be deemed to have been granted.

Decisions to refuse authorisation shall state the reasons and shall be actionable on the conditions of general law before the court competent to hear social security cases. Nevertheless, when challenges to those decisions relate to the assessment of the patient’s condition made by the medical officer, to the appropriateness to the patient’s condition of the treatment proposed or to whether the same or an equally effective treatment is available in

France they shall be subject to a medical report on the conditions laid down in Chapter I of Title IV of Book I of this Code.’

5 The application of Decree No 2005-386 was the subject of Circular DSS/DACI/2005/235 of 19 May 2005 (‘the circular of 19 May 2005’), which contains the following statements:

‘Decree No 2005-386 ... completes the integration into national law of Community case-law relating to freedom to provide services and the free movement of goods in the area of medical care.

...

It determines the conditions for payment for treatment received abroad depending on the geographical area in which it was provided: Article 3 creates four new articles (R. 332-3, R. 332-4, R. 332-5 and R. 332-6) particular to treatment received in the European Union European Economic Area (the EU EEA).

...

II – Responsibility for payment for treatment received in the EU-EEA (Articles R. 332-3, R. 332-4, R. 332-5, R. 332-6)

Those four new articles specifically concern treatment received in the EU-EEA.

They consist of one article of general application affirming the principle of responsibility for payment for treatment received abroad and three articles adapting to particular situations.

...

B – Particular adaptations (Articles R. 332-4, R. 332-5 and R. 332-6)

Articles R. 332-4, R. 332-5 and R. 332-6 supplement Article R. 332-3, making certain adaptations to the principle laid down by that article in the following situations:

1 – Hospital treatment (Article R. 332 4)

– Article R. 332 4 deals with payment for the hospital treatment and the use of major medical equipment – MRI, PET-SCAN type etc. – listed in part II of Article R. 712 2 of the

Public Health Code ..., to which access may be had outside hospital at a general practitioner's surgery.

– That article does not apply to unforeseen treatment provided during a temporary stay (undertaken for business, family, tourism reasons etc.), responsibility for payment of which must be taken on the basis of Regulations Nos 1408/71 and 574/72 coordinating social security schemes in Europe, whether or not the insured person has produced a Community document in the State of treatment certifying his entitlement.

– Responsibility for payment for hospital treatment and the use of major medical equipment remains subject to the issuing of prior authorisation by the organ to which the person seeking to obtain those services in the EU EEA is affiliated.

That restriction has been allowed by [the Court of Justice of the European Communities], hospital treatment such as use of major medical equipment being capable, in the case of absolute freedom of access outside national territory, of undermining the organisation of the health system or the financial balance of the social security system of the State in which the insured person is affiliated.

In practice, however, health insurance bodies must not systematically refuse to issue prior authorisation for that kind of service proposed in another Member State.

In point of fact, prior authorisation may not be refused if the treatment proposed is reimbursable in France and if that treatment, or treatment having equivalent effect, are not available in good time, that is to say, within a period compatible with the patient's condition and with the probable development of his illness.

...

– Reasons must, of course, be given for refusals. When prior authorisation is refused, the [Court of Justice] does not permit the decision not to inform the insured person specifically of the reasons why he is not allowed to obtain treatment in another Member State. Thus, the mere statement, without further details, that there exists treatment which could be provided in good time in France, cannot be considered sufficient having regard to the [Court of Justice's] requirements. If, therefore, the applicant is told that treatment having equivalent effect can be provided in France, the refusal must include the facts supporting that assertion. In particular, it

may be useful to provide a list of establishments or professionals capable of administering to the patient the treatment needed within the period required.

– In regions in which the supply of specific hospital treatment or major medical equipment is inadequate, the health insurance bodies must systematically authorise payment for certain categories of treatment proposed in the EU EEA. Another circular will soon specify the regions and the kinds of hospital treatment or major medical equipment concerned by that provision.’

6 The circular of 19 May 2005 was amended and added to by Circular DSS/DACI/2008/242 of 21 July 2008 on responsibility for payment for treatment received in another Member State of the EU EEA (‘the circular of 21 May 2008’) which states, in particular, that ‘even if the [Vanbraekel] decision is henceforth to be applied by the funds’, the latter face many real difficulties. In that circular, the competent minister ‘nevertheless calls on the competent authorities to continue to do what is necessary in order to give effect to the differential additional amount, when requested by the insured person’.

The Public Health Code

7 Article L. 6121 1 of the Public Health Code provides:

‘The object of the health organisation plan is to provide for and create the developments needed for the supply of preventive, curative and palliative care in order to satisfy physical and mental health needs. It also includes the supply of care to cover pregnant women and the newborn.

The health organisation plan is designed to give rise to alterations and additions in the supply of care, and to cooperation also, in particular among health establishments. It shall fix objectives for the purpose of improving the quality, accessibility and efficiency of the health organisation.

It shall take account of the linkage of the resources of health establishments to general practice and the social and medico-social sector and also of the supply of care in adjacent regions and cross-border territories.

A decree of the minister for health shall fix the list of subject areas, care activities and major equipment that must compulsorily be included in a health organisation plan.

The health organisation plan shall be drawn up on the basis of an assessment of the population's health needs and of their development, taking into account demographic and epidemiological data and progress in medical techniques and after a quantitative and qualitative analysis of the current supply of care.

The health organisation plan may be revised in whole or in part at any time. It shall be re-examined at least every five years.'

8 Article L. 6122-1 of that code states:

'Projects relating to the creation of any healthcare establishment, the creation, conversion and merging of healthcare services, including alternatives to hospitalisation, and the installation of major medical equipment shall require prior authorisation by the regional hospital authority.

The list of healthcare services and major medical equipment subject to authorisation shall be laid down by decree of the Council of State.'

9 Article R. 6122-26 of the Public Health Code, reproducing Article R. 712-2-II of that code, provides:

'The major medical equipment listed below shall be subject to the prior authorisation provided for in Article L. 6122 1:

1. Scintillation camera with or without positron emission coincidence detector, emission tomography or positron camera;
2. Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use;
3. Medical scanner;
4. Hyperbaric chamber;
5. Cyclotron for medical use.'

The pre-litigation procedure

10 In response to a complaint, on 18 October 2006 the Commission sent the French Republic a letter of formal notice in which it alleged that Article R. 332 4 of the Social Security Code was incompatible with Article 49 EC, as interpreted by the Court. Three specific complaints were set out in support of that allegation, viz.:

- the requirement of prior authorisation for reimbursement of certain non-hospital treatment provided in another Member State;
- the lack of any provision requiring acknowledgment of receipt to be sent to persons seeking prior authorisation of payment for hospital treatment given in another Member State;
- the lack of any provision enabling a person insured under the French system to receive an additional reimbursement in the circumstances laid down in paragraph 53 of *Vanbraekel and Others*.

11 Paragraph 53 of that judgment states:

‘ ...

Article [49 EC] is to be interpreted as meaning that, if the reimbursement of costs incurred on hospital services provided in a Member State of stay, calculated under the rules in force in that State, is less than the amount which application of the legislation in force in the Member State of registration would afford to a person receiving hospital treatment in that State, additional reimbursement covering that difference must be granted to the insured person by the competent institution.’

12 By letter of 1 March 2007, the French Republic answered that letter of formal notice.

13 With regard to the first complaint, that Member State made known its intention to amend Article R. 332 4 of the Social Security Code to the effect demanded by the Commission and, pending that amendment, to issue a circular designed to ensure compliance with the requirements imposed by European Union law.

14 The French Republic challenged the substance of the second complaint, arguing that the French social security bodies are bound, being administrative authorities to which the national legislation on the rights of citizens in their relations with the administration applies, to issue to applicants for prior authorisation for payment for treatment proposed in another Member State acknowledgement of receipt mentioning, in particular, the date of receipt of the request and the period at the end of which the latter may be deemed to have been approved.

15 With regard to the third complaint, the French Republic maintains that the circumstance alleged by the Commission was ascribable to uncertainty as to the precise implications of *Vanbraekel and Others*, which was to be discussed by the Member States in the Council of the

European Union. Referring to Circular DSS/DACI/2003/286 of 16 June 2003 on the application of the rules for ensuring access to treatment for persons insured under a French social security scheme within the European Union and the European Economic Area ('the circular of 16 June 2003'), that Member State added, however, that it was in no way its intention to conceal from those insured persons the existence of the right to additional reimbursement laid down in that judgment. Furthermore, it stressed that French administrative authorities afforded that judgment a broad meaning, in accordance with the case-law of the Cour de cassation.

16 In the light of that reply, the Commission sent to the French Republic a reasoned opinion on 23 October 2007 in which it stated, first, that it withdrew the second complaint set out in its letter of formal notice and, secondly, that it maintained its two other complaints and invited that Member State to take the measures necessary to comply with that reasoned opinion within a period of two months from its receipt.

17 In its answer to that reasoned opinion, dated 13 December 2007, the French Republic mentioned the forthcoming adoption of a decree intended to adapt Article R. 332-4 of the Social Security Code to the requirements of European Union law and to add to Articles R. 332-2 to R. 322-6 of that code with regard to the right to an additional reimbursement provided for by Vanbraekel. It stated also that a circular to replace that of 19 May 2005 was in the process of finalisation.

18 In response to a reminder sent to it by the Commission on 10 June 2008, the French Republic communicated to the latter the circular of 21 July 2008. In addition, it mentioned various technical difficulties delaying the definitive adoption of the reform of the Social Security Code announced in its reply to the reasoned opinion.

19 Being dissatisfied with those explanations, the Commission decided to bring this action.

The action

The first head of claim, concerning the requirement of prior authorisation in respect of responsibility for payment for non-hospital treatment proposed in another Member State and requiring the use of major medical equipment

Arguments of the parties

20 The Commission argues that the requirement of prior authorisation for the purpose of responsibility for payment by the competent institution for treatment available at a general practitioner's surgery in another Member State and requiring the use of major medical equipment constitutes a restriction of the freedom to provide services.

21 It argues that, while it is true that planning objectives may justify such a requirement for the purpose of social cover for hospital treatment proposed in another Member State, that requirement is not, by contrast, justified in the sphere of non-hospital treatment, as held by the Court in Case C 158/96 Kohll [1998] ECR I 1931 and Case C 385/99 Müller-Fauré and van Riet [2003] ECR I 4509.

22 Taking the view, in the light of paragraph 75 of Müller-Fauré and van Riet, that the characteristic feature of hospital treatment is that it cannot be offered except within a hospital setting, the Commission maintains that, so far as treatment requiring the use of major medical equipment available outside hospital infrastructures is concerned, there is no objective justification for maintaining a requirement of prior authorisation.

23 It adds that several circumstances, such as the application of limitations of cover and of conditions for the grant of social security benefits in force in the Member State of affiliation, linguistic and geographic factors, the lack of information about the nature of the treatment available in the other Member States or yet the living expenses inherent in staying in another Member State for medical purposes, permit the inference that to do away with the requirement of prior authorisation in the sphere of treatment involving the use of major medical equipment would not lead to a huge exodus of insured persons from the French system to other Member States and would not endanger the financial balance of the national social security system.

24 The French Republic, supported by the Kingdom of Spain, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland, challenges the merits of that first head of claim.

25 Those Member States argue that the Court's case-law allowing, for the sake of overall planning objectives, an authorisation decision before the competent institution may become liable to pay for hospital treatment given in another Member State (see Müller-Fauré and van Riet, paragraphs 67 and 77 to 80, and Case C 372/04 Watts [2006] ECR I 4325, paragraphs 104 and 108 to 111) can be transposed to the context of medical treatment calling for the use

of major medical equipment outside hospital infrastructures, having regard to the very high costs of that equipment and to its impact on the budget of social security systems.

Findings of the Court

26 A preliminary point to note is that under Article R. 332 4 of the Social Security Code the prior authorisation requirement does not apply in the case known as ‘unforeseen treatment’, that is to say, treatment the need for which arises while the insured person is temporarily staying in another Member State. As is apparent from the Commission’s pleadings, the first head of claim is thus confined to the case of what is known as ‘planned’ treatment, that is to say, treatment that the insured person intends to obtain in another Member State.

27 It is moreover to be stressed that that head of claim does not relate to any alleged failure to comply with Article 22(1)(c) of Regulation No 1408/71, under which the competent institution is, except in special situations relating, in particular, to the insured person’s state of health or to the urgency of the treatment needed (see, to that effect, Case C 173/09 Elchinov [2010] ECR I 0000, paragraphs 45 and 51), entitled to make subject to prior authorisation responsibility for the payment, on its own account, for treatment proposed in another Member State, by the institution of the Member State of stay depending on the rules governing cover in that latter Member State.

28 The first head of claim, based on Article 49 EC, seeks, therefore, to allege that it is not compatible with that article to require prior authorisation for the purpose of responsibility for payment by the competent institution, in accordance with the rules governing cover in force in the Member State of affiliation, for treatment planned in a non-hospital setting in another Member State and involving the use of major medical equipment.

29 Those preliminary points having been made, it is to be emphasised that, in the absence of harmonisation at European Union level, it is for the legislation of each Member State to determine, in particular, the conditions for the grant of social security benefits covering treatment such as that concerned by the first head of claim. The fact remains, nevertheless, that when exercising that power the Member States must comply with European Union law, in particular, with the provisions on freedom to provide services (see, to that effect, Case C 211/08 Commission v Spain [2010] ECR I 0000, paragraph 53 and the case-law cited).

30 According to settled case-law, medical services supplied for consideration fall within the scope of those provisions, there being no need to distinguish between care provided in a hospital environment and care provided outside such an environment (see, in particular, Case C 8/02 Leichtle [2004] ECR I 2641, paragraph 28; Watts, paragraph 86; and Case C 444/05 Stamatelaki [2007] ECR I 3185, paragraph 19).

31 It has also repeatedly been held that the freedom to provide services includes the freedom for the recipients of services, including persons in need of medical treatment, to go to another Member State in order to receive those services there without being hampered by restrictions (see, in particular, to that effect, Watts, paragraph 87, and *Commission v Spain*, paragraph 49).

32 In the circumstances of the case, the prior authorisation to which the national legislation makes subject responsibility for payment by the competent institution, in accordance with the rules governing cover in force in the Member State to which it belongs, for treatment planned in another Member State and involving the use of major medical equipment outside hospital infrastructures is capable of deterring, or even preventing, persons insured under the French system from applying to providers of medical services established in such another Member State in order to obtain the treatment in question. It constitutes, therefore, for both the insured persons and the providers of those services, a restriction of the freedom to provide services (see, to that effect, *Müller-Fauré and van Riet*, paragraphs 44 and 103, and Watts, paragraph 98).

33 With regard to objective justification of such a restriction, it is to be borne in mind that the Court has on several occasions held that planning requirements relating, on the one hand, to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned and, on the other, to the wish to control costs and avoid, so far as possible, any waste of financial, technical and human resources may justify the requirement of prior authorisation for financial responsibility on the part of the competent institution for treatment proposed in another Member State (see, to that effect, Case C 157/99 *Smits and Peerbooms* [2001] ECR I 5473, paragraphs 76 to 81; *Müller-Fauré and van Riet*, paragraphs 76 to 81, and Watts, paragraphs 108 to 110).

34 Such considerations, expressed in respect of medical services provided in a hospital setting, can be reproduced with regard to medical services involving the use of major medical

equipment, even if those services, like those at issue in the Commission's first head of claim, are supplied outside such a setting.

35 In this connection, it is true that in paragraph 75 of *Müller-Fauré and van Riet*, after emphasising how difficult it is to distinguish 'hospital services' from 'non hospital services', the Court pointed out that services provided in a hospital environment but that could also be provided by a practitioner in his surgery or in a health centre could, for that reason, be placed on the same footing as non-hospital services.

36 Contrary to the position defended by the Commission, it cannot, however, be deduced from that passage in that judgment that the fact that treatment involving the use of major medical equipment may be provided outside a hospital setting renders considerations relating to planning requirements quite irrelevant.

37 Regardless of the setting, hospital or otherwise, in which it is intended to be installed and used, it must be possible for the major medical equipment exhaustively listed in Article R. 6122 26 of the Public Health Code to be the subject of planning policy, such as that defined by the national legislation at issue, with particular regard to quantity and geographical distribution, in order to help ensure throughout national territory a rationalised, stable, balanced and accessible supply of up-to-date treatment, and also to avoid, so far as possible, any waste of financial, technical and human resources.

38 Such waste would be all the more damaging because the conditions for the installation, operation and use of the five types of equipment exhaustively listed in Article R. 6122 26 of the Public Health Code are especially onerous, while the budgetary resources which the Member States are able to make available for up to-date treatment and, in particular, the subsidising of such equipment, are not unlimited, whatever the mode of funding applied (see, by analogy, with regard to medicinal products, *Case C 531/06 Commission v Italy* [2009] ECR I 4103, paragraph 57, and *Joined Cases C 171/07 and C 172/07 Apothekerkammer des Saarlandes and Others* [2009] ECR I 4171, paragraph 33).

39 Without being contradicted by the Commission, the French Republic and the United Kingdom, taking as an example positron emission tomography, used in the detection and treatment of cancer, have emphasised that that equipment represents costs of hundreds of thousands, even millions, of euro, in both its purchase and in its installation and use.

40 If persons insured under the French system could, freely and in any circumstances, obtain at the expense of the competent institution, from service providers established in other Member States, treatment involving the use of major medical equipment corresponding to that listed exhaustively in the Public Health Code, the planning endeavours of the national authorities and the financial balance of the supply of up-to-date treatment would as a result be jeopardised.

41 That possibility could lead to under-use of the major medical equipment installed in the Member State of affiliation and subsidised by it or yet to a disproportionate burden on that Member State's social security budget.

42 Having regard to those dangers to the organisation of public health policy and to the financial balance of the social security system, the requirement, except in special circumstances such as those referred to at paragraph 27 above, of prior authorisation by the competent institution in order for the latter to be responsible for payment, according to the rules governing cover in force in the Member State to which it belongs, for treatment planned in a non-hospital setting in another Member State and involving the use of major medical equipment mentioned in Article R. 6122 26 of the Public Health Code, would appear, as European Union law now stands, to be a justified restriction (see, by analogy, Müller-Fauré and van Riet, paragraph 81).

43 It is to be borne in mind also that, according to settled case-law, a prior authorisation scheme must be based on objective, non-discriminatory criteria known in advance, in such a way as to circumscribe the exercise of the authorities' discretion so that it is not used arbitrarily. Such an authorisation system must, furthermore, be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time, and it must, in addition, be possible for refusals to grant authorisation to be challenged in judicial proceedings (see, to that effect, Smits and Peerbooms, paragraph 90; Müller-Fauré and van Riet, paragraph 85; and Watts, paragraph 116).

44 In this case, the Commission has put forward no specific criticism with regard to the procedural and substantive rules regulating the prior authorisation measure at issue, in particular to the exhaustive conditions on which that authorisation may, pursuant to Article R. 332 4 of the Social Security Code, be refused.

45 In those circumstances, the allegation in the first head of claim of failure to fulfil obligations under Article 49 EC is not well founded. That head must, therefore, be rejected.

The second head of claim, relating to the lack of any provision of French law providing for persons insured under the French system to be entitled to an additional reimbursement on the conditions laid down in paragraph 53 of *Vanbraekel and Others*

Arguments of the parties

46 The Commission maintains that, given the lack in French law of any provision making possible an additional reimbursement on the conditions laid down in paragraph 53 of *Vanbraekel and Others*, persons insured under the French system cannot be entitled to such reimbursement. The solution flowing from that judgment cannot, therefore, be considered to have been given effect in French law.

47 The Commission goes on to say that mere administrative practices cannot be regarded as constituting the proper fulfilment of obligations under the EC Treaty. Moreover, the circulars of 16 June 2003, 19 May 2005 and 21 July 2008, addressed to the French social security bodies by the Ministry of Health, are evidence of ambiguity existing in the French legislation apt to give rise to misunderstanding and, consequently, to make it impossible for persons insured under the French system actually to exercise the right stemming from *Vanbraekel and Others*.

48 The Commission maintains also that the cases, mentioned by the French Republic, of insured persons being able to receive additional reimbursement in accordance with that judgment, or being about to receive such reimbursement, are not enough to establish actual observance of the rights of the persons insured under the French system as a whole.

49 The French Republic, supported at the hearing by the United Kingdom, argues that, having regard to the direct effect of Article 49 EC and to the national courts' obligation to protect the rights conferred on individuals by that article, acquisition under that article of entitlement to an additional reimbursement on the conditions set out in paragraph 53 of *Vanbraekel and Others* does not call for any specific implementing measure in domestic legislation. It adds that Article R. 332 3 of the Social Security Code covers, in particular, the hypothesis mentioned in paragraph 53. The solution laid down in that judgment has, moreover, actually been applied by the Cour de cassation in a judgment of 28 March 2002.

50 The French Republic asserts that, in those circumstances, a circular intended to remind the competent bodies of that solution is enough to ensure its implementation. The circulars adopted to that end were, furthermore, followed by a practical effect, as shown by the establishment in the course of the year 2006 of a Centre national des soins à l'étranger (national centre for healthcare abroad) responsible for managing, in particular, in accordance with that solution, applications for reimbursement in respect of treatment provided in another Member State or in a non-member country to persons insured under the French system.

Findings of the Court

51 In paragraph 53 of *Vanbraekel and Others*, the Court, in connection with planned treatment provided in another Member State for which the authorisation necessary if the competent institution were to be responsible for its payment had been improperly refused, interpreted Article 49 EC as meaning that, if the reimbursement of costs incurred on hospital services provided in the Member State of stay, calculated under the rules in force in that State, is less than the amount which application of the legislation in force in the Member State of affiliation would afford to a person receiving hospital treatment in that State, additional reimbursement covering that difference must be granted to the insured person by that institution.

52 As the Court later made clear, the insured person's right to such additional reimbursement falls within the limits of the costs actually incurred in the Member State of stay (see, to that effect, *Watts*, paragraphs 131 and 143).

53 It is to be emphasised here that Article 49 EC¹, as interpreted in paragraph 53 of *Vanbraekel and Others*, being a directly applicable provision of the Treaty, binds all the authorities of the Member States, including administrative and judicial, which are, therefore, obliged to observe it, and there is no need to adopt domestic implementing measures (see, to that effect, *Case 168/85 Commission v Italy* [1986] ECR 2945, paragraph 11 and *Case C 412/04 Commission v Italy* [2008] ECR I 619, paragraphs 67 and 68).

54 The right of individuals to rely on that article, as interpreted by the Court, before national courts is only a minimum guarantee and is not sufficient in itself to ensure the full and complete implementation of that provision (see, to that effect, *Case 72/85 Commission v Netherlands* [1986] ECR 1219, paragraph 20; *Case 168/85 Commission v Italy*, paragraph 11;

and Joined Cases C 46/93 and C 48/93 *Brasserie du pêcheur and Factortame* [1996] ECR I 1029, paragraph 20).

55 It is necessary, in addition, that the legal order of the Member State in question should not give rise to an ambiguous situation that might keep the individuals concerned in a state of uncertainty as to the possibility of relying on that provision of European Union law with direct effect (see, to that effect, Case 168/85 *Commission v Italy*, paragraph 11; Case C 120/88 *Commission v Italy* [1991] ECR I 621, paragraph 9; and Case C 119/89 *Commission v Spain* [1991] ECR I 641, paragraph 8).

56 In that regard, it is, however, to be borne in mind that, in proceedings under Article 226 EC for failure to fulfil obligations, it is for the Commission to prove the alleged failure by placing before the Court all the information needed to enable the Court to establish that the obligation has not been fulfilled (see, in particular, Case C 160/08 *Commission v Germany* [2010] ECR I 0000, paragraph 116 and the case-law cited).

57 In this case, it is to be noted, first, that Article R. 332 3 of the Social Security Code lays down, as is confirmed by the circular of 19 May 2005, the general principle that the competent French institution is to be responsible for the costs of treatment provided to a person insured under the French system in another Member State or in a State party to the Agreement on the European Economic Area ‘on the same conditions as if the treatment had been received in France’, and within the limits of the costs actually incurred by the person insured.

58 Its terms being so general, that provision covers entitlement to an additional reimbursement to be paid by the competent French institution in the situation set out in paragraph 53 of *Vanbraekel and Others*, of which, moreover, the Commission has taken formal note during the procedure before the Court.

59 That finding is not shaken by the ‘intended amendments to Articles R. 332 4 to R. 332 6’ of the Social Security Code referred to by Article R. 332 3 of that code, which relate to the requirement of prior authorisation for responsibility for payment for certain kinds of treatment provided in another Member State, to the opportunity offered to French social security bodies to conclude with healthcare establishments in another Member State or in a State party to the Agreement on the European Economic Area agreements defining the conditions of the stay of persons insured under the French system in such establishments and the detailed rules for

reimbursement in respect of the treatment provided therein, and to the conditions for reimbursement of the costs of analyses carried out by a medical biology laboratory established in another Member State or in a State party to the Agreement on the European Economic Area, respectively.

60 As the French Republic observed at the hearing, the Commission has not, in any event, identified any provision of French law that might impede the application of the solution laid down in paragraph 53 of *Vanbraekel and Others*.

61 Secondly, it is to be noted that the Commission has not, in the present case, mentioned any decisions made by national courts that led to denying the right stemming from Article 49 EC for persons insured under the French system in the situation referred to in paragraph 53 of *Vanbraekel and Others*.

62 On the contrary, the applicant institution has taken note, during the procedure before the Court, of the judgment of the Cour de cassation of 28 March 2002, in which that court held that ‘it follows from Article 49 [EC], as interpreted by the Court of Justice [in *Vanbraekel and Others*], that the fund in the place of affiliation is obliged to take responsibility for medical costs incurred by its insured in another Member State according to the tariff applicable to the same treatment provided in France, with the result that if the reimbursement made in accordance with the rules in force in the State of stay is less than the amount which would have resulted from application of the legislation in force in the Member State of affiliation, additional reimbursement covering that difference must be granted to the insured person by the competent institution’.

63 Thirdly, the Commission has not established the existence of any administrative practice whatsoever that deprives persons insured under the French system of the right to additional reimbursement in the situation referred to in paragraph 53 of *Vanbraekel and Others*.

64 On the contrary, in its reasoned opinion it noted the statements in the French Republic’s answer to the letter of formal notice to the effect that, in accordance with the judgment of the Cour de cassation of 28 March 2002 mentioned in paragraph 62 above, French social security bodies give broad application to the solution laid down in *Vanbraekel and Others*.

65 With regard to the circulars of 16 June 2003, 19 May 2005 and 21 July 2008 issued by the competent ministerial authorities, their object was not, contrary to the Commission’s

argument before the Court, to clarify an allegedly ambiguous situation. Nor were they intended to put an end to allegedly divergent practices followed by the French social security bodies, some of them leading to non application of the solution laid down in *Vanbraekel and Others*.

66 As the Commission itself stated in its reasoned opinion, the circular of 16 June 2003 included, for the bodies concerned, a simple description of the solution provided by that judgment. The purpose of the circular of 19 May 2005, as is apparent from the passages from it in the file before the Court, was to explain the full significance of Articles R. 332 3 to R. 332 6 of the Social Security Code, introduced by Decree No 2005 386. For its part, the circular of 21 July 2008 contains the statement that that solution is ‘henceforth to be applied by the funds’ and calls on the latter to ‘continue to do what is necessary in order to give effect to the differential additional amount’, despite the real difficulties the funds had encountered in calculating that additional amount, on account, in particular, of the lack of any means of comparing the costs of the same treatment in France and in the other Member States, and of the slowness in cooperating of the national institutions concerned.

67 In the circumstances, while it is true that, in accordance with the settled case-law of the Court recalled by the Commission, mere administrative practices, by their nature alterable at will by the authorities, cannot, in the context of national legislation incompatible with European Union law, be regarded as constituting proper fulfilment of Treaty obligations (see Case C 197/96 *Commission v France* [1997] ECR I 1489, paragraph 14; Case C 358/98 *Commission v Italy* [2000] ECR I 1255, paragraph 17; and Case C 33/03 *Commission v United Kingdom* [2005] ECR I 1865, paragraph 25), the fact nevertheless remains that, in the circumstances of this case, the lack of any evidence of administrative practices contrary to European Union law bears out the finding that the French legislation, in particular Article R. 332 3 of the Social Security Code, does not give rise to a situation that deprives persons insured under the French system of the rights conferred by Article 49 EC, as interpreted in *Vanbraekel and Others*.

68 Fourthly, the Commission has not, in the instant case, set out any complaint concerning any alleged refusal by a French social security body to allow an insured person the right to an additional reimbursement in the situation referred to in paragraph 53 of *Vanbraekel and Others*. On the contrary, during the procedure before the Court the French Republic supplied several examples of cases of persons insured under the French system finding themselves in

the situation referred to in paragraph 53 of *Vanbraekel and Others* who had been, or were about to be, able to obtain an additional reimbursement in accordance with that judgment.

69 It follows from the foregoing considerations that the Commission has not established that the French legal order brings about a situation capable of depriving persons insured under the French system of the right to an additional reimbursement in the situation referred to in paragraph 53 of *Vanbraekel and Others*.

70 The second head of claim must, therefore, be rejected.

71 It follows that the action must be dismissed in its entirety.

2.5.3. Costs

71 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the French Republic has applied for costs to be awarded against the Commission and the latter has been unsuccessful, the Commission must be ordered to pay the costs. Under the first paragraph of Article 69(4) of those Rules, the Kingdom of Spain, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland, which have intervened in these proceedings, are to bear their own costs.

2.5.4. The Court's decision

On those grounds, the Court (Grand Chamber) hereby

1. Dismisses the action;
2. Orders the European Commission to pay the costs;
3. Orders the Kingdom of Spain, the Republic of Finland and the United Kingdom of Great Britain and Northern Ireland to bear their own costs.

3. Other significant cases

3.1 P. v S. and Cornwall County Council¹¹

3.1.1. Judgment

Grounds

1 By order of 11 January 1994, received at the Court on 13 January 1994, the Industrial Tribunal, Truro, referred to the Court for a preliminary ruling under Article 177¹⁶ of the EC Treaty two questions on the interpretation of Council Directive 76/207/EEC of 9 February 1976 on the implementation of the principle of equal treatment for men and women as regards access to employment, vocational training and promotion, and working conditions (OJ 1976 L 39, p. 40 hereinafter "the directive").

2 Those questions were raised in proceedings brought by P. against S. and Cornwall County Council.

3 P., the applicant in the main proceedings, used to work as a manager in an educational establishment operated at the material time by Cornwall County Council (hereinafter "the County Council"), the competent administrative authority for the area. In early April 1992, a year after being taken on, P. informed S., the Director of Studies, Chief Executive and Financial Director of the establishment, of the intention to undergo gender reassignment. This began with a "life test", a period during which P. dressed and behaved as a woman, followed by surgery to give P. the physical attributes of a woman.

¹¹ Judgment Of The Court 30 April 1996; In Case C-13/94, P. v S. and Cornwall County Council

4 At the beginning of September 1992, after undergoing minor surgical operations, P. was given three months' notice expiring on 31 December 1992. The final surgical operation was performed before the dismissal took effect, but after P. had been given notice.

5 P. brought an action against S. and the County Council before the Industrial Tribunal on the ground that she had been the victim of sex discrimination. S. and the County Council maintained that the reason for her dismissal was redundancy.

6 It appears from the order for reference that the true reason for the dismissal was P.' s proposal to undergo gender reassignment, although there actually was redundancy within the establishment.

7 The Industrial Tribunal found that such a situation was not covered by the Sex Discrimination Act 1975, inasmuch as it applies only to cases in which a man or woman is treated differently because he or she belongs to one or the other of the sexes. Under English law, P. is still deemed to be male. If P. had been female before her gender reassignment, the employer would still have dismissed her on account of that operation. However, the Industrial Tribunal was uncertain whether that situation fell within the scope of the directive.

8 According to Article 1(1), the purpose of the directive is to put into effect in the Member States the principle of equal treatment for men and women, in particular as regards access to employment, including promotion, and to vocational training, and as regards working conditions. Article 2(1) of the directive provides that the principle of equal treatment means that there is to be "no discrimination whatsoever on grounds of sex, either directly or indirectly".

9 Furthermore, the third recital in the preamble to the directive states that equal treatment for men and women constitutes one of the objectives of the Community, in so far as the harmonization of living and working conditions while maintaining their improvement is to be furthered.

10 Considering that there was doubt as to whether the scope of the directive is wider than that of the national legislation, the Industrial Tribunal decided to stay proceedings and refer the following questions to the Court for a preliminary ruling:

"(1) Having regard to the purpose of Directive No 76/207/EEC which is stated in Article 1 to put into effect the principle of equal treatment for men and women as regards access to

employment etc ... does the dismissal of a transsexual for a reason related to a gender reassignment constitute a breach of the Directive?

(2) Whether Article 3 of the Directive which refers to discrimination on grounds of sex prohibits treatment of an employee on the grounds of the employee's transsexual state."

11 Article 3 of the directive, to which the Industrial Tribunal refers, is concerned with application of the principle of equal treatment for men and women to access to employment.

12 A dismissal, such as is in issue in the main proceedings, must be considered in the light of Article 5(1) of the directive, which provides that:

"Application of the principle of equal treatment with regard to working conditions, including the conditions governing dismissal, means that men and women shall be guaranteed the same conditions without discrimination on grounds of sex."

13 The Industrial Tribunal's two questions, which may appropriately be considered together, must therefore be construed as asking whether, having regard to the purpose of the directive, Article 5(1) precludes dismissal of a transsexual for a reason related to his or her gender reassignment.

14 The United Kingdom and the Commission submit that to dismiss a person because he or she is a transsexual or because he or she has undergone a gender-reassignment operation does not constitute sex discrimination for the purposes of the directive.

15 In support of that argument, the United Kingdom points out in particular that it appears from the order for reference that the employer would also have dismissed P. if P. had previously been a woman and had undergone an operation to become a man.

16 The European Court of Human Rights has held that "the term 'transsexual' is usually applied to those who, whilst belonging physically to one sex, feel convinced that they belong to the other; they often seek to achieve a more integrated, unambiguous identity by undergoing medical treatment and surgical operations to adapt their physical characteristics to their psychological nature. Transsexuals who have been operated upon thus form a fairly well-defined and identifiable group" (judgment of 17 October 1986, in *Rees v United Kingdom*, paragraph 38, Series A, No 106).

17 The principle of equal treatment "for men and women" to which the directive refers in its title, preamble and provisions means, as Articles 2(1) and 3(1) in particular indicate, that there should be "no discrimination whatsoever on grounds of sex".

18 Thus, the directive is simply the expression, in the relevant field, of the principle of equality, which is one of the fundamental principles of Community law.

19 Moreover, as the Court has repeatedly held, the right not to be discriminated against on grounds of sex is one of the fundamental human rights whose observance the Court has a duty to ensure (see, to that effect, Case 149/77 Defrenne v Sabena [1978] ECR 1365, paragraphs 26 and 27, and Joined Cases 75/82 and 117/82 Razzouk and Beydoun v Commission [1984] ECR 1509, paragraph 16).

20 Accordingly, the scope of the directive cannot be confined simply to discrimination based on the fact that a person is of one or other sex. In view of its purpose and the nature of the rights which it seeks to safeguard, the scope of the directive is also such as to apply to discrimination arising, as in this case, from the gender reassignment of the person concerned.

21 Such discrimination is based, essentially if not exclusively, on the sex of the person concerned. Where a person is dismissed on the ground that he or she intends to undergo, or has undergone, gender reassignment, he or she is treated unfavourably by comparison with persons of the sex to which he or she was deemed to belong before undergoing gender reassignment.

22 To tolerate such discrimination would be tantamount, as regards such a person, to a failure to respect the dignity and freedom to which he or she is entitled, and which the Court has a duty to safeguard.

23 Dismissal of such a person must therefore be regarded as contrary to Article 5(1) of the directive, unless the dismissal could be justified under Article 2(2). There is, however, no material before the Court to suggest that this was so here.

24 It follows from the foregoing that the reply to the questions referred by the Industrial Tribunal must be that, in view of the objective pursued by the directive, Article 5(1) of the directive precludes dismissal of a transsexual for a reason related to a gender reassignment.

3.1.2. Costs

Decision on costs

25 The costs incurred by the United Kingdom and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

3.1.3. The Court's decision

On those grounds,

THE COURT,

in answer to the questions referred to it by the Industrial Tribunal, Truro, by order of 11 January 1994, hereby rules:

In view of the objective pursued by Council Directive 76/207/EEC of 9 February 1976 on the implementation of the principle of equal treatment for men and women as regards access to employment, vocational training and promotion, and working conditions, Article 5(1) of the directive precludes dismissal of a transsexual for a reason related to a gender reassignment.

3.2. Oliver Brüstle v Greenpeace e.V.¹²

Directive 98/44/EC – Article 6(2)(c) – Legal protection of biotechnological inventions – Extraction of precursor cells from human embryonic stem cells – Patentability – Exclusion of

¹² Judgment Of The Court (Grand Chamber) 18 October 2011; In Case C-34/10, Oliver Brüstle v Greenpeace e.V.

‘uses of human embryos for industrial or commercial purposes’ – Concepts of ‘human embryo’ and ‘use for industrial or commercial purposes’

3.2.1. Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13; ‘the Directive’).

2 The reference has been made in proceedings brought by Greenpeace e.V. (‘Greenpeace’) seeking annulment of the German patent held by Mr Brüstle, which relates to neural precursor cells and the processes for their production from embryonic stem cells and their use for therapeutic purposes.

3.2.2. Legal context

Agreements binding the European Union and/or the Member States

3 Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, which constitutes Annex 1 C to the Agreement establishing the World Trade Organisation (WTO), signed in Marrakech on 15 April 1994, approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1), states that:

‘1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public (public policy) or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.'

4 Article 52(1)²³ of the Convention on the Grant of European Patents, signed at Munich on 5 October 1973 ('the CGEP'), to which the European Union is not party, but of which the Member States are signatories, reads as follows:

'European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.'

5 Article 53²⁴ of the CGEP states:

'European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.'

3.2.3. European Union legislation

6 The preamble to the Directive states as follows:

(2) Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

(3) Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;

(5) Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States; whereas such differences could create barriers to trade and hence impede the proper functioning of the internal market;

(6) Whereas such differences could well become greater as Member States adopt new and different legislation and administrative practices, or whereas national case-law interpreting such legislation develops differently;

(7) Whereas uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market;

(14) Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;

(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;

(17) Whereas significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the human body and/or otherwise produced, such medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system;

(20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the

structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;

(21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;

(37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against ordre public or morality must also be stressed in this Directive;

(38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide referring courts and patent offices with a general guide to interpreting the reference to ordre public and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability;

(39) Whereas ordre public and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention;

(42) Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;

(43) Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they

result from the constitutional traditions common to the Member States, as general principles of Community law;

7 The Directive provides:

‘Article 1

1. Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.

2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(c) uses of human embryos for industrial or commercial purposes;

3.2.4. National law

8 Paragraph 2 of the Patentgesetz (Law on patents), as amended for the purposes of transposition of Article 6 of the Directive (BGBl. 2005 I, p. 2521; ‘the PatG’), is worded as follows:

‘1. Patents may not be granted for inventions whose commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. In particular, patents shall not be awarded for:..

(3) uses of human embryos for industrial or commercial purposes;

The application of points (1) to (3) shall be governed by the appropriate provisions of the Embryonenschutzgesetz [(Law on the protection of embryos; “the ESchG”).’

9 Paragraph 21²⁵ of the PatG provides:

‘1. A patent shall be revoked (Paragraph 61) if it appears that:

(1) the object of the patent is not patentable pursuant to Paragraphs 1 to 5.’

10 Under Paragraph 22(1) of the PatG:

‘A patent shall be declared void on application (Paragraph 81) if it appears that one of the grounds set out in Paragraph 21(1) applies, or that the scope of the protection conferred by the patent has been extended.’

11 Paragraphs 1(1), point 2, and 2(1) and (2) of the ESchG of 13 December 1990 define as a criminal offence the artificial fertilisation of ova for a purpose other than inducing pregnancy in the woman from whom they originate, the sale of human embryos conceived in vitro or removed from a woman before the end of the nidation process in the uterus, or their transfer, acquisition or use for a purpose other than their preservation, and the in vitro development of human embryos for a purpose other than inducing pregnancy.

12 Under Paragraph 8(1) of the ESchG, an embryo is a fertilised human ovum capable of development, from the time of karyogamy, and any cell removed from an embryo which is ‘totipotent’, that is to say, able to divide and develop into an individual provided that the other conditions necessary are satisfied. A distinction must be made between those cells and pluripotent cells, which are stem cells which, although capable of developing into any type of cell, cannot develop into a complete individual.

13 Under Paragraph 4 of the Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen (Law to ensure the protection of embryos in connection with the importation and use of human embryonic stem cells) (BGBl. 2002 I, p. 2277) of 28 May 2002:

‘(1) The importation and use of embryonic stem cells are prohibited.

(2) By derogation from subparagraph 1 above, the importation and use of embryonic stem cells shall be authorised for purposes of research on the conditions set out in Paragraph (6) if:

1. the authorising authority is satisfied that

(a) the embryonic stem cells were obtained before 1 May 2007 in accordance with the legislation in force in the State of origin and have been preserved in culture or stored thereafter in cryopreserved form (lineage of embryonic stem cells);

(b) the embryos from which they originate were produced by in vitro fertilisation with a view to inducing pregnancy and became definitively superfluous to that purpose and there is no evidence that this was for reasons connected with the embryos themselves;

(c) no remuneration or other valuable benefit has been granted or promised in consideration of the donation of the embryos for the purpose of obtaining stem cells, and,

2. the importation and use of the embryonic stem cells does not infringe any other provisions of law, in particular those of the ESchG.

(3) Authorisation shall be refused if the embryonic stem cells were manifestly obtained in contravention of the founding principles of the German legal order. It shall not be refused on the ground that the stem cells were obtained from human embryos.’

14 Under Paragraph 5(1) of that Law:

‘Research work on embryonic stem cells may be carried out only if it is scientifically established that

1. that work pursues high-level research aims for the increase of scientific knowledge in the area of basic research or serves to extend medical knowledge in connection with the development of diagnostic, preventive or therapeutic procedures for human use ...’

The dispute in the main proceedings and the questions referred for a preliminary ruling

15 Mr Brüstle is the holder of a German patent, filed on 19 December 1997, which concerns isolated and purified neural precursor cells, processes for their production from embryonic stem cells and the use of neural precursor cells for the treatment of neural defects.

16 It is claimed in the patent specification filed by Mr Brüstle that the transplantation of brain cells into the nervous system is a promising method of treatment of numerous

neurological diseases. The first clinical applications have already been developed, in particular for patients suffering from Parkinson's disease.

17 In order to remedy such neural defects, it is necessary to transplant immature precursor cells, still capable of developing. In essence, that type of cell exists only during the brain's development phase. The use of cerebral tissue from human embryos raises significant ethical questions and means that it is not possible to meet the need for the precursor cells which are required to provide publicly available cell treatment.

18 However, according to the specification, embryonic stem cells offer new prospects for the production of cells for transplantation. Being pluripotent, they can develop into all types of cells and tissues and can be conserved during many passages in the state of pluripotentiality and can multiply. The patent at issue seeks, in those circumstances, to make it possible to resolve the technical problem of producing an almost unlimited quantity of isolated and purified precursor cells having neural or glial properties, obtained from embryonic stem cells.

19 On application by Greenpeace, the Bundespatentgericht (Federal Patent Court) ruled, on the basis of Paragraph 22(1)²⁶ of the PatG, that the patent at issue was invalid in so far as it covers precursor cells obtained from human embryonic stem cells and processes for the production of those precursor cells. The defendant appealed against that judgment to the Bundesgerichtshof (Federal Court of Justice).

20 In the view of the referring court, the outcome of the application for annulment depends on whether the technical teaching of the patent at issue, in so far as it concerns precursor cells obtained from human embryonic stem cells, is excluded from patentability under Paragraph 2(2), first sentence, point 3, of the PatG. The answer to that question depends in turn on the interpretation which should be given in particular to Article 6(2)(c) of the Directive.

21 According to the referring court, having regard to the fact that Article 6(2) of the Directive does not allow the Member States any discretion as regards the fact that the processes and uses listed therein are not patentable (see Case C-377/98 *Netherlands v Parliament and Council* [2001] ECR I-7079, paragraph 39, and Case C-456/03 *Commission v Italy* [2005] ECR I-5335, paragraph 78 et seq.), the reference made in the second sentence of Paragraph 2(2) of the PatG to the ESchG, particularly to the definition of an embryo which Paragraph 8(1) of that Law gives, cannot be regarded as the fruit of the task left to Member States to put Article 6(2)(c) of the Directive into concrete terms in that regard, even though the Directive did not expressly define the concept of embryo. The only possible interpretation of that concept is European and unified. In other words, the second sentence of Paragraph 2(2) of the PatG and, in particular, the concept of embryo which it uses cannot be interpreted differently from that of the corresponding concept in Article 6(2)(c) of the Directive.

22 With that in mind, the referring court seeks, *inter alia*, to ascertain whether the human embryonic stem cells which serve as base material for the patented processes constitute ‘embryos’ within the meaning of Article 6(2)(c) of the Directive and whether the organisms from which those human embryonic stem cells can be obtained constitute ‘human embryos’ within the meaning of that article. In that regard, it notes that the human embryonic stem cells which serve as base material for the patented processes are not all totipotent cells, some being only pluripotent cells obtained from embryos at the blastocyst stage. It is also uncertain as to the classification, in the light of the concept of embryo, of blastocysts from which human embryonic stem cells can also be obtained.

23 In those circumstances, the Bundesgerichtshof decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

‘1. What is meant by the term “human embryos” in Article 6(2)(c) of [the Directive]?’

(a) Does it include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?

(b) Are the following organisms also included:

– unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted;

– unfertilised human ova whose division and further development have been stimulated by parthenogenesis?

(c) Are stem cells obtained from human embryos at the blastocyst stage also included?

2. What is meant by the expression “uses of human embryos for industrial or commercial purposes”? Does it include any commercial exploitation within the meaning of Article 6(1) of [the Directive], especially use for the purposes of scientific research?

3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching:

– because the patent concerns a product whose production necessitates the prior destruction of human embryos,

– or because the patent concerns a process for which such a product is needed as base material?’

3.2.5. The questions referred

The first question

24 By its first question, the referring court asks the Court to interpret the concept of ‘human embryo’ within the meaning of and for the purposes of the application of Article 6(2)(c) of the Directive, that is to say, for the sole purpose of ascertaining the scope of the prohibition on patentability laid down in that provision.

25 It must be borne in mind that, according to settled case-law, the need for a uniform application of European Union law and the principle of equality require that the terms of a provision of European Union law which makes no express reference to the law of the Member States for the purpose of determining its meaning and scope must normally be given an independent and uniform interpretation throughout the European Union (see, in particular, Case 327/82 Ekro [1984] ECR 107, paragraph 11; Case C-287/98 Linster [2000] ECR I-6917, paragraph 43; Case C-5/08 Infopaq International [2009] ECR I-6569, paragraph 27; and Case C-467/08 Padawan [2010] ECR I-0000, paragraph 32).

26 Although the text of the Directive does not define human embryo, nor does it contain any reference to national laws as regards the meaning to be applied to those terms. It therefore follows that it must be regarded, for the purposes of application of the Directive, as designating an autonomous concept of European Union law which must be interpreted in a uniform manner throughout the territory of the Union.

27 That conclusion is supported by the object and the aim of the Directive. It follows from recitals 3 and 5 to 7 in the preamble to the Directive that it seeks, by a harmonisation of the rules for the legal protection of biotechnological inventions, to remove obstacles to trade and to the smooth functioning of the internal market that are brought about by differences in national legislation and case-law between the Member States, and thus, to encourage industrial research and development in the field of genetic engineering (see, to that effect, *Netherlands v Parliament and Council*, paragraphs 16 and 27).

28 The lack of a uniform definition of the concept of human embryo would create a risk of the authors of certain biotechnological inventions being tempted to seek their patentability in the Member States which have the narrowest concept of human embryo and are accordingly the most liberal as regards possible patentability, because those inventions would not be patentable in the other Member States. Such a situation would adversely affect the smooth functioning of the internal market which is the aim of the Directive.

29 That conclusion is also supported by the scope of the listing, in Article 6(2) of the Directive, of the processes and uses excluded from patentability. It is apparent from the case-law of the Court that, unlike Article 6(1) of the Directive, which allows the administrative authorities and courts of the Member States a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to ordre public and morality, Article 6(2) allows the Member States no discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to delimit the exclusion laid down in Article 6(1). It follows that, by expressly excluding from patentability the processes and uses to which it refers, Article 6(2) of the Directive seeks to grant specific rights in this regard (see *Commission v Italy*, paragraphs 78 and 79).

30 As regards the meaning to be given to the concept of ‘human embryo’ set out in Article 6(2)(c) of the Directive, it should be pointed out that, although, the definition of human embryo is a very sensitive social issue in many Member States, marked by their multiple traditions and value systems, the Court is not called upon, by the present order for reference, to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive (see, to that effect, *Case C-506/06 Mayr* [2008] ECR I-1017, paragraph 38).

31 It must be borne in mind, further, that the meaning and scope of terms for which European Union law provides no definition must be determined by considering, inter alia, the context in which they occur and the purposes of the rules of which they form part (see to that effect, inter alia, *Case C-336/03 easyCar* [2005] ECR I-1947, paragraph 21; *Case C-549/07 Wallentin-Hermann* [2008] ECR I-11061, paragraph 17; and *Case C-151/09 UGT-FSP* [2010] ECR I-0000, paragraph 39).

32 In that regard, the preamble to the Directive states that although it seeks to promote investment in the field of biotechnology, use of biological material originating from humans must be consistent with regard for fundamental rights and, in particular, the dignity of the

person. Recital 16 in the preamble to the Directive, in particular, emphasises that ‘patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person’.

33 To that effect, as the Court has already held, Article 5(1) of the Directive provides that the human body at the various stages of its formation and development cannot constitute a patentable invention. Additional security is offered by Article 6 of the Directive, which lists as contrary to *ordre public* or morality, and therefore excluded from patentability, processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes. Recital 38 in the preamble to the Directive states that this list is not exhaustive and that all processes the use of which offends against human dignity are also excluded from patentability (see *Netherlands v Parliament and Council*, paragraphs 71 and 76).

34 The context and aim of the Directive thus show that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. It follows that the concept of ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive must be understood in a wide sense.

35 Accordingly, any human ovum must, as soon as fertilised, be regarded as a ‘human embryo’ within the meaning and for the purposes of the application of Article 6(2)(c) of the Directive, since that fertilisation is such as to commence the process of development of a human being.

36 That classification must also apply to a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis. Although those organisms have not, strictly speaking, been the object of fertilisation, due to the effect of the technique used to obtain them they are, as is apparent from the written observations

presented to the Court, capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so.

37 As regards stem cells obtained from a human embryo at the blastocyst stage, it is for the referring court to ascertain, in the light of scientific developments, whether they are capable of commencing the process of development of a human being and, therefore, are included within the concept of ‘human embryo’ within the meaning and for the purposes of the application of Article 6(2)(c) of the Directive.

38 In the light of the foregoing considerations, the answer to the first question is that:

– any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive;

– it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive.

The second question

39 By its second question, the referring court asks whether the concept of ‘uses of human embryos for industrial or commercial purposes’ within the meaning of Article 6(2)(c) of the Directive also covers the use of human embryos for purposes of scientific research.

40 In that regard, it must be pointed out that the purpose of the Directive is not to regulate the use of human embryos in the context of scientific research. It is limited to the patentability of biotechnological inventions.

41 With regard, therefore, solely to the determination of whether the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes also covers the use of human embryos for purposes of scientific research or whether scientific research entailing the use of human embryos can access the protection of patent law, clearly the grant of a patent implies, in principle, its industrial or commercial application.

42 That interpretation is supported by recital 14 in the preamble to the Directive. By stating that a patent for invention ‘entitles [its holder] to prohibit third parties from exploiting it for industrial and commercial purposes’, it indicates that the rights attaching to a patent are, in principle, connected with acts of an industrial or commercial nature.

43 Although the aim of scientific research must be distinguished from industrial or commercial purposes, the use of human embryos for the purposes of research which constitutes the subject-matter of a patent application cannot be separated from the patent itself and the rights attaching to it.

44 The clarification in recital 42 in the preamble to the Directive, that the exclusion from patentability set out in Article 6(2)(c) of the Directive ‘does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it’ also confirms that the use of human embryos for purposes of scientific research which is the subject-matter of a patent application cannot be distinguished from industrial and commercial use and, thus, avoid exclusion from patentability.

45 That interpretation is, in any event, identical to that adopted by the Enlarged Board of Appeal of the European Patent Office regarding Rule 28(c) of the Implementing Regulations

to the CGEP, which uses precisely the same wording as Article 6(2)(c) of the Directive (see decision of 25 November 2008, G 2/06, Official Journal EPO, May 2009, p. 306, paragraphs 25 to 27).

46 The answer to the second question is therefore that the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes in Article 6(2)(c) of the Directive also covers use for purposes of scientific research, only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable.

The third question

47 By its third question, the referring court asks the Court, in essence, whether an invention is unpatentable even though its purpose is not the use of human embryos, where it concerns a product whose production necessitates the prior destruction of human embryos or a process for which requires a base material obtained by destruction of human embryos.

48 It is raised in a case concerning the patentability of an invention involving the production of neural precursor cells, which presupposes the use of stem cells obtained from a human embryo at the blastocyst stage. It is apparent from the observations presented to the Court that the removal of a stem cell from a human embryo at the blastocyst stage entails the destruction of that embryo.

49 Accordingly, on the same grounds as those set out in paragraphs 32 to 35 above, an invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires the destruction of human embryos. In that case too, the view must be taken that there is use of human embryos within the meaning of Article 6(2)(c) of the Directive. The fact that destruction may occur at a stage long before the implementation of the invention, as in the case of the

production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of human embryos is, in that regard, irrelevant.

50 Not to include in the scope of the exclusion from patentability set out in Article 6(2)(c) of the Directive technical teaching claimed, on the ground that it does not refer to the use, implying their prior destruction, of human embryos would make the provision concerned redundant by allowing a patent applicant to avoid its application by skilful drafting of the claim.

51 Again, the Enlarged Board of Appeal of the European Patent Office reached the same conclusion when asked about the interpretation of Rule 28(c) of the Implementing Regulations to the CGEP, the wording of which is identical to that of Article 6(2)(c) of the Directive (see decision of 25 November 2008, paragraph 22, referred to in paragraph 45 above).

52 The answer to the third question is therefore that Article 6(2)(c) of the Directive excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.

3.2.6. Costs

53 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

3.2.7. The Court's decision

On those grounds, the Court (Grand Chamber) hereby rules:

1. Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that:

- any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a ‘human embryo’;
- it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a ‘human embryo’ within the meaning of Article 6(2)(c) of Directive 98/44.

2. The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of Directive 98/44 also covers the use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable.

3. Article 6(2)(c) of Directive 98/44 excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.

3.3. Commission of the European Communities v Kingdom of Spain¹³

Articles 28 EC and 30 EC – Free movement of goods – Directive 2001/83/EC – Products based on medicinal herbs – Products classified as medicinal products – Products lawfully produced or marketed as food supplements or dietary products in other Member States – Meaning of ‘medicinal product’ – Marketing authorisation – Restriction – Justification – Public health – Consumer protection – Proportionality – Decision No 3052/95/EC – Procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community

3.3.1. Judgment

1 By its action, the Commission of the European Communities asks the Court to declare that:

– by withdrawing from the market a number of herbal products lawfully produced and/or marketed in another Member State, under an administrative practice consisting in withdrawing from the market any product with herbal constituents not included in the annex to the Ministerial Order on the creation of a special register of medicinal herb-based preparations (Orden Ministerial por la que se establece el registro especial para preparados a base de especies vegetales medicinales) of 3 October 1973 (BOE No 247 of 15 October 1973, p. 19866), as amended (‘the 1973 Order’) on the ground that it is deemed to be a medicinal product marketed without the requisite authorisation, and

– by not communicating that measure to the Commission,

the Kingdom of Spain has failed to fulfil its obligations under Articles 28 EC and 30 EC and Articles 1 and 4 of Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national

¹³ Judgment Of The Court (First Chamber) 5 March 2009; In Case C 88/07; Commission of the European Communities v Kingdom of Spain

measures derogating from the principle of the free movement of goods within the Community (OJ 1995 L 321, p. 1).

2 The Commission states that its action relates to the marketing of products based on medicinal herbs, in other words products containing one or more herbs which, because of their properties and their physiological effects, can be used as ingredients in medicinal products or in other types of products, such as food supplements.

3.3.2. Legal context

Community legislation

Directive 2001/83/EC

3 Article 1 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34, ‘Directive 2001/83’), provides:

‘For the purposes of this Directive, the following terms shall bear the following meanings:

...

2. Medicinal product:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

3. Substance:

Any matter irrespective of origin which may be:

– vegetable, e.g:

micro-organisms, plants, parts of plants, vegetable secretions, extracts,

29. Traditional herbal medicinal product:

A herbal medicinal product that fulfils the conditions laid down in Article 16a(1);

30. Herbal medicinal product:

Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations;

31. Herbal substances:

All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);

32. Herbal preparations:

Preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or ground herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.’

4 Article 2(1) and (2) of Directive 2001/83 provide:

‘1. This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.

2. In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a “medicinal product” and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.’

5 The first subparagraph of Article 6(1) of Directive 2001/83 provides that ‘[n]o medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance

with this Directive or unless an authorisation has been granted in accordance with [Council] Regulation (EEC) No 2309/93 [of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1)]’.

6 Title III of Directive 2001/83 contains a Chapter 2a, headed ‘Specific provisions applicable to traditional herbal medicinal products’, which contains Articles 16a to 16i. That chapter establishes, under certain conditions, a simplified registration procedure for traditional herbal medicinal products.

7 To qualify for such a procedure, a traditional herbal medicinal product must have been in medicinal use throughout a period of at least 30 years preceding the date of the application for registration, including at least 15 years within the European Community (Articles 16a(1)(d) and 16c(1)(c) of Directive 2001/83).

8 It is also necessary that the data on the traditional use of the medicinal product be sufficient; in particular the product must prove not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product must be plausible on the basis of longstanding use and experience (Article 16a(1)(e) of Directive 2001/83).

9 Article 16f(1) and (2) of Directive 2001/83 provide:

‘1. A list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products shall be established in accordance with the procedure referred to in Article 121(2). The list shall contain, with regard to each herbal substance, the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance as a traditional medicinal product.

2. If an application for traditional-use registration relates to a herbal substance, preparation or a combination thereof contained in the list referred to in paragraph 1, the data specified in Article 16c(1)(b), (c) and (d) do not need to be provided. Article 16e(1)(c) and (d) shall not apply.’

Decision No 3052/95

10 The third to sixth recitals in the preamble to Decision No 3052/95 are worded as follows:

‘... the transparency of national measures banning products may make it easier to deal quickly and at the appropriate level with problems which may jeopardize the free movement of goods, inter alia by approximating such measures in good time or adjusting them pursuant to Article [28 EC];

..., in order to facilitate such transparency, a simple and pragmatic procedure should be established for the exchange of information between Member States and with the Commission so that any problems that may arise in connection with the operation of the internal market can be settled satisfactorily for both businesses and consumers;

... the main purpose of this procedure is to enhance knowledge concerning the implementation of the free movement of goods in non harmonised sectors and to identify the problems encountered with a view to finding appropriate solutions to them;

... such a procedure should cover only those cases in which a Member State takes steps to prevent, on grounds of non-conformity with its own national rules, the free movement or placing on the market of goods lawfully produced or marketed in another Member State’.

11 Article 1 of Decision No 3052/95 provides:

‘Where a Member State takes steps to prevent the free movement or placing on the market of a particular model or type of product lawfully produced or marketed in another Member State, it shall notify the Commission accordingly where the direct or indirect effect of the measure is:

- a general ban on the goods,
- a refusal to allow the goods to be placed on the market,

...

or

- withdrawal of the goods from the market.’

12 Article 4(2) of Decision No 3052/95 states that ‘[t]he information referred to in paragraph 1 shall be communicated within 45 days of the date on which the measure referred to in Article 1 is taken’.

3.3.3. National legislation

13 Article 8(1) of Law No 25/1990 on medicinal products (Ley 25/1990 del Medicamento) of 20 December 1990 (BOE No 306 of 22 December 1990, p. 38228), provides:

‘For the purposes of this legislation, the following terms have the following meanings ... “medicinal product”: any medicinal substance and any association or combination of such substances intended for use by human beings or animals which is presented as having properties which facilitate the prevention, diagnosis, treatment, relief or cure of diseases or illnesses, or which affect physical functions or mental state. Medicinal substances or combinations of such substances which can be administered to human beings or animals for the above purposes, even if they are offered for sale without explicit reference to those purposes, are also deemed to be medicinal products.’

14 Under Article 9(1) of Law No 25/1990, ‘no proprietary medicinal product or any other medicinal product for human use manufactured industrially may be placed on the market without prior marketing authorisation from the Spanish Medicines Agency and inclusion in the register of proprietary medicinal products, or without a Community authorisation in accordance with the provisions of Regulation ... No 2309/93’.

15 Article 42 of Law No 25/1990, headed ‘Herbal medicinal products’, provides:

‘1. Herbs and mixtures of them and any preparations obtained from herbs in the form of extracts, lyophilisates, distillations, tinctures, decoctions or any other galenic preparation, which are presented as having a therapeutic, diagnostic or preventive value will be subject, as appropriate, to the rules relating to magistral formulas, officinal formulas or proprietary medicinal products, and in accordance with the specific requirements laid down by legislation.

2. The Ministry of Health and Consumer Affairs shall establish a list of herbs the sale of which to the public is restricted or prohibited because of their toxicity.

3. Herbs which are traditionally regarded as medicinal and which are offered for sale without reference to therapeutic, diagnostic or preventive properties may be freely sold to the public, but door-to-door selling of them is prohibited.’

16 The list referred to in Article 42(2) of Law No 25/1990 is to be found in the annex to Order SCO/190/2004 of the Ministry of Health and Consumer Affairs establishing the list of plants sale of which to the public is prohibited or restricted because of their toxicity (Orden SCO/190/2004 por la que se establece la lista de plantas cuya venta al público queda prohibida o restringida por razón de su toxicidad) of 28 January 2004 (BOE No 32 of 6 February 2004, p. 5061, ‘the 2004 Order’).

17 Article 1 of the 2004 Order states that ‘sale [of the plants listed] and sale of preparations based on them to the public is prohibited because of their toxicity’ and that ‘their use and their placing on the market are limited to the production of proprietary medicinal products, magistral formulas, officinal preparations and homeopathic strains, and to the purposes of research’. The annex in question lists 197 herbs.

18 Article 1 of the 1973 Order provides:

‘Preparations the constituents of which are exclusively one or more medicinal herbs, whole parts of such herbs, or such herbs in crushed or ground form shall be listed in a special register by the appropriate departments of the Directorate General for Health.’

19 Article 2 of the 1973 Order provides:

‘There shall not be listed in that special register:

- (a) preparations for immediate use which contain a single medicinal herb – or parts of it – listed in the annex and which state that fact clearly on the external packaging of the product;
- (b) preparations for immediate use based on extracts, tinctures, distillations, decoctions or any other galenic preparation, obtained from medicinal herbs, in which case they shall in all circumstances be treated as proprietary medicinal products.’

20 The 1973 Order has annexed to it the list of medicinal herbs referred to in Article 2(a) of that order. That list was last updated in 1976 and extends to 119 herbs.

21 It is common ground that ‘herbs which are traditionally regarded as medicinal’, within the meaning of Article 42(3) of Law No 25/1990 are treated by the competent Spanish authorities in the same way as the medicinal herbs listed in the annex to the 1973 Order, with the result that preparations which, first, satisfy the conditions of Article 2(a) of the 1973 Order and, secondly, are offered for sale without reference to therapeutic, diagnostic or preventive

properties may be freely sold to the public, in accordance with Article 42(3) of Law No 25/1990.

22 Law No 25/1990 was repealed by Law No 29/2006 on the guarantees and rational use of medicines and health products (Ley 29/2006 de garantías y uso racional de los medicinal productos y productos sanitarios) of 26 July 2006 (BOE No 178 of 27 July 2006, p. 28122), which came into force on 28 July 2006. Article 51 of the latter law essentially reproduces Article 42 of Law No 25/1990.

Pre-litigation procedure

23 In several letters sent in 2004 to departments of the Commission, three Spanish companies, Ynsadiet SA ('Ynsadiet'), Laboratorios Tregor SL ('Tregor') and Laboratorios Taxón SL ('Taxón') complained that, between 2002 and 2003, the Agencia española de medicamentos y productos sanitarios (Spanish Drugs and Health Products Agency, 'AEMPS') had withdrawn from the Spanish market more than 200 products based on medicinal herbs on the ground that they were medicinal products without any authorisation to be placed on the market ('marketing authorisation'), although those products were lawfully marketed in other Member States as food supplements or dietary products. Other complaints on the same ground were made to the Commission in 2005 and 2006.

24 According to those complaints, the classification by AEMPS of those products as medicinal products was often based on the fact that the products withdrawn from the market contained medicinal herbs which were not listed in the annex to the 1973 Order.

25 The Commission considered that the abovementioned decisions to withdraw goods from the market were contrary to Article 28 EC and that the failure to communicate those decisions was an infringement of Articles 1 and 4 of Decision No 3052/95, and accordingly on 21 March 2005 sent a letter of formal notice asking the Spanish authorities to clarify the matter.

26 The Commission was not satisfied with the responses of the Spanish authorities and sent on 10 April 2006 to the Kingdom of Spain a reasoned opinion, requesting that the necessary measures for compliance be taken within a period of two months from the date of receipt of the opinion.

27 Since the Spanish authorities do not accept that the Commission's criticism is well founded, the Commission has brought this action.

The alleged failure to fulfil obligations under Articles 28 EC and 30 EC

Arguments of the parties

28 The Commission claims that there is at present no harmonisation at Community level either as regards herbs and herbal extracts used in the composition of food supplements or as regards the classification of products based on medicinal herbs as medicinal products or food supplements. The Commission states in particular that Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ 2002 L 183, p. 51) postponed to a later stage the adoption of specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect, such as various herbs and herbal extracts.

29 In the absence of such harmonisation, products based on medicinal herbs lawfully marketed in one Member State ought, as a general rule, to move freely pursuant to the principle of the free movement of goods set out in Article 28 EC, unless it is properly demonstrated that they carry a risk to human health, in accordance with Article 30 EC.

30 First, the Commission claims that the Spanish authorities have adopted a consistent administrative practice, which involves the systematic classification of products based on medicinal herbs which are not listed in the annex to the 1973 Order as medicinal products by function, without first submitting each of those products to detailed analysis, and, consequently, in the absence of marketing authorisation, the withdrawal of those products from the Spanish market.

31 However, according to the Court's case-law, in order to determine whether or not a product is a medicinal product by function, it is appropriate to have regard to its composition, its pharmacological properties, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail. Products can be described as medicinal products by function only on a case by case basis, taking account of their pharmacological properties.

32 Accordingly, the mere presence in a product lawfully produced or marketed in another Member State of medicinal herbs not listed in the annex to the 1973 Order is not a criterion

which can justify treating such a product as a medicinal product and withdrawing it from the Spanish market in the absence of marketing authorisation.

33 Consequently, the practice of the Spanish authorities is a measure having equivalent effect to a quantitative restriction, prohibited by Article 28 EC.

34 The Commission does not accept the assertion by the Kingdom of Spain that, before the decision to withdraw a product from the market is taken, a detailed examination, product by product, is carried out. The Commission claims, first, that the reality of the practice complained of is clear from the complaints submitted to it by businesses whose products based on medicinal herbs have been withdrawn from the market, from the Report on the marketing of various products based on medicinal herbs (*Informe sobre la comercialización de diversos productos a base de plantas medicinas*) dated 26 March 2004 issued by AEMPS, and from the court judgments rejecting actions brought by those businesses against the decisions to withdraw their products from the market, in particular the judgment of the contentious administrative division of the Audiencia Nacional of 30 June 2004 in relation to the action brought by Tregor. The Commission emphasises, secondly, that the Kingdom of Spain makes no reference to any individual withdrawal decisions and the reasons for them, with the result that the Kingdom of Spain has not proved that a case by case examination is made prior to the classification of a product containing medicinal herbs as a medicinal product.

35 Secondly, in the Commission's opinion, the practice of the Spanish authorities cannot be justified on the basis of Article 30 EC.

36 Contrary to the requirements laid down by the Court's case-law in relation to Article 30 EC, the systematic nature of the Spanish administrative practice makes it impossible either to identify or evaluate any actual risk to public health, when there is no thorough evaluation, on a case by case basis, of the negative effects on human health which consumption of the products in question might entail. The practice is based on a presumption of danger going beyond what is necessary and proportionate for the protection of public health.

37 First, the Kingdom of Spain denies that there is a practice such as described by the Commission.

38 The decision to submit the marketing of a product containing medicinal herbs to the rules applicable to medicinal products is the result of an analysis of that product in relation to its composition, the properties which the producer associates with it and the form in which it

is offered for sale. As part of that analysis, investigation is also made into whether herbs prohibited under the 2004 Order or authorised under the 1973 Order are constituents of the product. Only when, as a result of that analysis, the conclusion is unavoidable that the marketing of the product in question ought to have been monitored in the way required for the marketing of medicinal products is that product withdrawn from the market.

39 Such a withdrawal is therefore not systematic, but is prompted by the dangerousness of the product examined. There are moreover many herbal products marketed freely in Spain which are categorised as food supplements.

40 As regards, more particularly, the products the withdrawal of which from the market led to the complaints which initiated the pre-litigation procedure, the Kingdom of Spain states that a detailed individual analysis of each of those products was carried out, which consisted of identifying the substances present as constituents and also examining their presentation and the properties associated with those substances. The principal objective of that analysis was to evaluate both the capacity of those products to correct or modify physiological functions and the risks to health, actual or potential, entailed in their consumption.

41 In respect of each of the products concerned, the withdrawal decision was not based exclusively on the fact that medicinal herbs not listed in the annex to the 1973 Order were among its constituents, but was founded on the results of that analysis.

42 According to the Kingdom of Spain, all the products the withdrawal of which from the market led to the complaints which initiated the pre-litigation procedure fell under the harmonised definition of 'herbal medicinal product' within the meaning of Directive 2001/83, since they were either products presented as associated with therapeutic, curative or preventive properties in respect of human health, or products associated with purposes unrelated to health, but in any event likely to cause in human beings some modification of physiological functions by pharmacological action.

43 All those products contained one or more substances derived from medicinal herbs whose possible effects on human health and medical uses regarded by other European health authorities as acceptable had been established by a scientific study by AEMPS.

44 Furthermore, most of those substances are to be found in a provisional list of medicinal herbs dated 11 January 2007 and published by the Working Party on Community Monographs and Community Lists of the Committee on Herbal Medicinal Products set up by Article 16h

of Directive 2001/83, which shows that that committee has already taken the decision to classify those substances as medicinal herbs. It follows, according to the Kingdom of Spain, that products composed of those substances necessarily fall under the definition of ‘herbal medicinal product’ within the meaning of that directive.

45 The Kingdom of Spain adds that, under Article 2(2) of Directive 2001/83, in cases of doubt, when a product may fall within the definition of a medicinal product within the meaning of that directive and also within the definition of a product covered by other Community legislation, classification as a medicinal product must prevail.

46 The Kingdom of Spain considers that the legislation and practice in Spain are consistent with the Court’s case-law on medicinal products, from which it is clear in particular that the national authorities have some discretion in relation to the classification of a product as a medicinal product.

47 Secondly, if the Court were to consider that the practice complained of by the Commission exists, that the products withdrawn from the market were not medicinal products, and that those withdrawals constituted a restriction on the free movement of goods within the meaning of Article 28 EC, the Kingdom of Spain contends that such a withdrawal is justified by the exception, provided for by Article 30 EC, concerning the protection of public health.

48 First, in the current state of scientific research, there is uncertainty as regards the harmlessness of the products withdrawn from the market that justifies their withdrawal under the precautionary principle, in accordance with the case-law of the Court and in particular Case C 24/00 *Commission v France* [2004] ECR I 1277, paragraph 56.

49 Products based on medicinal herbs are almost always products the safety of which has not been thoroughly examined. On many occasions, preparations based on medicinal herbs have had undesirable, and sometimes serious effects. Moreover, there is a risk that such preparations may interact with other medicinal products.

50 The mere presence in a product of substances which present a risk to public health undeniably constitutes a reason for the health authorities, on the basis of available scientific and technical knowledge, to withdraw that product from the market.

51 The Kingdom of Spain considers moreover that the analysis made by the Court in Case C 150/00 *Commission v Austria* [2004] ECR I 3887 is not transposable to the present case. In that judgment, which concerned a consistent and generalised practice of classifying foodstuffs containing vitamins as medicinal products, the Court's finding that there was a failure to fulfil obligations was based on the fact that as a general rule vitamins are harmless. On the other hand, in the present case, most of the products concerned could have serious consequences for human health, especially since the Commission has provided no data to suggest that the harmlessness of those products has been established.

52 Secondly, a decision to withdraw goods from the market is always taken by the Spanish authorities on an ad hoc, case by case, basis, taking into account a complex set of circumstances, in which the role of the 1973 Order is secondary, and the undertakings concerned always have the possibility of bringing proceedings before the courts which would review all aspects of the withdrawal decision. Furthermore, it is always open to those undertakings to apply for a marketing authorisation as a medicinal product. Consequently, the withdrawal decisions appear proportionate.

53 Alternatively, the Kingdom of Spain considers that the withdrawal from the market of the products concerned was justified by the overriding requirement of consumer protection, recognised in the case-law of the Court.

3.3.4. Findings of the Court

Whether there is an administrative practice

54 It is settled case-law that an administrative practice can be made the object of an action for failure to fulfil obligations when it is, to some degree, of a consistent and general nature (see, inter alia, Case C 135/05 *Commission v Italy* [2007] ECR I 3475, paragraph 21).

55 It is clear from the Commission's pleadings that its criticism of the Spanish authorities relates to an administrative practice which consists of systematically classifying as medicinal products by function and, in the absence of marketing authorisation, withdrawing from the Spanish market products based on medicinal herbs lawfully produced and/or marketed as food supplements or dietary products in other Member States, where, and solely because, the herbs they contain are not listed in the annex to the 1973 Order.

56 The Kingdom of Spain contends that there is no such administrative practice.

57 In that regard, first, the Kingdom of Spain correctly submits that some of the products the withdrawal of which from the Spanish market led to the complaints received by the Commission were not withdrawn from the market for the reason that the medicinal herbs they contained were not listed in the annex to the 1973 Order, but because those medicinal herbs were listed in the annex to the 2004 Order. The latter annex, which corresponds to the list referred to in Article 42(2) of Law No 25/1990, refers to herbs whose toxicity in the opinion of the Spanish authorities precludes their use in products other than medicinal products.

58 Accordingly, the withdrawal of such herbal products follows from Article 42(2) of Law No 25/1990, read in conjunction with the 2004 Order; those provisions of national law prohibit sale to the public of those herbs and of preparations containing them other than as medicinal products, because of their toxicity.

59 The Commission, which did not refer to the 2004 Order either in the letter of formal notice, the reasoned opinion, or its pleadings before the Court, does not claim that those provisions might be incompatible with Community law.

60 Secondly, as is contended by the Kingdom of Spain and confirmed by the judgment of the Audiencia Nacional of 30 June 2004 referred to in paragraph 34 of this judgment, the marketing of some of the products based on medicinal herbs which are not listed in either the annex to the 1973 Order or in the annex to the 2004 Order is not subject to obtaining a marketing authorisation. It is clear from Article 1 of the 1973 Order that the marketing of preparations the constituents of which are exclusively medicinal herbs, whole parts of such herbs, or crushed or ground parts of such herbs, requires merely that those preparations be included in the special register provided for by that order.

61 On the other hand, as regards other products based on medicinal herbs not listed in the annex to the 1973 Order, the reality and consistency of their systematic classification as medicinal products and the need to obtain marketing authorisation if they are to be marketed are established in the AEMPS report referred to in paragraph 34 of this judgment. It is clear from that report that, apart from products based on herbs traditionally considered to be medicinal and listed in the annex to the 1973 Order, products based on medicinal herbs are subject to the legislation on medicinal products as regards their manufacture, their marketing, their distribution and their sale.

62 That practice has been validated by the national courts. In its judgment of 30 June 2004 referred to in paragraph 34 of this judgment, the contentious administrative division of the Audiencia Nacional made the finding that the classification of products based on medicinal herbs marketed by Trégor as medicinal products was a consequence of ‘the fact that they contain herbs not listed in the annex to the 1973 Order’.

63 It must moreover be observed, first, that the Kingdom of Spain has provided no evidence, such as individual withdrawal decisions, to establish that any case by case examination, going beyond a simple check whether the medicinal herbs contained in a given product are or are not listed in either the annex to the 1973 Order or in the annex to the 2004 Order, is carried out prior to the classification of that product as a medicinal product. Next, the Kingdom of Spain has offered no instance of a product based on medicinal herbs not listed in the annex to the 1973 Order which is marketed freely. Lastly, it is clear that the Kingdom of Spain does not contend that, between 2004 and the date of expiry of the period allowed in the reasoned opinion, there was any change in the national legislation or in the practices of AEMPS.

64 It must be added that the Kingdom of Spain does not submit, and it is in no way suggested in the court file, that the practice of systematically classifying products based on medicinal herbs not listed in the Annex to the 1973 Order as medicinal products does not apply to products lawfully produced and marketed in other Member States. Consequently, it is clear that no distinction is made on the basis of the origin of the products.

65 It follows from the above considerations that, when the period allowed in the reasoned opinion expired, the administrative practice complained of was established in relation to products based on medicinal herbs which are not listed in either the annex to the 1973 Order or in that of the 2004 Order, other than preparations the constituents of which are exclusively medicinal herbs or whole parts of such herbs, or crushed or ground parts of such herbs, and that that practice had a sufficient degree of consistency and generality to justify an action for failure to fulfil obligations.

66 In the remainder of this judgment, reference to products based on medicinal herbs not listed in the Annex to the 1973 Order will refer exclusively to those products based on medicinal herbs which are not listed either in the annex to the 1973 Order or in the annex to the 2004 Order, other than preparations the constituents of which are exclusively medicinal herbs or whole parts of such herbs, or crushed or ground parts of such herbs.

Classification as medicinal product by function

67 It is clear from Articles 2 and 6(1) of Directive 2001/83 that no medicinal product manufactured industrially can be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authority of that Member State or unless an authorisation has been issued in accordance with Regulation No 2309/93.

68 It follows that, if a product manufactured industrially comes within the definition of medicinal product in Article 1(2) of Directive 2001/83, the obligation on the importer of that product to obtain a marketing authorisation in accordance with that directive prior to marketing it in the Member State of importation cannot, in any event, constitute a restriction on trade between Member States prohibited by Article 28 EC (Case C 319/05 *Commission v Germany* [2007] ECR I 9811, paragraph 35).

69 Moreover, as the harmonisation of national legislation in relation to the production and distribution of medicinal products currently stands, the fact that a product is classified as a foodstuff in another Member State cannot prevent it from being classified as a medicinal product in the Member State of importation, if it displays the characteristics of such a product (see *Joined Cases C 211/03, C 299/03 and C 316/03 to C 318/03 HLH Warenvertrieband Orthica* [2005] ECR I 5141, paragraph 56, and *Commission v Germany*, paragraphs 36 and 37).

70 As regards, more particularly, products based on medicinal herbs, as stated by the Commission, in the Community legislation there is no harmonisation as regards classification of such products either as medicinal products or as food products.

71 The Court must therefore determine, first, whether products based on medicinal herbs not listed in the annex to the 1973 Order are necessarily medicinal products by function within the meaning of Article 1(2)(b) of Directive 2001/83.

72 In order to determine whether a product falls under the definition of medicinal product by function within the meaning of Directive 2001/83, the national authorities, subject to review by the courts, must decide on a case by case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological, immunological and/or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (*HLH*

Warenvertrieb and Orthica, paragraph 51; Commission v Germany, paragraph 55, and Case C 140/07 Hecht-Pharma [2009] ECR I 0000, paragraph 32).

73 As clarified by the Commission itself, medicinal herbs are plants which, because of their properties and physiological effects, can be used as ingredients in medicinal products or in other types of products, such as food supplements.

74 However, the mere fact that one or more medicinal herbs are among the constituents of a product is not sufficient to permit the conclusion that that product contributes to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis, within the meaning of Article 1(2)(b) of Directive 2001/83.

75 It is possible that, having regard, in particular, to the small amount of the active substance contained in it and/or the manner in which it is used, a product based on medicinal herbs will have no effect on physiological functions or that its effects will not suffice for it to be a medicinal product by function (see, by analogy, as regards preparations containing vitamins or minerals, Commission v Austria, paragraph 63; see also, to that effect, Hecht-Pharma, paragraph 42). In that regard, the Court has held that substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions should not be classified as medicinal products by function (see Commission v Germany, paragraph 60, and Hecht-Pharma, paragraph 41).

76 A consequence of the Spanish administrative practice complained of, in so far as it is applied systematically to all products based on medicinal herbs not listed in the annex to the 1973 Order, may therefore be that some of those products are classified as medicinal products, even when they are not capable of restoring, correcting or modifying human physiological functions.

77 That conclusion is not invalidated by the results of the scientific study referred to in paragraph 43 of this judgment, from which it emerges, according to the Kingdom of Spain, that all the products of Ynsadiet, Tregor and Taxón withdrawn from the market in 2002 and 2003 contained herbs which can be harmful to human health. As was stated by the Advocate General in points 40 to 42 of his Opinion, that scientific study relates to the harmfulness of the medicinal herbs themselves, but not to the pharmacological, immunological or metabolic properties of the products withdrawn from the market or to the risks which their use might

entail. Furthermore, that study relates to only 34 herbs, whereas the practice complained of is applied to all products based on medicinal herbs not listed in the annex to the 1973 Order, the number of which is potentially unlimited.

78 The Court must also reject the argument of the Kingdom of Spain that, in accordance with Article 2(2) of Directive 2001/83, and given the doubt on the matter, products based on medicinal herbs other than those listed in the annex to the 1973 Order must be classified as medicinal products by function.

79 Article 2(2) of Directive 2001/83 must be interpreted as meaning that that directive does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, without its being possible to exclude that possibility (Hecht-Pharma, paragraph 29). Moreover, given the systematic nature of the Spanish administrative practice, it is possible that products based on medicinal herbs other than those listed in the annex to the 1973 Order will be classified as medicinal products by function although that is clearly not the case.

80 It follows from the foregoing that the Spanish administrative practice complained of in the present case cannot be defended on the basis of Directive 2001/83.

Whether there is a restriction

81 It is accordingly necessary to consider, secondly, whether the requirement of marketing authorisation for products based on medicinal herbs not listed in the annex to the 1973 Order, imposed by the Spanish administrative practice, constitutes a measure having equivalent effect to a quantitative restriction on imports, prohibited by Article 28 EC.

82 The prohibition on measures having equivalent effect to quantitative restrictions set out in Article 28 EC covers all measures which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade (see, in particular, Case 8/74 Dassonville [1974] ECR 837, paragraph 5; Case C 192/01 Commission v Denmark [2003] ECR I 9693, paragraph 39; Commission v France, paragraph 22; and Commission v Germany, paragraph 80).

83 In the present case, the Spanish administrative practice creates an obstacle to intra-Community trade in so far as a product based on medicinal herbs not listed in the annex to the 1973 Order, lawfully produced and/or marketed in another Member State as a food

supplement or dietary product, can be marketed in Spain only after going through the marketing authorisation procedure (see, by analogy, *Commission v Austria*, paragraph 82, and *Commission v Germany*, paragraph 81).

84 The Spanish administrative practice complained of in the present case therefore constitutes a measure having equivalent effect to a quantitative restriction, within the meaning of Article 28 EC.

Whether there is justification

85 It must therefore be determined, thirdly, whether, as contended by the Kingdom of Spain, the practice in question can be justified by the need to protect human health, referred to in Article 30 EC, or by the overriding requirement of consumer protection, established in the Court's case-law.

86 In accordance with the Court's case-law, it is for the Member States, in the absence of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research, to decide on the level of protection of human health and life they wish to ensure and on whether to require prior authorisation for the marketing of foodstuffs, always taking into account the requirements of the free movement of goods within the Community (see *Commission v Denmark*, paragraph 42; *Commission v France*, paragraph 49; and *Commission v Germany*, paragraph 86).

87 It follows that Community law does not therefore, in principle, preclude a Member State from prohibiting, unless there is prior authorisation, the marketing of foodstuffs to which nutrients, such as vitamins or minerals other than those whose use is lawful under Community legislation, have been added (*Commission v Denmark*, paragraph 44; *Commission v France*, paragraph 51; and *Commission v Austria*, paragraph 87).

88 However, in exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health or to meet overriding requirements such as, for example the protection of consumers; they must be proportional to the objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade (see *Commission v Denmark*, paragraph 45; *Commission v France*, paragraph 52; *Commission v Austria*, paragraph 88; and *Commission v Germany*, paragraph 87).

89 Furthermore, since Article 30 EC provides for an exception, to be interpreted strictly, to the rule of free movement of goods within the Community, it is for the national authorities which invoke it to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk to public health (Commission v Denmark, paragraph 46; Commission v France, paragraph 53; Commission v Austria, paragraph 89; and Commission v Germany, paragraph 88).

90 That case-law, which was developed in relation to foodstuffs enriched with nutrients such as vitamins and minerals, is also applicable to products based on medicinal herbs intended for human consumption.

91 In the present case, while, as was stated in paragraph 87 of this judgement, Community law does not, in principle, preclude a system of prior authorisation, it remains however clear that the issuing of marketing authorisation pursuant to Article 8 of Directive 2001/83 is subject to particularly strict requirements (Commission v Germany, paragraph 89). In that regard, it must be observed that the Kingdom of Spain has not contended that all or some of the products withdrawn from the market in 2002 and 2003 could take advantage of a simplified registration procedure such as that established by Articles 16a to 16i of that directive for traditional herbal medicinal products.

92 In those circumstances, the obligation to obtain marketing authorisation before being able to market products based on medicinal herbs on Spanish territory may be regarded as in accordance with the principle of proportionality only if it is actually necessary, in each case, to safeguard public health (see, to that effect, Commission v Austria, paragraph 94, and Commission v Germany, paragraph 90).

93 Such a restriction on the free movement of goods must therefore necessarily be based on a detailed assessment, on a case by case basis, of the risk alleged by the Member State invoking Article 30 EC (see, to that effect, Commission v Austria, paragraph 96, and Commission v Germany, paragraph 91).

94 However, the criterion used by the Spanish authorities for requiring marketing authorisation, namely the fact that the medicinal herb on which the manufactured product is based is not listed in the Annex to the 1973 Order, does not allow, on the basis of the most

recent scientific data, account to be taken of the actual risk to public health presented by such products.

95 It follows from the foregoing that the Spanish administrative practice complained of in this plea does not meet the requirements of Community law, as set out in the case-law of the Court referred to in paragraphs 89 to 93 of this judgment, and in particular the requirement that there be a detailed assessment, on a case by case basis, of the risk to public health which the marketing of a product based on medicinal herbs might entail.

96 It cannot be argued that traders have the option of applying for the inclusion of the herb contained in their product in the annex to the 1973 Order. As clarified by the Kingdom of Spain itself, a trader can have a herb included in that annex only if he proves that it has been traditionally used. The fact that a product contains a medicinal herb which has not been traditionally used does not necessarily imply that that product presents a risk to public health.

97 Moreover, as regards effective consumer protection, to which the Kingdom of Spain also refers, it is naturally legitimate to seek to ensure that consumers are properly informed about the products which they consume (Commission v France, cited above, paragraph 74).

98 However, the Kingdom of Spain has not explained why appropriate labelling, informing consumers of the nature, the ingredients and the characteristics of products based on medicinal herbs, would not adequately meet that objective where the classification of those products as medicinal products is not justified on grounds of public health (see, by analogy, Commission v France, paragraph 75).

99 Consequently, the first complaint, alleging infringement of Articles 28 EC and 30 EC, is well founded.

The alleged failure to fulfil obligations under Articles 1 and 4 of Decision No 3052/95

Arguments of the parties

100 The Commission considers that the Kingdom of Spain ought to have notified it of the market withdrawal measures taken in 2002 and 2003 in respect of products of Ynsadiet, Tregor and Taxón, within a period of 45 days from the date when each of those measures was taken. By failing to do so, the Kingdom of Spain has infringed Articles 1 and 4 of Decision No 3052/95.

101 The Commission claims that the products based on medicinal herbs withdrawn from the market by the Spanish authorities were lawfully marketed in other Member States, generally as food supplements or dietary products.

102 The Commission claims that the Spanish authorities had been made aware of that fact. First, the undertakings whose products were involved had stated to those authorities that some of those products were lawfully produced or marketed in other Member States. Secondly, the Commission had previously noted that fact in its reasoned opinion sent to the Kingdom of Spain, which did not challenge the truth of the matter.

103 The Kingdom of Spain contends, first, that some of the products withdrawn from the market were manufactured in Spain and that, on no occasion did Ynsadiet, Tregor and Taxón submit to the Spanish authorities documents establishing that those products were lawfully marketed in another Member State. Second, the defendant Member State maintains that it was not informed that some of the products withdrawn from the market had been imported from another Member State where they were lawfully produced. Also, the Commission has not so far provided any detailed information on that matter.

104 Consequently, in accordance with Article 1 of Decision No 3052/95, since the procedure laid down by that decision was not applicable, the Kingdom of Spain was not obliged to notify the abovementioned withdrawal decisions.

Findings of the Court

105 Under Article 1 of Decision No 3052/95, '[w]here a Member State takes steps to prevent the free movement or placing on the market of a particular model or type of product lawfully produced or marketed in another Member State, it shall notify the Commission accordingly where the direct or indirect effect of the measure is', in particular, 'a general ban on the goods', 'a refusal to allow the goods to be placed on the market' or 'withdrawal of the goods from the market'.

106 Decision No 3052/95 defines 'measure' as any measure taken by a Member State, except for judicial decisions, which has the effect of restricting the free movement of goods lawfully produced or marketed in another Member State, regardless of its form or the authority from which it emanates (Joined Cases C 388/00 and C 429/00 *Radiosistemi* [2002] ECR I 5845, paragraph 68, and Case C 432/03 *Commission v Portugal* [2005] ECR I 9665, paragraph 57).

107 The wording ‘a particular model or type of product lawfully produced or marketed in another Member State’ of Article 1 of Decision No 3052/95 indicates that the obligation to notify laid down by that provision falls on the Member State concerned not only where products produced or marketed in another Member State are withdrawn from the market, but also where products produced in its own territory are withdrawn from the market while products of the same model or of the same type are lawfully produced and/or marketed in another Member State and would also be subject to withdrawal from the market if they were imported into the Member State concerned.

108 That interpretation is also consistent with the purpose of Decision No 3052/95. The mere existence of legislation or of a practice in a Member State applicable without distinction to domestic and imported products is likely to deter traders from importing into that Member State goods lawfully produced or marketed in another Member State and therefore has the effect of restricting the free movement of those goods.

109 However, the obligation to notify laid down in Article 1 of Decision No 3052/95 falls on the Member State concerned only if it knows, or could reasonably be expected to know, that the measure adopted by it has the effect of hindering the marketing in its territory of products lawfully produced or marketed in another Member State. The onus is on the Commission to provide evidence to that effect.

110 In the present case, it must therefore be ascertained, first, whether, when the Spanish authorities withdrew in 2002 and 2003 the products of Ynsadiet, Tregor and Taxón from the Spanish market, there were products based on medicinal herbs not listed in the annex to the 1973 Order that were lawfully produced and/or marketed in another Member State and, secondly, whether the Spanish authorities were aware of that fact.

111 In that regard, the Kingdom of Spain contends that it was the Commission itself, in the reasoned opinion, that informed it that some of the products marketed by Ynsadiet in Spain and withdrawn from the Spanish market had been lawfully produced by Biover NV in Belgium, where the products were certified by the Belgian Ministry of Health and Social Affairs.

112 However, as the Commission correctly points out, immediately after the inspection which was carried out on 15 and 16 July 2003 at the premises of Ynsadiet, that company informed the Spanish authorities that the products in the Biover range were imported from

Belgium, where they were lawfully produced and marketed, and repeated that information in its action against the decision to withdraw its products from the Spanish market.

113 The Commission has also correctly stated that the Belgian origin of those products was not disputed by the Spanish authorities, since it was mentioned in a fax sent on 21 November 2003 by AEMPS to Ynsadiet.

114 It must also be observed that the objective of the procedure for the exchange of information between the Member States themselves and the Commission established by Decision No 3052/95 is not to protect the rights of any specific trader, but, as is clear from the fifth recital of the preamble to that decision, to identify the problems encountered in the implementation of the free movement of goods with a view to finding appropriate solutions to them. Accordingly, when the Spanish authorities were informed that products in the Biover range had been imported from Belgium, it was their duty, if they considered the evidence that those products were lawfully produced and/or marketed in Belgium to be insufficient, to check the facts with the Belgian authorities, in accordance with the duty of genuine cooperation laid down in Article 10 EC, and they could not take refuge behind any failings on the part of Ynsadiet.

115 Consequently, the second ground of complaint, that there was an infringement of Articles 1 and 4 of Decision No 3052/95, is also well founded.

116 In light of all of the foregoing, it must be held that:

– by withdrawing from the market products based on medicinal herbs lawfully produced and/or marketed in another Member State, under an administrative practice consisting in withdrawing from the market any product containing medicinal herbs not included either in the annex to the 1973 Order or in the annex to the 2004 Order, other than a preparation the constituents of which are exclusively one or more medicinal herbs or whole parts of such herbs, or crushed or powdered parts of such herbs, on the ground that that product is deemed to be a medicinal product marketed without the requisite marketing authorisation, and

– by not communicating that measure to the Commission,

the Kingdom of Spain has failed to fulfil its obligations under Articles 28 EC and 30 EC and Articles 1 and 4 of Decision No 3052/95.

3.3.5. Costs

117 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the Kingdom of Spain has been unsuccessful, the Kingdom of Spain must be ordered to pay the costs.

3.3.6. The Court's decision

On those grounds, the Court (First Chamber) hereby:

1. – declares that, by withdrawing from the market products based on medicinal herbs lawfully produced and/or marketed in another Member State, under an administrative practice consisting in withdrawing from the market any product based on medicinal herbs not included either in the annex to the Ministerial Order on the creation of a special register of medicinal herb-based preparations (Orden Ministerial por la que se establece el registro especial para preparados a base de especies vegetales) of 3 October 1973, as amended, or in the annex to the Order SCO/190/2004 of the Ministry of Health and Consumer Affairs, establishing the list of plants sale of which to the public is prohibited or restricted because of their toxicity (Orden SCO/190/2004 por la que se establece la lista de plantas cuya venta al público queda prohibida o restringida por razón de su toxicidad) of 28 January 2004, other than a preparation the constituents of which are exclusively one or more medicinal herbs or whole parts of such herbs, or crushed or powdered parts of such herbs, on the ground that that product is deemed to be a medicinal product marketed without the requisite marketing authorisation, and

– by not communicating that measure to the Commission of the European Communities, the Kingdom of Spain has failed to fulfil its obligations under Articles 28 EC and 30 EC and Articles 1 and 4 of Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community.
2. Orders the Kingdom of Spain to pay the costs.

3.4. Duphar BV and others v The Netherlands State¹⁴

3.4.1. Judgment

1 by order dated 16 september 1982 , which was received at the court on 29 september 1982 , the president of the arrondissementsrechtbank (district court) , the hague , referred to the court for a preliminary ruling under article 177 of the eec treaty several questions on the interpretation of articles 3 , 5 , 30 , 34 , 36 , 85 and 86 of the treaty and of council directive 65/65/eec of 26 january 1965 on the approximation of provisions laid down by law , regulation or administrative action relating to proprietary medicinal products (official journal , english special edition 1965-66 , p . 20) and of council directive 75/319/eec of 20 may 1975 on the approximation of provisions laid down by law , regulation or administrative action relating to proprietary medicinal products (official journal 1975 , l 147 , p . 13) , to enable it to decide whether certain national rules concerning the supply of medicinal preparations and dressings under a sickness insurance scheme were compatible with those provisions .

2 the questions were raised in an action brought against the netherlands state by 23 pharmaceutical undertakings for the adoption of an interim decision declaring that articles 2 and 3 of the besluit farmaceutische hulp ziekenfondsverzekering (sickness insurance fund (provision of medicinal preparations) order) 1982 (staatscourant no 139 of 23 july 1982) and the annexes thereto were inoperative since they were incompatible with community law and in particular with articles 3 , 5 , 30 , 34 , 36 , 85 and 86 of the treaty and directives 65/65 and 75/319 , cited above .

3 the order is intended to enhance the quality of pharmaco-therapeutical services and to eliminate the considerable deficit of the netherlands health-care scheme . To that end , article 2 provides that persons insured under the compulsory health-care scheme are no longer to be entitled to be supplied with the medicinal preparations and health products exhaustively listed

¹⁴ Judgment of the Court of 7 February 1984; Case 238/82; Duphar BV and others v The Netherlands State.

in annex 1 and 2 to the order , and article 3 provides that they are not to be entitled to be supplied with the medicinal preparations listed in annex 4 to the order except with the prior authorization of the sickness fund , which is to be granted only if it may reasonably be assumed that if the preparations in question are not supplied this will have an unacceptably harmful effect on the outcome of the treatment .

4 according to the explanatory memorandum to the order in question , the exclusion of products as a result of their being listed in the annexes thereto is justified by considerations relating specifically to each annex . The exclusion of the medical preparations listed in annex 1 is based on their price and the fact that , in the view of the central medico-pharmaceutical committee , there are in each case other medicinal preparations which have the same therapeutic effect but whose price is lower . The products listed in annex 2 are excluded because they are over-the-counter products which can be marketed otherwise than through a pharmacist . The exclusion of the medicinal preparations listed in annex 4 is justified by the fact that , in the view of the abovementioned central medico-pharmaceutical committee they must , for reasons described as being ' ' of a pharmaco-therapeutical nature ' ' , be prescribed only in very specific cases .

5 considering that the decision in the case turned on the interpretation of various rules of community law , the president of the arrondissementsrechtbank referred the following questions to the court for a preliminary ruling :

' ' (A) must community law , laid down in articles 30 , 34 and 36 of the eec treaty , be construed as meaning that those articles prevent a member state from introducing , with a view to making savings in the field of the supply of medicinal preparations to persons insured under sickness insurance schemes , unilateral provisions under which insured persons are deprived of a right to be supplied with specific named medicinal preparations and dressings?

(b) must community law , laid down in article 5 of the eec treaty , in conjunction with article 21 read with articles 11 , 12 and 5 of directive 65/65 and article 32 read with articles 28 and 31 of directive 75/319 , be construed as meaning that those provisions have direct effect?

(c) if so , must those provisions be construed as set out in subparagraph (a) above?

(d) must community law , laid down in article 3 (f) in conjunction with articles 85 and 86 of the eec treaty , be construed as set out in subparagraph (a) above?

I - the first question

6 the first question seeks in substance to ascertain whether the prohibition of measures having an effect equivalent to quantitative restrictions on imports (article 30) and on exports (article 34) applies to measures (of the type described above) whereby a member state , with a view to achieving economies regarding compulsory health-care insurance , prevents specifically named medicinal preparations and dressings from being supplied to persons insured under the scheme . The national court also wishes to know whether , if that part of the question is answered in the affirmative , article 36 of the treaty allows an exception to that prohibition .

7 for the purpose of answering the first question , it is appropriate to consider how articles 30 , 34 and 36 of the treaty are to be interpreted in relation to the particular features of the national legislation in question .

A - the interpretation of articles 30 and 36 of the treaty

8 the plaintiffs in the main proceedings propose that article 30 should be interpreted as meaning that rules such as those with which this case is concerned constitute a measure having an effect equivalent to a quantitative restriction on imports because they restrict intra-community trade and make it impossible for the suppliers of certain imported medicinal preparations to sell them on the market in question since the proportion of the total consumption of medicinal preparations charged to the sickness funds amounts to 70% .

9 the plaintiffs in the main proceedings argue that such a measure does not escape the prohibition contained in article 30 merely because it applies without distinction to national and imported products . According to previous decisions of the court , even measures which apply without distinction to national products and those imported from other member states but give rise to obstacles to intra-community trade do not escape the prohibition of measures having equivalent effect unless :

(a) no community rules exist ;

(b)the obstacles are the result of disparities between national laws regarding the marketing of a product ;

(c)imperative grounds exist relating inter alia to the effectiveness of fiscal controls , the protection of public health , the fairness of commercial transactions or the protection of the consumer ; and

(d)those imperatives render the obstacles necessary .

10 according to the plaintiffs in the main proceedings those conditions are not satisfied in any of the three cases in which medicinal preparations are excluded by the annexes to the contested order . As regards exclusion of medicinal preparations by reason of their price (annex 1) they claim that even if the concern to achieve economies in the costs of health care justifies certain restrictions upon the fundamental rule of the free movement of goods , a national measure which entails such a wide-ranging prohibition is excessive . The desired aim could be attained by measures which did not affect the functioning of the common market and competition to such an extent . As regards the over-the-counter products (annex 2), they deny that any of the imperative reasons accepted by the previous decisions of the court exist , in particular the justification based on the protection of public health . As regards medicinal preparations excluded for reasons described as ' ' pharmaco-therapeutical ' ' (annex 4), they also deny that the conditions mentioned above are satisfied , contending in particular that the obstacle is not the result of any disparity between national laws on the marketing of the products in question .

11 the netherlands state , the defendant in the main proceedings , submits that the prohibition contained in article 30 cannot extend to measures of the type with which the main proceedings are concerned . It considers in the first place that there is no question of any obstacle to intra-community trade . Where a public authority finances by far the greater part of the consumption of medicinal preparations and other health-care products , it is in the position of an economic operator and accordingly is , like any other such operator , entitled to make a choice and to choose among the preparations on the market , giving preference to one rather than to another . Where , as in this case , the national authority made its decision on the basis of objective considerations inspired by the concern to safeguard the quality of the care , there can be no question of obstacles to trade between member states .

12 the defendant in the main proceedings adds that , even if measures of the type in question could be regarded as capable of hindering trade , they nevertheless do not constitute measures having an effect equivalent to quantitative restrictions prohibited by article 30 . Those measures , which apply without distinction to national and imported products , were adopted

for imperative reasons - in this case the rationalization , and therefore the continuation , of a national health-care scheme - which , by virtue of the judgment of the court of 20 february 1979 (case 120/79 rewe (1979) ecr 649), justify obstacles of that kind so that they escape the prohibition contained in article 30 . Finally , the defendant in the main proceedings claims , in the alternative , that even if the measures in question were to be regarded as measures having an effect equivalent to quantitative restrictions they would fall within the exception provided for in article 36 of the treaty as restrictions justified on the grounds of the protection of health .

13 the commission considers that the order in question constitutes a measure having an effect equivalent to a quantitative restriction . It points out however that , in its judgment of 20 february 1979 (cited above) , the court did not give an exhaustive list of the imperative requirements which might justify a national measure affecting the volume of imports . It considers that the order , which is intended to rationalize the financial management of a sickness insurance scheme , could be regarded as compatible with article 30 even if it affected trade . The measure applies objectively to medicinal preparations manufactured in the netherlands and to imported medicinal preparations . The products are not treated differently according to their origin . Moreover , no measure capable of directly affecting the marketing of the products in the strict sense has been adopted . Such marketing remains wholly unrestricted , so that anyone can obtain the medicinal preparations in question , if necessary on the basis of a prescription . However , if the court should decide that the contested measures are incompatible with article 30 of the treaty , the commission considers that the grounds of justification set out in article 36 do not apply in this case .

14 the danish government observes that it does not consider national rules which , for social reasons and on the basis of objective criteria , provide for a public scheme for assistance with the provision of pharmaceutical preparations is contrary to article 30 et seq . Of the treaty , provided that , in the selection of the proprietary medicinal preparations in respect of which assistance may be granted , account is taken exclusively , on the basis of an objective and fair assessment , of their therapeutic value and of the expenses incurred for normal and necessary medical treatment .

15 in order to determine the scope of the prohibition contained in article 30 of the treaty in relation to national measures of the type in question , it should , in the first place , be noted that the rules whose compatibility with national law is to be considered by the national court

display the particular feature that , in principle , they provide for reimbursement , to a substantial percentage of the population , of the price paid for all medicinal preparations which may be prescribed to patients by an approved doctor . In that respect they are different from the legislation of other member states which draw up a restrictive list of the medicinal preparations or like products in respect of which reimbursement is permitted . That is why the netherlands rules , with a view to attaining their objective of reducing costs , set out limitative lists excluding preparations .

16 although it is not possible , contrary to the contention of the defendant in the main proceedings , to equate the competent authority of a member state which , within the framework of a health-care insurance scheme financed by contributions from the insured persons and by financing from the public authorities , draws up rules governing and limiting reimbursement of the costs of health care , with an economic operator who in each case freely chooses the goods which he acquires on the market , it must be recognized that community law does not detract from the powers of member states to organize their social security systems and to adopt , in particular , provisions intended to govern the consumption of pharmaceutical preparations in order to promote the financial stability of their health-care insurance schemes .

17 likewise , it must be recognized that in a scheme which - like that in force in the netherlands - is based on the principle of reimbursement in respect of all medicinal preparations which may be prescribed , it is not in principle incompatible with community law for the member state concerned , with a view to achieving its aim of limiting costs , to prepare limitative lists excluding certain products from the reimbursement scheme .

18 even if measures such as the provisions in question do not relate directly to the importation of medicinal preparations from other member states , the fact cannot be overlooked that , depending on the manner of their application and the use made of them , they may affect the possibilities of marketing the preparations and , to that extent , they may indirectly influence the possibilities of importation .

19 in that connection it should be borne in mind that 80% of the medicinal preparations consumed in the netherlands are imported and that the proportion thereof charged to the public insurance schemes amounts in all to 70% . It follows that , where reimbursement by the insurance authority is excluded in respect of a medicinal preparation , purchases of that

preparation fall and consequently there is a risk that the preparation in question will be totally eliminated from the national market .

20 however , in view of the special nature , in that respect , of the trade in pharmaceutical products , namely the fact that social security institutions are substituted for consumers as regards responsibility for the payment of medical expenses , legislation of the type in question cannot in itself be regarded as constituting a restriction on the freedom to import guaranteed by article 30 of the treaty if certain conditions are satisfied .

21 in that regard it must be stressed that for such legislation to be in conformity with the treaty the choice of the medicinal preparations to be excluded must be free of any discrimination to the detriment of imported medicinal preparations . To that end , the exclusionary lists must be drawn up in accordance with objective criteria , without reference to the origin of the products , and must be verifiable by any importer . If those conditions are fulfilled , an importer may secure access to the netherlands market provided that he is in a position to market a product which , whilst having the same therapeutic value , offers a price advantage over some other product available on the market . Such rules would in no way detract from the freedom to market any product meeting that requirement , which relates not to the nature of the product but only to its price .

22 the answer to the first question should therefore be that provisions adopted within the framework of a compulsory national health-care scheme with the object of refusing insured persons the right to be supplied , at the expense of the insurance institution , with specifically named preparations are compatible with article 30 of the treaty if the determination of the excluded medicinal preparations involves no discrimination regarding the origin of the products and is carried out on the basis of objective and verifiable criteria , such as the existence on the market of other , less expensive products having the same therapeutic effect , the fact that the preparations in question are freely marketed without the need for any medical prescription , or are products excluded from reimbursement for reasons of a pharmacotherapeutic nature justified by the protection of public health , and provided that it is possible to amend the lists whenever compliance with the specified criteria so requires .

23 if the national court should find that the measure whose compatibility with community law it is called upon to consider does not meet the conditions to which such conformity is subject , it should be borne in mind with regard to the application of article 36 of the treaty , as the court has held on many occasions (for example the judgment of 19 december 1961 in case

7/61 commission v italy (1961) ecr 317), that article 36 relates to measures of a non-economic nature . That provision cannot therefore justify a measure whose primary objective is budgetary inasmuch as it is intended to reduce the operating costs of a sickness insurance scheme .

B - the interpretation of article 34²⁰ of the treaty

24 the first question also seeks to ascertain whether article 34 of the treaty must be interpreted as meaning that it precludes national rules of the type in question . The plaintiffs in the main proceedings maintain that the contested order constitutes a measure having an effect equivalent to a quantitative restriction on exports within the meaning of that article .

25 as the court has already stated in its judgment of 8 november 1979 (case 15/79 groenveld (1979) ecr 3409), article 34 concerns national measures which have as their specific object or effect the restriction of patterns of exports and thereby the establishment of a difference in treatment between the domestic trade of a member state and its export trade in such a way as to provide a particular advantage for national production or for the domestic market of the state in question .

26 that part of the first question must therefore be answered in the negative .

Ii - the second and third questions

27 the second and third questions submitted by the president of the arrondissementsrechtbank seek essentially to ascertain whether the provisions of article 5 of the treaty in conjunction with the provisions of articles 5 , 11 , 12 and 21 of council directive 65/65 of 26 january 1965 and the provisions of article 32 in conjunction with the provisions of articles 28 and 31 of council directive 75/319 of 20 may 1975 have direct effect (second question) and , if so , whether they preclude rules of the kind at issue in this case (third question) .

28 as the commission has rightly contended , the order in question does not concern access to the market within the meaning of the two directives cited , since the validity of the authorizations granted by application of those directives is not called in question . New products brought onto the netherlands market may be granted authorization as soon as they satisfy the prescribed conditions . The third question must therefore be answered in the negative . In view of those considerations , the second question becomes devoid of purpose .

Iii - the fourth and fifth questions

29 in his fourth and fifth questions , the president of the arrondissementsrechtbank asks whether the provisions of article 3 (f), combined with those of articles 85 and 86 of the treaty , have direct effect and preclude rules of the kind at issue in this case .

30 articles 85 and 86 of the treaty form part of the competition rules ' ' applicable to undertakings ' ' and therefore are not relevant to an assessment of the question whether the legislation of the type at issue in the main proceedings is in conformity with community law .

3.4.2. Costs

31 the costs incurred by the government of the kingdom of denmark , the government of the italian republic and the commission of the european communities , which have submitted observations to the court , are not recoverable . As these proceedings are , so far as the parties to the main proceedings are concerned , in the nature of a step in the matter for that court , the decision on costs is a matter for that court .

3.4.3. The Court's decision

On those grounds ,

The court

In reply to the questions submitted to it by the president of the arrondissementsrechtbank , the hague , by order of 16 december 1982 , hereby rules :

1 . Provisions adopted within the framework of a compulsory national health-care scheme with the object of refusing insured persons the right to be supplied , at the expense of the insurance institution , with specifically named medicinal preparations are compatible with article 30 of the treaty if the determination of the excluded medicinal preparations involves no discrimination regarding the origin of the products and was carried out on the basis of objective and verifiable criteria , such as the existence on the market of other , less expensive products having the same therapeutic effect , the fact that the preparations in question are freely marketed without the need for any medical prescription , or are products excluded from

reimbursement for reasons of a pharmaco-therapeutic nature justified by the protection of public health , and provided that it is possible to amend the lists whenever compliance with the specified criteria so requires .

2 . Article 36⁹ of the eec treaty cannot justify a measure whose primary objective is budgetary inasmuch as it is intended to reduce operating costs of a sickness insurance scheme .

3 . Article 34²⁰ of the treaty does not preclude a system of the kind described in the order making the reference .

4 . Article 5²⁷ of the treaty and the provisions of council directives 65/65 of 26 january 1965 (official journal , english special edition 1965-66 , p . 20) and 75/319 of 20 may 1975 (official journal 1975 , l 147 , p . 1) do not preclude such a system .

5 . Articles 85²⁸ and 86²⁹ of the treaty are not relevant to the question whether legislation of the type at issue in the main proceedings is in conformity with community law .

3.5. Commission of the European Communities v Italian Republic¹⁵

3.5.1. Judgment

1 By its application, the Commission of the European Communities requests the Court to declare that, by failing to adopt the laws, regulations and administrative provisions necessary to comply with Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13; ‘the Directive’), the Italian Republic has failed to fulfil its obligations under Article 15 of the Directive.

¹⁵ Judgment of the Court (Third Chamber), 16 June 2005; Case C-456/03; Commission of the European Communities v Italian Republic

3.5.2. Legal context

Community legislation

2 Article 1(1) of the Directive provides:

‘Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.’

3 Article 3(1) of the Directive states:

‘For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.’

4 Article 5 of the Directive provides:

‘1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.’

5 Article 6 of the Directive states:

‘1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.’

6 Chapter II of the Directive is devoted to the scope of the protection conferred by a patent relating to a biotechnological invention. It contains the following provisions:

‘Article 8

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product [is] incorporated and in which the genetic information is contained and performs its function.

Article 10

The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

Article 11

1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.’

7 Article 12 of the Directive provides:

‘1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;

(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

...’

8 Finally, Article 15 of the Directive provides:

‘1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.’

3.5.3. National legislation

9 Article 5 of the Italian Civil Code provides:

‘Acts of disposition of one’s body are prohibited when they cause a permanent diminution of physical integrity or are otherwise contrary to law, public policy or morality.’

10 Article 1bis(1) of Royal Decree No 1127 of 29 June 1939 (GURI, No 189, of 14 August 1939; ‘Royal Decree No 1127/39’) provides:

‘In particular, a patent shall confer on its holder the following exclusive rights:

(a) where the patent relates to a product, the right to prohibit third parties, without his authorisation, to produce, use, market or sell the product concerned or to import it for such purposes;

(b) where the patent relates to a process, the right to prohibit third parties, without his authorisation, to apply the process and to use, market, sell or import for such purposes the product directly obtained from the process concerned.’

11 Article 12 of Royal Decree No 1127/39 provides:

‘Inventions which are new, involve an inventive step and are susceptible of industrial application shall be patentable.

The following, in particular, shall not be considered to be inventions for the purposes of the preceding paragraph:

(a) discoveries, scientific theories and mathematical models;

The provisions of the preceding paragraph shall prevent the matters referred to therein from being patentable only in so far as the patent application or the patent relates to discoveries, theories, plans, principles, processes and programmes considered as such.

Processes for the surgical or therapeutic treatment of humans or animals and diagnostic procedures used on humans and animals shall not be considered to be inventions for the purposes of the first paragraph ...’

12 Article 13 of Royal Decree No 1127/39 states:

‘Inventions shall not be patentable where their exploitation would be contrary to public policy or morality; however, exploitation of an invention cannot be deemed to be contrary thereto merely because it is prohibited by law or administrative provision.

Animal breeds and essentially biological processes for obtaining them shall also not be patentable; this provision shall not apply to microbiological processes or the product of those processes.’

13 Article 54(2) of Royal Decree No 1127/39 provides:

‘A compulsory licence as referred to in paragraph 1 may also be granted

(b) if the invention protected by the patent cannot be used without infringing the rights arising from a patent granted on the basis of a prior application. In this case, a licence may be granted to the holder of the subsequent patent to the extent necessary for exploitation of the invention so long as the latter constitutes significant technical progress of considerable economic importance compared with the subject-matter of the prior patent. Without prejudice to Article 54bis(5), the licence thus obtained shall not be assignable separately from the invention which depends thereon. The holder of the patent on the principal invention is entitled in turn to grant of a compulsory licence, on reasonable terms, in respect of the patent on the dependent invention.’

3.5.4. Pre-litigation procedure

14 After establishing that the Italian Republic had not informed it of the laws, regulations and administrative provisions adopted by the Italian Republic to comply with the Directive, and in the absence of any other information from which it could conclude that those measures had been adopted, the Commission sent a letter of formal notice under Article 226 EC⁶ to that Member State on 30 November 2000, calling on it to submit its observations within a period of two months.

15 On 19 December 2002, having received no reply within the period set, the Commission issued a reasoned opinion in which it concluded that, by not adopting the provisions necessary to comply with the Directive, the Italian Republic had failed to fulfil its obligations under the Directive. The Commission called on the Italian Republic to adopt those provisions within a period of two months from receipt of the reasoned opinion.

16 The Italian authorities replied by letter of 6 February 2003. Subsequently, by letter of 10 July 2003, they indicated to the Commission that preparation of the provisions needed to transpose the Directive had reached an advanced stage.

17 Taking the view that this information was unsatisfactory, the Commission decided to bring the present action.

The action

18 It is to be observed at the outset that the Italian Government, while not expressly raising a plea of inadmissibility, puts forward a number of objections of a procedural nature which may affect the admissibility of the action. These objections relating to admissibility should accordingly be examined first, before assessing the merits of the action.

Admissibility

19 The Italian Government contends that, given the wording of Article 1 of the Directive, according to which the Member States must adapt their national patent law ‘if necessary’ – an obligation which presupposes that there is already a high degree of protection and of harmonisation of national legislation – the Commission could not in its application merely record the formal lack of transposition of the Directive within the period laid down, but had the task, at this stage of the proceedings, of adducing the necessary specific proof that the domestic law in force failed wholly or partially to comply with the Directive. The particulars put forward in this regard by the Commission in its reply were submitted out of time and consequently cannot be taken into account.

20 The Commission submits that Article 1 of the Directive does not impose any particular burden of proof on it when it complains that a Member State has not enacted any

implementing measures. Here, the Italian authorities never stated during the pre-litigation procedure that domestic law complied with the Directive. Quite to the contrary, by indicating that an implementing law was in the course of being drawn up, they admitted, at least implicitly, that specific provisions had to be adopted in order to transpose the Directive.

21 It must be stated that the Italian Government's arguments in this respect in effect contest on two counts the proper conduct of the infringement procedure initiated by the Commission and, therefore, the admissibility of the present action.

22 First, by pointing out that the application merely records the absence of any transposition of the Directive and does not show in what way the domestic law in force does not already comply with the Directive, the Italian Government complains not only that the Commission has not proved the substance of the failure to fulfil obligations but also that it did not place before the Court in the application the particulars needed to establish that that failure has occurred. Second, by objecting to the possibility of this material being put forward for the first time in the reply, the Italian Government complains that the Commission has put forward pleas out of time.

23 So far as concerns the first of those contentions, in accordance with the case-law an application must, by virtue of Article 21 of the Statute of the Court of Justice and Article 38(1)(c) of the Rules of Procedure of the Court of Justice, contain *inter alia* a brief statement of the pleas in law on which the application is based. Accordingly, in any application lodged under Article 226 EC, the Commission must indicate the specific complaints upon which the Court is called to rule and, at the very least in summary form, the legal and factual particulars on which those complaints are based (see, *inter alia*, Case C-347/88 *Commission v Greece* [1990] ECR I-4747, paragraph 28).

24 The application lodged by the Commission, according to which it essentially alleges that the Italian Republic has not adopted any measure necessary for transposing the Directive,

contains a clear statement of this complaint and of the legal and factual particulars on which it is based.

25 Admittedly, it is common ground that in that pleading the Commission did not seek to show in what way the Italian law in force did not comply with the Directive.

26 However, it should be remembered that while, in proceedings under Article 226 EC for failure to fulfil obligations, it is indeed incumbent upon the Commission, which has the burden of proving the allegation that the obligation has not been fulfilled, to place before the Court the information needed to enable the Court to establish that it has not been fulfilled, in doing which the Commission may not rely on any presumption, it is also for the Member States, under Article 10 EC, to facilitate the achievement of the Commission's tasks, which consist in particular, pursuant to Article 211 EC, in ensuring that the provisions of the EC Treaty and the measures taken by the institutions pursuant thereto are applied (see, *inter alia*, Case 96/81 *Commission v Netherlands* [1982] ECR 1791, paragraphs 6 and 7, and Case C-408/97 *Commission v Netherlands* [2000] ECR I-6417, paragraphs 15 and 16). It is for that reason that Article 15 of the Directive, like other directives, imposes upon the Member States an obligation to provide information.

27 The information which the Member States are thus obliged to supply to the Commission must be clear and precise. It must indicate unequivocally the laws, regulations and administrative provisions by means of which the Member State considers that it has satisfied the various requirements imposed on it by the directive. In the absence of such information, the Commission is not in a position to ascertain whether the Member State has genuinely implemented the directive completely. The failure of a Member State to fulfil that obligation, whether by providing no information at all or by providing insufficiently clear and precise information, may of itself justify recourse to the procedure under Article 226 EC in order to establish the failure to fulfil the obligation (Case 96/81 *Commission v Netherlands*, cited above, paragraph 8).

28 In the present case, it is common ground that the Italian Government not only did not reply to the Commission's letter of formal notice but additionally did not state in its response to the reasoned opinion that the Directive was to be regarded as already transposed by the domestic law in force. Quite to the contrary, since it informed the Commission, both in its response to the reasoned opinion and in its subsequent letter of 10 July 2003, of the fact that the provisions needed to transpose the Directive were about to be adopted, the Italian Government implicitly, but certainly, gave the Commission to understand that the domestic law in force was not capable, without the adoption of specific measures, of transposing the Directive correctly and completely.

29 In those circumstances, the Italian Government cannot complain that the Commission, in its application, simply stated that the Directive had not been transposed at all within the period laid down and did not seek to show in what way the provisions of Italian domestic law in force did not comply with the Directive. As the Advocate General has stated in point 43 of his Opinion, the alleged lack of precision in the application results from the Italian Government's own conduct during the pre-litigation procedure (see, to this effect, Case C-408/97 *Commission v Netherlands*, cited above, paragraph 17).

30 That finding is not called into question by the fact that Article 1(1) of the Directive provides that the Member States are, 'if necessary', to adjust their national patent law to take account of the Directive's provisions. While this article allows the Member States to secure the substantive transposition of the Directive by means of their domestic legal rules in force, it does not in any event absolve them from the formal obligation to inform the Commission of the existence of those rules so that it can be in a position to assess whether the rules comply with the Directive.

31 Consequently, the Italian Government's present argument must be rejected. To the extent that, as to the remainder, the Italian Republic's line of argument seeks to dispute the allegation that it has failed to fulfil its obligations, that failure is to be examined when considering the substance.

32 So far as concerns, second, the admissibility of the arguments put forward in the reply in order to demonstrate that the domestic law in force did not comply with certain provisions of the Directive, it is to be remembered that it was only in its defence that the Italian Government pleaded that the domestic law in force complied with the Directive.

33 In these circumstances, the Commission cannot be reproached for having responded to those arguments for the first time in its reply; the Commission is entitled, as the Court has held, to clarify the form of order sought in order to take into account information furnished by a Member State in its defence (Case C-243/89 *Commission v Denmark* [1993] ECR I-3353, paragraph 20). Also, Article 42(2) of the Rules of Procedure expressly provides that a party is entitled to introduce a new plea in law in the course of proceedings in order to take account of matters of law or fact which come to light in the course of the procedure.

34 Consequently, the Italian Government cannot complain that the Commission put forward in its reply arguments which did not appear in its application.

35 It is, however, to be remembered that, in accordance with settled case-law, the subject-matter of an action under Article 226 EC for failure to fulfil obligations is also delimited by the pre-litigation procedure provided for by that provision, so that the application must be based on the same grounds and pleas as the reasoned opinion (see, *inter alia*, Case C-96/95 *Commission v Germany* [1997] ECR I-1653, paragraph 23, Case C-439/99 *Commission v Italy* [2002] ECR I-305, paragraph 11, and Case C-287/00 *Commission v Germany* [2002] ECR I-5811, paragraph 18).

36 According to the case-law, the purpose of the pre-litigation procedure is to give the State concerned the opportunity, on the one hand, to comply with its obligations under Community law and, on the other, to avail itself of its right to defend itself against the complaints formulated by the Commission (see Case C-392/96 *Commission v Ireland* [1999] ECR I-

5901, paragraph 51, *Commission v Italy*, cited above, paragraph 10, and Case C-117/02 *Commission v Portugal* [2004] ECR I-5517, paragraph 53).

37 The proper conduct of that procedure constitutes an essential guarantee required by the Treaty not only in order to protect the rights of the Member State concerned, but also so as to ensure that any contentious procedure will have a clearly defined dispute as its subject-matter (see Case C-1/00 *Commission v France* [2001] ECR I-9989, paragraph 53, and Case C-287/00 *Commission v Germany*, cited above, paragraph 17).

38 In the present case, it is clear that, as the Italian Government submits, in complaining in the course of the pre-litigation procedure that the Italian Republic had not adopted the provisions necessary to comply with the Directive, the Commission was essentially alleging that the Italian Republic had not transposed the Directive at all. On the other hand, in the arguments put forward in its reply regarding the domestic law in force, the Commission submits that the Italian Republic has not transposed certain provisions of the Directive, thereby requiring the domestic law in force to be examined in detail in order to ascertain which of those provisions have not in fact been transposed correctly or completely.

39 However, the requirement that the subject-matter of an action brought under Article 226 EC be circumscribed by the pre-litigation procedure provided for by that provision cannot be stretched so far as to mean that in every case the statement of complaints set out in the letter of formal notice, the operative part of the reasoned opinion and the form of order sought by the action must be exactly the same, provided that the subject-matter of the proceedings has not been extended or altered (see, to this effect, Case C-279/94 *Commission v Italy* [1997] ECR I-4743, paragraph 25, and Case C-139/00 *Commission v Spain* [2002] ECR I-6407, paragraph 19).

40 That is the case where, as here, the Commission, after alleging that a Member State has failed to transpose a directive at all, specifies in its reply that the transposition pleaded for the first time by the Member State concerned in its defence is in any event incorrect or

incomplete so far as certain provisions of the directive are concerned. Such a complaint is necessarily included in the complaint alleging a complete failure to transpose and is subsidiary to that complaint (see, to this effect, *Commission v Portugal*, cited above, paragraph 55).

41 It should be noted that in this instance the pre-litigation procedure attained its objective of protecting the rights of the Member State in question. The Italian Republic had the opportunity to comply with its obligations under the Directive since, as its response to the reasoned opinion and its subsequent letter of 10 July 2003 attest, it informed the Commission of the point reached in the procedure for adoption of the legislation envisaged for that purpose. In addition, the Italian Republic had the opportunity, in the course of this procedural phase, to show that its domestic law in force complied with the requirements laid down by the Directive, even if it considered it unnecessary to avail itself of that opportunity in this instance (see, in this regard, *Case 274/83 Commission v Italy* [1985] ECR 1077, paragraph 20).

42 Consequently, the Italian Government cannot complain that the Commission has extended or altered the subject-matter of the action as defined by the pre-litigation procedure.

43 In light of those considerations, the Italian Government's objections seeking to contest the admissibility of the present action must be rejected in their entirety.

3.5.6. Substance

44 In the form of order sought as set out in its application, the Commission complains that the Italian Republic has failed to adopt the provisions necessary to comply with the Directive. In its reply it submits 'for completeness' in response to the arguments put forward by the Italian Republic in this respect that the domestic law in force does not, in any event, comply with the Directive, in particular inasmuch as it does not adequately transpose Articles 3(1), 5(2), 6(2) and 8 to 12 of the Directive.

45 The Italian Government concedes that the Law transposing the Directive was not adopted within the period laid down by the Directive, since the legislative procedure was in progress. However, it submits that as the Commission did not adduce proof in its application that the domestic law in force did not comply with the Directive, the action must be dismissed. In any event, the Italian Government considers that domestic patent law complies with the Directive.

46 It is to be noted first of all that, as is common ground, the Italian Government, contrary to its obligation under Article 10 EC and Article 15 of the Directive, did not inform the Commission, whether during the period for transposition or during the pre-litigation procedure, of the domestic legal measures by means of which it considered that it had transposed the Directive. For the reasons set out in paragraph 30 of this judgment, it is irrelevant in this regard that the transposition pleaded did not have to be carried out because the domestic law in force complied with the Directive.

47 However, since the present action concerns not a failure to fulfil the obligation to provide information but a failure to fulfil the obligation to bring into force the laws, regulations and administrative provisions necessary to comply with the Directive, the mere fact that the Italian Republic did not inform the Commission that, in its view, the Directive was already transposed by the domestic law in force cannot, contrary to what the Commission appears to suggest, be sufficient to prove the alleged failure to fulfil an obligation.

48 In so far as the domestic legal provisions pleaded by the Italian Government were in force when the period set in the reasoned opinion expired, the Court must take them into account when determining whether that obligation has not been fulfilled (see, to this effect, Case C-152/98 *Commission v Netherlands* [2001] ECR I-3463, paragraph 21).

49 Accordingly, given the subject-matter of the action, in examining its merits the provisions of the Directive should be compared with the national laws, regulations and administrative measures by which the Italian Republic considers that it has implemented the Directive, in order to establish whether they transpose it adequately.

50 It should be remembered that, according to settled case-law, each of the Member States to which a directive is addressed is obliged to adopt, within the framework of its national legal system, all the measures necessary to ensure that the directive is fully effective, in accordance with the objective that it pursues (see, *inter alia*, Case C-478/99 *Commission v Sweden* [2002] ECR I-4147, paragraph 15, and Case C-233/00 *Commission v France* [2003] ECR I-6625, paragraph 75).

51 While it is therefore essential that the legal situation resulting from national implementing measures is sufficiently precise and clear to enable the individuals concerned to know the extent of their rights and obligations, it is none the less the case that, according to the very words of the third paragraph of Article 249 EC³⁰, Member States may choose the form and methods for implementing directives which best ensure the result to be achieved by the directives, and that provision shows that the transposition of a directive into national law does not necessarily require legislative action in each Member State. The Court has thus repeatedly held that it is not always necessary formally to enact the requirements of a directive in a specific express legal provision, since the general legal context may be sufficient for implementation of a directive, depending on its content. In particular, the existence of general principles of constitutional or administrative law may render superfluous transposition by specific legislative or regulatory measures provided, however, that those principles actually ensure the full application of the directive by the national authorities and that, where the relevant provision of the directive seeks to create rights for individuals, the legal situation arising from those principles is sufficiently precise and clear and that the persons concerned are put in a position to know the full extent of their rights and, where appropriate, to be able to rely on them before the national courts (see, *inter alia*, Case 29/84 *Commission v Germany* [1985] ECR 1661, paragraphs 22 and 23, and Case C-233/00 *Commission v France*, cited above, paragraph 76).

52 Consequently, it is important in each individual case to determine the nature of the provision, laid down in a directive, to which the action for failure to fulfil obligations relates, in order to gauge the extent of the obligation to transpose imposed on the Member States (Case C-233/00 Commission v France, paragraph 77).

53 It is in the light of those considerations that the various complaints raised by the Commission to demonstrate incomplete or incorrect transposition of the Directive should be examined.

The complaint alleging breach of Article 3(1) of the Directive

54 The Commission pleads that Italian legislation, in particular Article 12 of Royal Decree No 1127/39, contains no provision relating to the possibility of obtaining a patent for an invention concerning a product consisting of or containing biological material.

55 According to the Italian Government, the term ‘industrial invention’ adopted by Article 12 of Royal Decree No 1127/39 and as interpreted by national case-law is, however, broad enough to include biological material.

56 As to those submissions, by virtue of Article 3(1) of the Directive inventions which are new, involve an inventive step and are susceptible of industrial application are to be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

57 It follows from the very wording of this provision that it provides for a specific right allowing inventions making use of biological material to be patented, by requiring the

Member States, as is apparent from the third and eighth recitals in the preamble to the Directive, to adapt or add to national patent law in order to ensure effective and harmonised protection of biotechnological inventions that is such as to maintain and encourage investment in that field.

58 The Court has already held that, by requiring the Member States to protect biotechnological inventions by means of their national patent law, the Directive aims to prevent damage to the unity of the internal market which might result from the Member States' deciding unilaterally to grant or refuse such protection (Case C-377/98 *Netherlands v Parliament and Council* [2001] ECR I-7079, paragraph 18). In so doing, the Directive seeks, as is apparent from the fourth, fifth and sixth recitals in its preamble, to clarify the legal protection of biotechnological inventions in a context marked by differences between national laws and practices that could well become greater, in particular as a result of national case-law interpreting those laws.

59 In the present case, it is not in dispute that Italian patent law does not expressly provide that inventions making use of biological material are patentable, since Article 12 of Royal Decree No 1127/39, which is relied on by the Italian Government in this connection, does no more than set out generally the conditions for the patentability of any invention.

60 Furthermore, while the Italian Government submits that the national courts interpret broadly the term 'invention' adopted by domestic patent law, it has not cited any judicial decision affirming the patentability of inventions making use of biological material.

61 In those circumstances it appears that, despite the objective of clarification pursued by the Directive, a state of uncertainty remains as to whether it is possible to obtain protection for biotechnological inventions under Italian patent law.

62 Consequently, the Commission's complaint alleging breach of Article 3(1) of the Directive is well founded.

The complaint alleging breach of Article 5(2) of the Directive

63 The Commission submits that Italian legislation does not provide for the possibility of patenting an element isolated from the human body or otherwise produced by means of a technical process.

64 The Italian Government contends that Article 13 of Royal Decree No 1127/39 complies with Article 5(2) of the Directive. In addition, the only rule-making element of this provision is to be found in the final part of the sentence, according to which a genetic sequence 'may constitute a patentable invention, even if the structure of that element is identical to that of a natural element'. Given the broad definition adopted by national case-law of the term 'invention', the patentability of artificial reproduction of an element present in nature has never been precluded.

65 As to those submissions, under Article 5(2) of the Directive an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

66 As the Court has held in this connection, the elements of the human body are not patentable in themselves and their discovery cannot be the subject of protection. Only inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be the subject of an application for a patent (*Netherlands v Parliament and Council*, cited above, paragraph 72).

67 Thus, as is stated in the 20th and 21st recitals in the preamble to the Directive, an element of the human body may be part of a product which is patentable but it may not, in its natural environment, be appropriated (Netherlands v Parliament and Council, paragraph 73).

68 That distinction applies to work on the sequence or partial sequence of human genes. The result of such work can give rise to the grant of a patent only if the application is accompanied by both a description of the original method of sequencing which led to the invention and an explanation of the industrial application to which the work is to lead, as required by Article 5(3) of the Directive. In the absence of an application in that form, there would be no invention, but rather the discovery of a DNA sequence, which would not be patentable as such (Netherlands v Parliament and Council, paragraph 74).

69 Thus, the protection envisaged by the Directive covers only the result of inventive scientific or technical work, and extends to biological data existing in their natural state in human beings only where necessary for the achievement and exploitation of a particular industrial application (Netherlands v Parliament and Council, paragraph 75).

70 It follows that Article 5(2) of the Directive thus seeks to grant specific rights as regards the patentability of elements of the human body. Even though it provides merely for the possibility that a patent be granted, it obliges the Member States, as is apparent from the 17th to 20th recitals in the preamble to the Directive, to provide that their national law does not preclude the patentability of elements isolated from the human body, in order to encourage research aimed at obtaining and isolating such elements valuable to medicinal production.

71 In the present case, it is clear that Italian patent law makes no provision for the possibility of elements isolated from the human body constituting a patentable invention. In particular, contrary to the Italian Government's submissions, Article 13 of Royal Decree No 1127/39 contains no provision to this effect.

72 Furthermore, while the Italian Government submits that the national courts interpret broadly the term ‘invention’ adopted by domestic patent law, it has not cited any judicial decision acknowledging that it is possible to patent elements isolated from the human body.

73 In those circumstances it appears that, despite the objective of clarification pursued by the Directive, a state of uncertainty remains as to whether it is possible to obtain protection for such elements under Italian patent law.

74 Consequently, the Commission’s complaint alleging breach of Article 5(2) of the Directive is well founded.

The complaint alleging breach of Article 6(2) of the Directive

75 The Commission observes that Italian legislation, in particular Article 13 of Royal Decree No 1127/39, does not lay down that certain specific processes, such as the cloning of human beings and uses of human embryos for industrial and commercial purposes, are not patentable. Law No 40 of 19 February 2004 on medically assisted reproduction (GURI, No 45, of 24 February 2004; ‘Law No 40/2004’) which prohibits physical activities relating to embryos does not relate to the patentability of inventions.

76 The Italian Government contends that Article 13 of Law No 40/2004, read in conjunction with Article 13 of Royal Decree No 1127/39, implements adequately the principles laid down in Article 6(2) of the Directive, since Law No 40/2004 classifies human cloning and modification of the genetic identity of human beings as practices contrary to public policy and morality and therefore prevents them from being patentable. It further submits that Article 5 of the Civil Code prohibits acts of disposition of the human body, so that any processes intended to modify the genetic identity of a human being cannot have patent protection under Italian law.

77 It is to be remembered that, by virtue of Article 6(2) of the Directive, the following, in particular, are to be considered unpatentable: processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes; and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

78 Unlike Article 6(1) of the Directive, which allows the administrative authorities and courts of the Member States a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to *ordre public* (public policy) and morality, Article 6(2) allows the Member States no discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to give definition to the exclusion laid down in Article 6(1) (see, to this effect, *Netherlands v Parliament and Council*, paragraphs 37 to 39). It is apparent from the 40th recital in the preamble to the Directive that processes for cloning human beings must be excluded ‘unequivocally’ from patentability, since there is a consensus on this question within the Community.

79 It follows that, by expressly excluding from patentability the processes and uses to which it refers, Article 6(2) of the Directive seeks to grant specific rights in this regard.

80 It is clear that neither Article 13 of Royal Decree No 1127/39 nor Article 5 of the Civil Code provides expressly that the processes and uses set out in Article 6(2) of the Directive are not patentable, since those provisions merely preclude in general terms, respectively, the patentability of inventions whose exploitation would be contrary to public policy and morality and acts of disposition of the human body.

81 In those circumstances it appears that, despite the objective of clarification pursued by the Directive, a state of uncertainty remains as to the patentability of the processes and uses concerned.

82 This uncertainty constitutes a breach of the Directive all the more because Article 6(1) thereof itself states that the commercial exploitation of an invention is not to be deemed contrary to ordre public or morality merely because it is prohibited by law or regulation. As the Advocate General has correctly observed in point 55 of his Opinion, this statement is to be interpreted as requiring express transposition of the principle that commercial processes involving the use of human embryos are not patentable.

83 As to the provisions of Law No 40/2004, it is common ground that this Law was adopted after the time-limit set in the reasoned opinion. It is settled case-law that in the context of proceedings under Article 226 EC the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion, and the Court cannot take account of any subsequent changes (see, *inter alia*, Case C-378/98 *Commission v Belgium* [2001] ECR I-5107, paragraph 25, and Case C-352/02 *Commission v Greece* [2003] ECR I-5651, paragraph 8).

84 Therefore, the Commission's complaint alleging breach of Article 6(2) of the Directive is well founded.

The complaint alleging breach of Articles 8 to 11 of the Directive

85 The Commission pleads that Italian legislation does not contain any provision concerning the scope of the protection conferred by a patent relating to a biotechnological invention, in breach of Articles 8 to 11 of the Directive.

86 The Italian Government contends, however, that Article 1bis of Royal Decree No 1127/39 provides for protection conferred by a patent that is as wide as the protection prescribed by those provisions of the Directive, inasmuch as the latter merely extend the protection given by a patent relating to a biotechnological invention to material resulting directly from the application of the patented process.

87 As to those submissions, Articles 8 to 11 of the Directive clearly seek to grant specific rights since they define the scope of protection conferred by patents relating to a biological invention.

88 In the present case, since Italian law does not expressly provide that biological inventions are patentable, it is undisputed that it likewise does not contain provisions specifying the scope of the protection conferred by a patent relating to such an invention.

89 Article 1bis of Royal Decree No 1127/39 simply defines generally the rights conferred by any patent relating to any product or process. On the other hand that provision, contrary to the requirements of Articles 8 and 9 of the Directive, does not refer to the scope of the rights specifically conferred by the various types of patents envisaged by those provisions, namely patents on biological material, patents on a process that enables a biological material to be produced and patents on a product containing or consisting of genetic information.

90 Thus, although it is correct, as the Italian Government submits, that Article 1bis(1)(b) of Royal Decree No 1127/39 provides that a patent on a process confers on its holder the right to prohibit third parties from using the product directly obtained from that process, the fact remains that this provision does not require, as Article 8(2) of the Directive does, that the protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention is to extend to biological material directly obtained through that process and to any other biological material derived

through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

91 Nor, contrary to Articles 8(1) and 9 of the Directive, does Italian patent law provide that the protection conferred, first, by a patent on biological material and, second, by a patent on a product containing or consisting of genetic information extends, respectively, to any biological material derived from that biological material through propagation or multiplication, and to all material in which the product is incorporated and in which the genetic information performs its function.

92 Furthermore, Article 1bis of Royal Decree No 1127/39 does not contain any of the restrictions and derogations provided for in Articles 10 and 11 of the Directive.

93 In those circumstances it appears that, despite the objective of clarification pursued by the Directive, a state of uncertainty remains as to the precise extent of the protection conferred by a patent relating to a biological invention.

94 Therefore, the Commission's complaint alleging breach of Articles 8 to 11 of the Directive is well founded.

The complaint alleging breach of Article 12 of the Directive

95 The Commission submits that Article 54 of Royal Decree No 1127/39, which provides for the grant of compulsory licences, does not take account of the case where there is a relationship of interdependence between a patent on a biotechnological invention and a regime governing plant variety rights.

96 The Italian Government points out that, in the situation referred to in Article 12 of the Directive, the Italian authorities do not in practice have any discretion notwithstanding the use of the words ‘may be granted’ in Article 54 of Royal Decree No 1127/39 and that they are therefore required to grant the compulsory licence applied for.

97 Under Article 12 of the Directive, a non-exclusive compulsory licence may be applied for, first, in respect of a prior patent, by the holder of a plant variety right and, second, in respect of a prior plant variety right, by the holder of a patent on a biotechnological invention, where the exploitation of their plant variety right and patent respectively would infringe those prior rights.

98 It is manifest that such a provision, which provides for the grant of a compulsory licence to exploit an invention protected by a patent or by a plant variety right, seeks to confer specific rights in this regard.

99 While Article 54(2) of Royal Decree No 1127/39 provides for the grant of a compulsory licence where an invention protected by a patent cannot be used without infringing the rights arising from another, prior, patent, it does not provide, as Article 12(1) and (2) of the Directive does, for the grant of such a licence in the case of interdependence between a patent on a biotechnological invention and a plant variety right. Furthermore, Article 54(2) of Royal Decree No 1127/39 does not oblige the applicant for the compulsory licence either to pay an appropriate royalty, as Article 12(1) and (2) of the Directive requires, or to have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence, as Article 12(3) of the Directive prescribes.

100 Accordingly, the Commission’s complaint alleging breach of Article 12 of the Directive is well founded.

The complaint alleging a failure to transpose the other provisions of the Directive

101 Despite the specific complaints which it raised in its reply, concerning breach by the Italian Republic of certain provisions of the Directive, the Commission has not modified the initial subject of its application, which essentially seeks a declaration that the Italian Republic has failed to transpose the Directive at all.

102 According to the case-law, in proceedings for failure to fulfil obligations under Article 226 EC it is incumbent upon the Commission to prove the allegation that the obligation has not been fulfilled and in so doing it may not rely on any presumption (see, *inter alia*, Case 96/81 Commission v Netherlands, cited above, paragraph 6, Case C-408/97 Commission v Netherlands, cited above, paragraph 15, and Commission v Portugal, cited above, paragraph 80).

103 Therefore, since the Italian Government contended in its defence that the Italian domestic law in force complied with the Directive, the Commission had the task, in order to prove that the Directive had not been transposed at all, of placing before the Court the information needed to enable the latter to establish that such a failure to fulfil obligations had occurred.

104 It is clear, however, that in its reply the Commission provides such information only in relation to Articles 3(1), 5(2), 6(2) and 8 to 12 of the Directive, with which the complaints examined above were concerned, and not in relation to all the remaining provisions of the Directive.

105 Contrary to what the Commission appears to suggest, the mere fact that certain provisions of the Directive, put forward by way of example, cannot be regarded as having been transposed correctly by the domestic law in force does not establish in the slightest that the remaining provisions of the Directive cannot be regarded as being correctly transposed by the domestic law in force.

106 Accordingly, since the Commission has adduced no probative evidence in this regard, the action must be dismissed in so far as it seeks a declaration that the Italian Republic has failed to transpose the Directive at all.

107 In light of all the foregoing considerations, it is to be held that, by having failed to adopt the laws, regulations and administrative provisions necessary to comply with Articles 3(1), 5(2), 6(2) and 8 to 12 of the Directive, the Italian Republic has failed to fulfil its obligations under Article 15 of the Directive.

108 The remainder of the application must be dismissed.

3.5.7. Costs

109 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

110 Under the first subparagraph of Article 69(3) of the Rules of Procedure, the Court may order that the costs be shared or that the parties bear their own costs in particular where each party succeeds on some and fails on other heads. However, by virtue of the second subparagraph of Article 69(3), the Court may also order a party, even if successful, to pay costs which the Court considers that party to have unreasonably or vexatiously caused the opposite party to incur,.

111 In the present case, the Commission has been partially unsuccessful in its pleas, in that it sought a declaration that the Italian Republic had failed to transpose the Directive at all.

112 In these circumstances, since the Italian Republic has not applied for the Commission to pay the costs it must be ordered to bear its own costs.

113 As regards the Commission's costs, since the Italian Republic did not provide all the relevant information concerning the domestic legal provisions by means of which it considered that it had fulfilled the various obligations imposed on it by the Directive, it cannot be held against the Commission that it brought before the Court infringement proceedings seeking a declaration that the Directive had not been transposed at all, rather than a declaration that some of its provisions had not been transposed completely or correctly.

114 Furthermore, by not permitting the Commission to examine in the course of the pre-litigation procedure whether the domestic law pleaded complies with the Directive, the Italian Republic also required the Commission to devote resources thereto in the course of the contentious procedure, thus obstructing, as the Advocate General has rightly pointed out in paragraph 67 of his Opinion, the normal course of the proceedings by an evasive procedural strategy.

115 Consequently, the Italian Republic must be ordered to bear all the costs.

3.5.8. The Court's decision

On those grounds, the Court (Third Chamber) hereby:

1. Declares that, by having failed to adopt the laws, regulations and administrative provisions necessary to comply with Articles 3(1), 5(2), 6(2) and 8 to 12 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, the Italian Republic has failed to fulfil its obligations under Article 15 of that directive;

2. Dismisses the action as to the remainder;
3. Orders the Italian Republic to bear all the costs.

3.6. Commission of the European Communities v Italian Republic¹⁶

3.6.1. Judgment

1 In its action, the Commission of the European Communities requests the Court to declare that:

– by keeping in force legislation which restricts the right to operate a private retail pharmacy to natural persons who have graduated in pharmacy and to operating companies and firms composed exclusively of members who are pharmacists; and

– by keeping in force legislative provisions which make it impossible for undertakings engaged in the distribution of pharmaceutical products (‘distribution undertakings’) to acquire stakes in companies which operate municipal pharmacies,

the Italian Republic has failed to fulfil its obligations under Articles 43 EC³¹ and 56 EC¹³.

¹⁶ Judgment Of The Court (Grand Chamber) 19 May 2009 In Case C-531/06, Commission of the European Communities v Italian Republic

2 By order of the President of the Court of 22 June 2007, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Latvia and the Republic of Austria were granted leave to intervene in the present case in support of the form of order sought by the Italian Republic.

3.6.2. Legal context

Community legislation

3 Recital 26 in the preamble to Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255, p. 22) states:

‘This Directive does not coordinate all the conditions for access to activities in the field of pharmacy and the pursuit of these activities. In particular, the geographical distribution of pharmacies and the monopoly for dispensing medicines should remain a matter for the Member States. This Directive leaves unchanged the legislative, regulatory and administrative provisions of the Member States forbidding companies from pursuing certain pharmacists’ activities or subjecting the pursuit of such activities to certain conditions.’

4 That recital repeats, in essence, the 2nd recital in the preamble to Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy (OJ 1985 L 253, p. 34) and the 10th recital in the preamble to Council Directive 85/433/EEC of 16 September 1985 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy (OJ 1985 L 253, p. 37). Those two directives were repealed with effect from 20 October 2007 and replaced by Directive 2005/36.

3.6.3. National legislation

5 The national legislation lays down two regimes for the operation of pharmacies, namely a regime governing private pharmacies and a regime governing municipal pharmacies.

The regime governing private pharmacies

6 Article 4 of Law No 362 of 8 November 1991 relating to a reorganisation of the pharmaceutical sector ('Law No 362/1991') lays down, with regard to operation of pharmacies, a competition procedure organised by the regions and the provinces which is restricted to citizens of the Member States in possession of their civic rights and entered, as pharmacists, on the register of pharmacists.

7 Article 7 of Law No 362/1991 states:

'1. The operation of private pharmacies shall be restricted to natural persons, in accordance with the provisions in force, to partnerships and to cooperative societies with limited liability.

2. The sole object of the firms and companies covered by paragraph 1 shall be to operate a pharmacy. Their members shall be pharmacists who are entered on the register and possess the qualifications prescribed in Article 12 of Law No 475 of 2 April 1968 [laying down provisions applicable to the pharmaceutical service; 'Law No 475/1968'], as subsequently amended.

3. The running of the pharmacy operated by the firm or company shall be entrusted to one of the members, who shall be responsible for it.

...

5. Each of the firms and companies covered by paragraph 1 may operate a single pharmacy and obtain the corresponding licence provided that the pharmacy is situated in the province in which the firm or company has its statutory office.

6. Each pharmacist may have a stake in only one firm or company covered by paragraph 1.

7. The operation of private pharmacies shall be restricted to pharmacists entered on the register of pharmacists of the province in which the pharmacy has its seat.

...

9. If, following the acquisition by succession of a stake in a firm or company covered by paragraph 1, the conditions set out in the second sentence of paragraph 2 cease to be met, the successor must assign the stake within three years from acquisition. Where the successor is the spouse or the heir in the direct line up to the second degree, that time-limit is deferred until the successor reaches the age of 30 or, if later, until 10 years from the date of acquisition of the stake. That time-limit of 10 years shall apply solely if, within one year from the date of acquisition of the stake, the successor enrolls as a student at a pharmacy faculty of a State university or a university entitled to award a qualification having legal value. ...

10. Paragraph 9 shall also apply where the private pharmacy is operated by successors within the meaning of Article 12(12) of [Law No 475/1968], as amended.

...’

8 Under the latter provision, if the holder dies the heirs may, within a period of one year, transfer the rights to operate the pharmacy to a pharmacist registered with the association of pharmacists who already has the status of holder of a pharmacy or who is considered suitable on the basis of a previous competition. During that period, the heirs are entitled to continue to operate the pharmacy provisionally under the responsibility of a manager.

9 Article 8 of Law No 362/1991 provides:

‘1. Holding a stake in a firm or company covered by Article 7 ... shall be incompatible:

(a) with any other activity in the sector of manufacture and distribution of medicinal products and dissemination of scientific information about medicinal products;

...’

10 Article 12(8) of Law No 475/1968 states:

‘A pharmacy may be transferred to a pharmacist entered on the register of pharmacists, who has the requisite qualifications or has at least two years’ professional experience certified by the competent health authority.’

The regime governing municipal pharmacies

11 Under the regime applicable to municipal pharmacies, it is municipalities which are the holders of the pharmacy (hereinafter ‘municipal pharmacy’). For the management of those pharmacies, municipalities may set up, in accordance with Article 116 of Legislative Decree No 267 of 18 August 2000, companies limited by shares whose members are not necessarily pharmacists.

12 Article 116(1) of that decree provides:

‘Local authorities may, for the performance of public services and for the carrying out of the works necessary for the proper operation of the service, as well as for the creation of infrastructure and the carrying out of other works in the public interest which, under the national and regional legislation in force, do not fall within the institutional powers of other authorities, set up companies limited by shares without a requirement of majority public ownership, even in derogation from specific legislative provisions. The authorities concerned shall provide for selection of the private shareholders and for any offer of shares on the market by a tender procedure. The instrument setting up the company must impose an obligation on the public authority to appoint one or more directors and auditors. ...’

13 By judgment of 24 July 2003, the Corte costituzionale (Constitutional Court) extended to those companies the prohibition laid down in Article 8 of Law No 362/1991 against simultaneously engaging in distribution activity, which until then had applied only to companies and firms operating private pharmacies.

14 Simultaneous engagement in the wholesale distribution of medicinal products and their retail sale was also declared unlawful by Article 100(2) of Legislative Decree No 219 of 24 April 2006 concerning the transposition of Directive 2001/83/EC (and subsequent amending

directives) on the Community code relating to medicinal products for human use and of Directive 2003/94/EC (ordinary supplement to GURI No 142 of 21 June 2006).

Decree-Law No 223 of 4 July 2006

15 National pharmacy legislation was amended by Decree-Law No 223 of 4 July 2006 laying down urgently required provisions for economic and social revival and the control and rationalisation of public expenditure, and providing for action in respect of tax revenue and the combating of tax evasion (known as ‘the Bersani Decree’).

16 In particular, Article 5 of the Bersani Decree repealed Article 7(5) to (7) of Law No 362/1991 and Article 100(2) of Legislative Decree No 219 of 24 April 2006, and it amended Article 8(1)(a) of Law No 362/1991 by deleting from it the words ‘and distribution’.

Pre-litigation procedure

17 Since the Commission took the view that the Italian system for the operation of pharmacies was not compatible with Articles 43 EC and 56 EC, it initiated the infringement procedure laid down in the first paragraph of Article 226 EC. After giving the Italian Republic formal notice on 21 March 2005 to submit its observations, the Commission delivered a reasoned opinion in accordance with that provision on 13 December 2005 calling on it to take the measures necessary to comply with its obligations arising from the EC Treaty within two months of receipt of the opinion. As the Commission was not satisfied with the Italian authorities’ response to the reasoned opinion, it decided to bring the present action.

Admissibility

18 The Italian Republic has put forward three pleas of inadmissibility against the Commission's action.

19 First, restriction of the ownership of pharmacies to natural persons who have graduated in pharmacy ('pharmacists') and to operating companies and firms composed exclusively of members who are pharmacists is provided for not only in Italian law, but by the majority of the Member States. It is therefore necessary for the Commission's position to be defined in a uniform manner in relation to all Member State legislation, avoiding the drawing of distinctions between Member States or between sets of enactments.

20 The Italian Republic contends, second, that the Commission pleads primarily a breach of Articles 43 EC and 56 EC but fails to take account of the directives which have implemented freedom of establishment. These directives contain express provisions confirming the conditions for access to the pharmaceutical sector – which have not yet been harmonised – by specifying that the rules concerned fall within Member State competence. In those circumstances, it is incumbent upon the Commission to set out the alleged breach of Community law precisely and specifically because, in regulating the role of pharmacists, the Italian Republic applied correctly those directives and the reservation of national competence which they contain.

21 The Italian Republic contends, third, that the amendment introduced by the Bersani Decree removes the prohibition preventing distribution undertakings from acquiring stakes in companies and firms which operate pharmacies but that, despite this, the Commission takes the view that such a prohibition may still be applied by the Italian courts. Thus, the alleged failure to fulfil obligations is not real and existing but arises from future hypothetical decisions of those courts.

22 These arguments must be rejected.

23 So far as concerns the first plea of inadmissibility, it is for the Commission, in performing the task conferred upon it by Article 211 EC, to ensure that the provisions of the Treaty are applied and verify whether the Member States have acted in accordance with those provisions. If the Commission considers that a Member State has infringed provisions of the Treaty, it is for it to determine whether it is expedient to take action against that State and what provisions the State has infringed, and to choose the time at which it will initiate infringement proceedings; the considerations which determine its choice of time cannot affect the admissibility of its action (see Case C-35/96 *Commission v Italy* [1998] ECR I-3851, paragraph 27, and Case C-33/04 *Commission v Luxembourg* [2005] ECR I-10629, paragraph 66).

24 Given this discretion, the Commission is free to initiate infringement proceedings against only some of the Member States which are in a comparable position from the point of view of compliance with Community law. It may thus, in particular, decide to initiate infringement proceedings against other Member States subsequently, after becoming aware of the outcome of the earlier proceedings.

25 As regards the second and third pleas of inadmissibility put forward by the Italian Republic, first, the Commission has explained the nature of the alleged failure to fulfil obligations sufficiently precisely, both in its application and in its reply. Second, the question whether the Member State's acts should be assessed in the light of Articles 43 EC and 56 EC or of the directives which have implemented those articles falls within the substance of the case. The same is also true of whether the alleged failure to fulfil obligations existed at the material time for its assessment.

26 Therefore, the action brought by the Commission must be declared admissible.

3.6.4. Substance

The first complaint

Arguments of the parties

27 The Commission contends that, by laying down a rule which prevents natural persons who have not graduated in pharmacy and legal persons which are not composed exclusively of members who are pharmacists from operating a pharmacy ('the rule excluding non-pharmacists'), the national legislation infringes Articles 43 EC³¹ and 56 EC¹³.

28 That rule constitutes a restriction within the meaning of those articles which may be justified only by overriding reasons in the general interest, in particular by the objective of protecting public health.

29 However, first, the rule excluding non-pharmacists is not appropriate for securing attainment of such an objective since it is based on an incorrect presumption that a pharmacist operating a pharmacy is less inclined than a non-pharmacist to favour his personal interest at the expense of the public interest.

30 Second, the legislation goes beyond what is necessary for attaining the objective of protecting public health, because that objective could be attained by other measures that restrict the freedoms laid down by Articles 43 EC and 56 EC less, such as an obligation that a pharmacist be present in the pharmacy, an obligation to take out insurance or a system of adequate controls and effective penalties.

31 The Italian Republic, supported by the Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Latvia and the Republic of Austria, submits that the national legislation concerning the operation of pharmacies does not infringe Articles 43 EC and 56 EC.

32 First of all, Community law leaves the Member States the power to regulate the pharmacy sector, with the exception of questions relating to the mutual recognition of diplomas, certificates and other evidence of formal qualifications.

33 Next, the restrictions which flow from that national legislation are justified by the general interest of protection of public health. The legislation applies without discrimination and ensures that the proper provision of medicinal products to the public takes precedence over economic considerations. It is only if operators of pharmacies, who exert influence over pharmacies' management, have knowledge and comprehensive specific experience that the interest of health protection is systematically put before economic objectives in their management.

34 Finally, the abovementioned Member States contend that other measures which are less restrictive do not attain the objectives in the general interest with the same effectiveness as the national legislation.

Findings of the Court

– Preliminary observations

35 First, it is clear, both from the case-law of the Court and from Article 152(5) EC and recital 26 in the preamble to Directive 2005/36, that Community law does not detract from the power of the Member States to organise their social security systems and to adopt, in

particular, provisions intended to govern the organisation of health services such as pharmacies. In exercising that power, however, the Member States must comply with Community law, in particular the provisions of the Treaty on the freedoms of movement, including freedom of establishment and the free movement of capital. Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of those freedoms in the healthcare sector (see, to this effect, Case C-372/04 Watts [2006] ECR I-4325, paragraphs 92 and 146, and Case C-169/07 Hartlauer [2009] ECR I-0000, paragraph 29).

36 When assessing whether that obligation has been complied with, account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since the level may vary from one Member State to another, Member States must be allowed discretion (see, to this effect, Case C-322/01 Deutscher Apothekerverband [2003] ECR I-14887, paragraph 103; Case C-141/07 Commission v Germany [2008] ECR I-0000, paragraph 51; and Hartlauer, paragraph 30).

37 Second, neither Directive 2005/36 nor any other measure implementing the freedoms of movement guaranteed by the Treaty lays down conditions governing access to activities in the pharmacy field that specify the category of persons who are entitled to operate a pharmacy. Consequently, the national legislation must be examined in the light of the provisions of the Treaty alone.

38 Third, the regime applicable to persons entrusted with the retail supply of medicinal products varies from one Member State to another. Whereas, in certain Member States, only self-employed pharmacists can own and operate pharmacies, other Member States accept that persons not having the status of self-employed pharmacist may own a pharmacy while entrusting its management to employed pharmacists.

39 Since the Commission alleges that the Italian Republic has simultaneously infringed Article 43 EC and Article 56 EC, it should be examined, fourth, whether the national legislation concerned must be assessed in the light of the provisions relating to freedom of establishment or those relating to the free movement of capital.

40 It is to be recalled that, if the legislation under examination concerns a stake which gives its holder definite influence over the decisions of the company concerned and allows him to determine its activities, it is the provisions relating to freedom of establishment which are applicable (Case C-251/98 Baars [2000] ECR I-2787, paragraphs 21 and 22, and Case C-436/00 X and Y [2002] ECR I-10829, paragraphs 37 and 66 to 68). However, if that legislation is not intended to apply only to stakes which enable the holder to have a definite influence on a company's decisions and to determine the company's activities, it should be examined in relation to both Article 43 EC and Article 56 EC (see, to this effect, Case C-446/04 Test Claimants in the FII Group Litigation [2006] ECR I-11753, paragraphs 36 and 38, and Case C-157/05 Holböck [2007] ECR I-4051, paragraphs 23 and 25).

41 Here, the Commission's action relates to two different situations to which the national legislation at issue is intended to apply. First, the Commission envisages the situation where that legislation prevents non-pharmacists from holding, in companies or firms operating pharmacies, significant stakes giving them definite influence over their decisions. Second, the Commission's complaints concern the situation where that legislation prevents investors from other Member States who are not pharmacists from acquiring in those companies or firms smaller stakes which do not confer such influence.

42 In those circumstances, the national legislation should be examined in the light of both Article 43 EC and Article 56 EC.

– Existence of restrictions on freedom of establishment and the free movement of capital

43 As regards Article 43 EC, according to settled case-law that provision precludes any national measure which, even though it is applicable without discrimination on grounds of nationality, is liable to hinder or render less attractive the exercise by Community nationals of the freedom of establishment that is guaranteed by the Treaty (see, in particular, Case C-19/92 Kraus [1993] ECR I-1663, paragraph 32, and Case C-299/02 Commission v Netherlands [2004] ECR I-9761, paragraph 15).

44 Legislation which makes the establishment in the host Member State of an economic operator from another Member State subject to the issue of a prior authorisation and allows self-employed activity to be pursued only by certain economic operators who satisfy predetermined requirements, compliance with which is a condition for the issue of that authorisation, constitutes a restriction within the meaning of Article 43 EC. Such legislation deters or even prevents economic operators from other Member States from pursuing their activities in the host Member State through a fixed place of business (see, to this effect, Hartlauer, paragraphs 34, 35 and 38).

45 The rule excluding non-pharmacists constitutes such a restriction because it allows only pharmacists to operate pharmacies, denying other economic operators access to this self-employed activity in the Member State concerned.

46 As to Article 56 EC, national measures must be regarded as restrictions within the meaning of Article 56(1) EC if they are liable to prevent or limit the acquisition of stakes in the undertakings concerned or to deter investors from other Member States from investing in their capital (see Case C-112/05 Commission v Germany [2007] ECR I-8995, paragraph 19, and Joined Cases C-463/04 and C-464/04 Federconsumatori and Others [2007] ECR I-10419, paragraph 21).

47 Here, the national legislation provides that the members of companies and firms operating pharmacies can only be pharmacists. That legislation thus prevents investors from

other Member States who are not pharmacists from acquiring stakes in companies and firms of that kind.

48 Consequently, the national legislation imposes restrictions within the meaning of Articles 43 EC and 56(1) EC.

– Justification of the restrictions on freedom of establishment and the free movement of capital

49 Restrictions on freedom of establishment and on the free movement of capital which are applicable without discrimination on grounds of nationality may be justified by overriding reasons in the general interest, provided that the restrictions are appropriate for securing attainment of the objective pursued and do not go beyond what is necessary for attaining that objective (see Case C-370/05 Festersen [2007] ECR I-1129, paragraph 26, and Hartlauer, paragraph 44).

50 In the present instance, first, the national legislation applies without discrimination on grounds of nationality.

51 Second, the protection of public health is one of the overriding reasons in the general interest which can justify restrictions on the freedoms of movement guaranteed by the Treaty such as the freedom of establishment (see, *inter alia*, Hartlauer, paragraph 46) and the free movement of capital.

52 More specifically, restrictions on those freedoms of movement may be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality (see, to this effect, *Deutscher Apothekerverband*, paragraph 106, and Case C-141/07 *Commission v Germany*, paragraph 47).

53 Third, it must be examined whether the rule excluding non-pharmacists is appropriate for securing such an objective.

54 It is important that, where there is uncertainty as to the existence or extent of risks to human health, a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. Furthermore, a Member State may take the measures that reduce, as far as possible, a public-health risk (see, to this effect, Case C-170/04 *Rosengren and Others* [2007] ECR I-4071, paragraph 49), including, more specifically, a risk to the reliability and quality of the provision of medicinal products to the public.

55 In this context, attention is to be drawn to the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods (see, to this effect, Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 54).

56 Those therapeutic effects have the consequence that, if medicinal products are consumed unnecessarily or incorrectly, they may cause serious harm to health, without the patient being in a position to realise that when they are administered.

57 Overconsumption or incorrect use of medicinal products leads, moreover, to a waste of financial resources which is all the more damaging because the pharmaceutical sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied (see by analogy, with regard to hospital treatment, Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, paragraph 80, and *Watts*, paragraph 109). There is a direct link between those financial resources and the profits of businesses operating in the pharmaceutical sector because in most Member States the prescription of medicinal products is borne financially by the health insurance bodies concerned.

58 In the light of those risks to public health and to the financial balance of social security systems, the Member States may make persons entrusted with the retail supply of medicinal products subject to strict requirements, including as regards the way in which the products are marketed and the pursuit of profit. In particular, the Member States may restrict the retail sale of medicinal products, in principle, to pharmacists alone, because of the safeguards which pharmacists must provide and the information which they must be in a position to furnish to consumers (see, to this effect, *Delattre*, paragraph 56).

59 In this connection, given the power accorded to the Member States to determine the level of protection of public health, it must be accepted that Member States may require that medicinal products be supplied by pharmacists enjoying genuine professional independence. They may also take measures which are capable of eliminating or reducing a risk that that independence will be prejudiced because such prejudice would be liable to affect the degree to which the provision of medicinal products to the public is reliable and of good quality.

60 In this context, three categories of potential pharmacy operators must be distinguished, namely natural persons having the status of pharmacist, persons operating in the pharmaceutical products sector as manufacturers or wholesalers, and persons neither having the status of pharmacist nor operating in that sector.

61 It is undeniable that an operator having the status of pharmacist pursues, like other persons, the objective of making a profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence.

62 Unlike pharmacists, non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists. Accordingly, they do not provide the same safeguards as pharmacists.

63 A Member State may therefore take the view, in the exercise of its discretion referred to in paragraph 36 of the present judgment, that, unlike the case of a pharmacy operated by a pharmacist, the operation of a pharmacy by a non-pharmacist may represent a risk to public health, in particular to the reliability and quality of the supply of medicinal products at retail level, because the pursuit of profit in the course of such operation does not involve moderating factors such as those, noted in paragraph 61 of the present judgment, which characterise the activity of pharmacists (see by analogy, with regard to the provision of social welfare services, Case C-70/95 *Sodemare and Others* [1997] ECR I-3395, paragraph 32).

64 It is therefore permissible for a Member State *inter alia* to assess, in the exercise of that discretion, whether such a risk exists in the case of manufacturers and wholesalers of pharmaceutical products on the ground that they might compromise the independence of employed pharmacists by encouraging them to promote the medicinal products which they produce or market themselves. Likewise, a Member State may determine whether operators lacking the status of pharmacist are liable to compromise the independence of employed pharmacists by encouraging them to sell off medicinal products which it is no longer profitable to keep in stock or whether those operators are liable to make reductions in operating costs which may affect the manner in which medicinal products are supplied at retail level.

65 The Commission submits in the alternative that, in the present case, the rule excluding non-pharmacists cannot be justified in the general interest because that objective is pursued in an inconsistent manner.

66 As to those submissions, it is apparent from the Court's case-law that national legislation is appropriate for securing attainment of the objective relied upon only if it

genuinely reflects a concern to attain that objective in a consistent and systematic manner (see Joined Cases C-338/04, C-359/04 and C-360/04 *Placanica and Others* [2007] ECR I-1891, paragraphs 53 and 58; Case C-500/06 *Corporación Dermoestética* [2008] ECR I-0000, paragraphs 39 and 40; and *Hartlauer*, paragraph 55).

67 In this context, it is to be observed that the national legislation does not exclude the operation of pharmacies by non-pharmacists absolutely.

68 Article 7(9) and (10) of Law No 362/1991 provides, by way of exception, that the heirs of a pharmacist who do not themselves have the status of pharmacist may operate the pharmacy which they have inherited for a period of 1, 3 or 10 years, depending on the heirs' personal situation.

69 However, the Commission has not proved that that exception renders the national legislation inconsistent.

70 First of all, the exception proves justified having regard to protection of the legitimate property rights and interests of the members of the deceased pharmacist's family. It must be found that the Member States may take the view that the interests of a pharmacist's heirs are not such as to jeopardise the requirements and guarantees flowing from their respective legal systems which operators who have the status of pharmacist must meet. In this context, account is to be taken especially of the fact that throughout the transitional period a qualified pharmacist must be responsible for operating the inherited pharmacy. Therefore, the heirs cannot, in this specific context, be equated with other operators who do not have the status of pharmacist.

71 Also, it should be noted that the effects of the exception are only temporary. The heirs must, as a general rule, transfer the rights to operate the pharmacy to a pharmacist within the period of just one year. It is only in the case of a stake in a company or firm composed of

pharmacists who operate a pharmacy that the successors have a longer period to assign the stake, as the period is three years from acquisition of the stake.

72 These exceptions are thus designed to enable the successors to assign the pharmacy to a pharmacist within a period which does not prove unreasonable.

73 Finally, although Article 7(9) and (10) of Law No 362/1991 grants certain heirs a period of 10 years to assign the pharmacy, a period which might prove unreasonable, it must be stated that, in the light of its particularly restricted field of application, limited to the case where the successor is the spouse or the heir in the direct line up to the second degree of the deceased pharmacist, and of the fact that this successor must enrol as a student at a pharmacy faculty within a period of one year from the date of acquisition of the pharmacy, this provision cannot be sufficient to conclude that the national legislation concerned is inconsistent.

74 Nor has the Commission proved that the national legislation is inconsistent on the ground that it permits certain non-pharmacists to operate municipal pharmacies as it provides that municipalities may set up, for the management of those pharmacies, companies limited by shares whose members are not necessarily pharmacists.

75 First of all, there is nothing on the case file indicating that the municipalities, which are holders of public powers, might allow themselves to be guided by a particular commercial objective and operate municipal pharmacies to the detriment of public health requirements.

76 Next, the Commission has not contested the evidence adduced before the Court by the Italian Republic intended to show that municipalities have extensive supervisory powers over companies entrusted with the management of municipal pharmacies and that those powers enable them to ensure that the public interest is pursued.

77 According to these particulars, the municipality concerned continues to hold the pharmacies, it sets out the specific detailed rules for managing the pharmaceutical service in the pharmacies and it issues an invitation to tender in order to select the member of the company entrusted with managing the pharmacy, while the provisions intended to ensure that those detailed rules are complied with are included both in the invitation to tender and in the contractual documents which govern legal relations between the municipality and the company concerned.

78 It is also apparent from the uncontested particulars supplied by the Italian Republic that the municipality retains the power to appoint one or more directors and auditors of the company entrusted with managing the municipal pharmacy, and it participates in this way in the company's decision making and in the internal supervision of its activities. The persons appointed have the power to ensure that the municipal pharmacy systematically pursues the public interest and to prevent the professional independence of the employed pharmacists from being compromised.

79 Finally, according to the same particulars, the municipality concerned is not denied the possibility of changing, modifying or terminating the legal relationship with the company entrusted with managing the municipal pharmacy in order to implement a commercial policy which promotes to the utmost the pursuit of the public interest.

80 Consequently, in the absence of adequate evidence adduced by the Commission, the national legislation concerning municipal pharmacies cannot be considered inconsistent.

81 In view of all the foregoing, it must be found that the legislation to which the alleged failure to fulfil obligations relates is appropriate for securing attainment of the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality and, therefore, that public health is protected.

82 Fourth, it must be examined whether the restrictions on freedom of establishment and the free movement of capital go beyond what is necessary for attaining that objective, that is to say whether there are measures restricting the freedoms guaranteed by Articles 43 EC and 56 EC less which would enable the objective to be attained just as effectively.

83 The Commission submits that that objective could be attained by less restrictive measures, such as an obligation that a pharmacist be present in the pharmacy, an obligation to take out insurance or a system of adequate controls and effective penalties.

84 However, having regard to the discretion which the Member States are allowed, as referred to in paragraph 36 of the present judgment, a Member State may take the view that there is a risk that legislative rules designed to ensure the professional independence of pharmacists would not be observed in practice, given that the interest of a non-pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator could make it difficult for them to oppose instructions given by him.

85 The Commission has not put forward, apart from general considerations, anything to show what the specific system would be that would be capable of ensuring – with the same effectiveness as the rule excluding non-pharmacists – that those legislative rules are observed in practice notwithstanding the considerations set out in the previous paragraph of the present judgment.

86 Nor, contrary to the Commission's submissions, can the risks to the independence of the profession of pharmacist be excluded with the same effectiveness by the means consisting in the imposition of an obligation to take out insurance, such as insurance for vicarious civil liability. While that measure might enable the patient to obtain financial reparation for any harm suffered by him, it operates after the event and would be less effective than the rule

excluding non-pharmacists in that it would not in any way prevent the operator concerned from exerting influence over the employed pharmacists.

87 Accordingly, it has not been established that another measure that restricts the freedoms guaranteed by Articles 43 EC and 56 EC less than the rule excluding non-pharmacists would make it possible to ensure just as effectively the level of reliability and quality in the provision of medicinal products to the public that results from the application of that rule.

88 Consequently, the national legislation proves appropriate for securing attainment of the objective pursued by it and does not go beyond what is necessary for attaining that objective. It must therefore be accepted that the restrictions flowing from the national legislation may be justified by that objective.

89 This conclusion is not called into question by the judgment in Case C-140/03 *Commission v Greece* [2005] ECR I-3177, upon which the Commission relies, where the Court ruled that the Hellenic Republic had failed to fulfil its obligations under Articles 43 EC and 48 EC by enacting and maintaining in force national provisions under which the establishment by a legal person of an optician's shop was subject *inter alia* to the condition that authorisation for the establishment and operation of that shop had to have been granted to a recognised optician who was a natural person and the person holding the authorisation to operate the shop had to hold at least 50% of the company's share capital and participate at least to that extent in the profits and losses of the company.

90 Given the particular nature of medicinal products and of the medicinal-product market, and as Community law currently stands, the Court's findings in *Commission v Greece* cannot be transposed to the field of the retail supply of medicinal products. Unlike optical products, medicinal products prescribed or used for therapeutic reasons may none the less prove seriously harmful to health if they are consumed unnecessarily or incorrectly, without the consumer being in a position to realise that when they are administered. Furthermore, a

medically unjustified sale of medicinal products leads to a waste of public financial resources which is not comparable to that resulting from unjustified sales of optical products.

91 In view of all the foregoing, the first complaint in the action must be rejected as unfounded.

The second complaint

Arguments of the parties

92 In the second complaint, the Commission submits that the regime governing municipal pharmacies is contrary to Articles 43 EC and 56 EC. It accepts that that regime permits non-pharmacists to operate municipal pharmacies in certain circumstances, by providing that companies limited by shares whose members are not necessarily pharmacists may be set up for the management of those pharmacies. However, the national legislation prevents distribution undertakings from acquiring stakes in those companies and such a restriction cannot in any way be justified by objectives linked to the protection of public health.

93 First, such legislation is not appropriate for attaining those objectives. It is based on an incorrect presumption that a distribution undertaking would be more tempted, when operating a municipal pharmacy, to favour its personal interest at the expense of the public interest than persons not active in the pharmaceutical distribution sector.

94 Also, the legislation is inconsistent since it allows derogations of considerable scope. In particular, a person may become a member of a distribution undertaking and, notwithstanding that, operate a municipal pharmacy provided that he does not hold in that undertaking a position entailing decision making and control.

95 Second, the prohibition preventing distribution undertakings from acquiring a stake in municipal pharmacies is not necessary as the objective relied upon can be attained by other measures that are less restrictive, such as an obligation that a pharmacist be present in the pharmacy, an obligation to take out insurance or the establishment of a system of adequate controls and effective penalties.

96 The Italian Republic, on the other hand, submits that the second complaint is unfounded on the ground that the Bersani Decree removed the prohibition preventing distribution undertakings from acquiring stakes in municipal pharmacies.

97 In any event, such a prohibition is not contrary to Article 43 EC, since it can be justified by the general interest of protection of public health. The prohibition applies without discrimination and is indeed intended to prevent distribution undertakings from promoting the medicinal products which they market by means of municipal pharmacies. Other measures which are less restrictive would not attain that objective in the general interest with the same effectiveness.

Findings of the Court

98 As regards, first of all, the Italian Republic's argument deriving from the adoption of the Bersani Decree, it is well established case-law that the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion and that the Court cannot take account of any subsequent changes (see, *inter alia*, Case C-103/00 *Commission v Greece* [2002] ECR I-1147, paragraph 23, and Case C-152/05 *Commission v Germany* [2008] ECR I-39, paragraph 15).

99 In the present case, it is common ground that, on the date on which the period laid down in the reasoned opinion expired, the national legislation did not allow distribution undertakings to acquire a stake in companies entrusted with the operation of municipal pharmacies as the Bersani Decree was not adopted until after that date.

100 Next, it must be found that the national legislation results in restrictions within the meaning of Articles 43 EC and 56 EC in the light of the case-law cited in paragraphs 43 and 46 of the present judgment. It prevents certain economic operators, namely those who are engaged in the distribution of pharmaceutical products, from concomitantly engaging in activity in municipal pharmacies. Also, such legislation prevents investors from Member States other than the Italian Republic which are distribution undertakings from acquiring stakes in certain companies, namely those entrusted with the operation of municipal pharmacies.

101 So far as concerns the possible justification of those restrictions, it is to be observed at the outset that the national legislation applies without discrimination on grounds of nationality and pursues the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality.

102 Moreover, the national legislation is appropriate for securing attainment of that objective. First, as follows from paragraphs 62 to 64 of the present judgment, a Member State may take the view that distribution undertakings are capable of exerting a certain amount of pressure on employed pharmacists with the objective of favouring the interest of making a profit.

103 Second, having regard to the considerations set out in the same paragraphs, the Member State concerned may take the view, in the exercise of its discretion, that the municipalities' supervisory powers over companies entrusted with the management of municipal pharmacies are not sufficient to prevent the influence of distribution undertakings over employed pharmacists.

104 Third, the Commission has not adduced concrete and specific evidence or arguments on whose basis the Court would be able to conclude that the legislation to which the second complaint relates is inconsistent in the light of other national rules, such as the rule which permits a person to become a member of a distribution undertaking and a member of a company entrusted with the operation of a municipal pharmacy provided that he does not hold in the distribution undertaking a position entailing decision making and control.

105 Finally, with regard to whether the national legislation is necessary, it must be found that, similarly to what is stated in paragraphs 84 to 86 of the present judgment, a Member State may take the view that there is a risk that legislative rules protecting the professional independence of pharmacists will not be observed or will be circumvented in practice. Nor can the risks to the reliability and quality of the provision of medicinal products to the public be excluded with the same effectiveness by an obligation to take out insurance, because such a means would not necessarily prevent the operator concerned from exerting influence over the employed pharmacists.

106 Consequently, the second complaint in the action must be also rejected as unfounded.

107 Since none of the pleas relied upon by the Commission in support of its action is founded, the action must be dismissed in its entirety.

3.6.5. Costs

108 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. In the present case, the Italian Republic has requested the Court to declare the Commission's action inadmissible or unfounded 'with the measures which in consequence follow'. That form of order sought by it cannot be regarded as a request that the applicant should be ordered to pay

the costs (see, to this effect, Case C-255/90 P *Burban v Parliament* [1992] ECR I-2253, paragraph 26). Consequently, it must be decided that the Commission and the Italian Republic will bear their own costs.

109 In accordance with Article 69(4) of the Rules of Procedure, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Latvia and the Republic of Austria are, as interveners, to bear their own costs.

3.6.6. The Court's decision

On those grounds, the Court (Grand Chamber) hereby:

1. Dismisses the action;
2. Orders the Commission of the European Communities, the Italian Republic, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Republic of Latvia and the Republic of Austria to bear their own costs.

3.7. Booker Aquaculture Ltd, trading as Marine Harvest McConnell and Hydro Seafood GSP Ltd v The Scottish Ministers¹⁷

3.7.1. Judgment

1

By orders of 11 January 2000 (C-20/00) and 18 February 2000 (C-64/00), received at the Court of Justice on 24 January and 28 February 2000 respectively, the Court of Session (Scotland) referred to the Court for a preliminary ruling under Article 234 EC⁸ several questions on the interpretation of the principles of Community law on the protection of fundamental rights, in particular of the right to property, and on the validity of Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases (OJ 1993 L 175, p. 23).

2

Those questions were raised in actions brought, respectively, by Booker Aquaculture Ltd (hereinafter Booker) and Hydro Seafood GSP Ltd (hereinafter Hydro Seafood) against the Scottish Ministers.

3

By order of the President of the Court of 10 May 2000, Cases C-20/00 and C-64/00 were joined for the purposes of the written procedure, the oral procedure and judgment.

Legal framework

Community legislation

Directive 91/67/EEC

¹⁷ Judgment of the Court, 10 July 2003 I – 0000; Joined Cases C-20/00 and C-64/00; Booker Aquaculture Ltd, trading as Marine Harvest McConnell and Hydro Seafood GSP Ltd v The Scottish Ministers

4

Article 3(1) and (3) of Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products (OJ 1991 L 46, p. 1), as amended by Council Directive 93/54/EEC of 24 June 1993 (OJ 1993 L 175, p. 34), provides:

1.

The placing on the market of aquaculture animals shall be subject to the following general requirements:

(a)

they must show no clinical signs of disease on the day of loading;

(b)

they must not be intended for destruction or slaughter under a scheme for the eradication of a disease listed in Annex A;

(c)

they must not come from a farm which is subject to a prohibition for animal health reasons and must not have been in contact with animals from such a farm and, in particular, from a farm which is subject to control measures in the context of ... Directive 93/53/EEC ...

...

3.

Aquaculture products being placed on the market for human consumption must originate from animals which satisfy the requirement laid down in paragraph 1(a).

5

Article 2(1), (2) and (3) of Directive 91/67, as amended, provides: For the purposes of this Directive:

1.

aquaculture animals means live fish ... coming from a farm, including those from the wild intended for a farm;

2.

aquaculture products means products derived from aquaculture animals, whether intended for farming, such as eggs and gametes, or for human consumption;

3.

fish ... means any fish ..., at any stage of development

.

6

Annex A to Directive 91/67, as amended, entitled Listed diseases/pathogens of fish, molluscs and crustacea, sets out certain illnesses in column 1 and states against them, in column 2, the species which are susceptible to them. List I in that Annex includes, in column 1, only one disease, infectious salmon anaemia (ISA), and designates, in column 2, Atlantic salmon as the species which is susceptible to it. Viral haemorrhagic septicaemia (VHS) is one of the diseases in List II in that Annex, and turbot appears in column 2 in that list among the species susceptible to that disease.

7

The distinction between Lists I and II in that Annex, and the difference in the treatment laid down for the diseases mentioned therein, is justified by the fact that the diseases appearing in List I (hereinafter List I diseases) were not endemic in the Community, whereas the diseases in List II (hereinafter List II diseases) were already present in certain parts of the territory of the Community.

8

Article 5 of Directive 91/67, as amended, lays down the procedure to be followed to obtain approval of a zone within the territory of the Community, in which one or more of the List II diseases is not present (hereinafter approved zone). Article 6 of that directive institutes a similar procedure for farms situated in non-approved zones (hereinafter approved farms).

9

The criteria for approval of a zone are laid down in Annex B to Directive 91/67, as amended. Annex C to that directive contains similar provisions for the approval of farms.

10

Article 7(1) of Directive 91/67, as amended, reads as follows: The placing on the market of live fish belonging to the susceptible species referred to in Annex A, column 2 of List II, their eggs or gametes, shall be subject to the following additional guarantees:

(a)

where they are to be introduced into an approved zone, they must, in accordance with Article 11, be accompanied by a movement document corresponding to the model set out in Annex E, Chapter 1 or 2, certifying that they come from an approved zone or an approved farm ...;

(b)

where they are to be introduced into a farm which, although not situated in an approved zone, fulfils the conditions set out in Annex C I, they must in accordance with Article 11, be accompanied by a movement document corresponding to the model set out in Annex E, Chapter 1 or 2, certifying that they come respectively from an approved zone or from a farm of the same health status as the farm of destination.

11

Article 9(1) of Directive 91/67, as amended, provides: The placing on the market in an approved zone of aquaculture animals and products for human consumption originating in a non-approved zone shall be subject to the following requirements:

1.

Fish susceptible to the diseases referred to in Annex A, column 1, list II, must be slaughtered and eviscerated prior to dispatch. However, pending the outcome of the review provided for in Article 28, the obligation to eviscerate shall not be required, if the fish come from an approved farm in a non-approved zone. Derogations from this principle may be adopted under the procedure provided for in Article 26. Pending that decision, national rules shall continue to apply subject to compliance with the general provisions of the Treaty.

12

It is therefore apparent from the provisions of Directive 91/67, as amended, that the requirement that fish must come from an approved zone or an approved farm if they are to be placed live on the market applies in relation to the species susceptible to List II diseases, including VHS, but not in relation to List I diseases, namely ISA. Species of fish susceptible to the diseases in List II, which come from neither an approved zone nor an approved farm, may be allowed into an approved zone only if they have been slaughtered and eviscerated prior to dispatch.

Decision 92/538/EEC

13

The zones of Great Britain and Northern Ireland were approved with regard to infectious haematopoietic necrosis and VHS by Commission Decision 92/538/EEC of 9 November 1992 (OJ 1992 L 347, p. 67).

Directive 93/53

14

Directive 93/53 applies to the diseases in Lists I and II. The 12th recital in its preamble states: ... Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ..., and in particular Article 5 thereof, applies in the event of an outbreak of one of the diseases listed in Annex A to Directive 91/67/EEC.

15

Article 3 of Directive 93/53 requires Member States to register farms which raise or keep fish which are susceptible to the diseases in Lists I and II. Under Article 4 of that directive they are required to make compulsory the notification of any case in which the existence of such a disease is suspected.

16

Article 5 of the same directive covers the situation in which fish are suspected of infection by a List I disease. It requires the adoption of various measures, including an official census of all species and categories of fish, the imposition of a safety zone around the affected farm, the

disposal of dead fish or their offal under the supervision of the official service, the use of appropriate means of disinfection at the entrances and exits of the farm and an epizootic investigation.

17

Article 6 of Directive 93/53 states: As soon as the presence of a List I disease has been officially confirmed, Member States shall ensure that the official service orders that, in addition to the measures listed in Article 5(2), the following measures be applied:

(a)

in an infected farm:

—

all fish must be immediately withdrawn,

—

in the case of inland farms all pools must be drained for the purposes of cleaning and disinfection,

—

all eggs and gametes, dead fish and fish showing clinical signs of disease shall be regarded as high-risk material and must be destroyed under the supervision of the official service, in accordance with Directive 90/667/EEC ...,

—

all live fish shall either be killed and destroyed under the supervision of the official service in accordance with Directive 90/667/EEC, or else, in the case of fish which have reached commercial size and show no clinical sign of disease, be slaughtered under the supervision of the official service for marketing or processing for human consumption. In the latter case, the official service shall ensure that the fish are immediately slaughtered and gutted, that these operations are carried out in conditions such as to prevent the spread of pathogens, that the fish waste and offal are regarded as high-risk material and are submitted to a treatment to destroy pathogens in accordance with Directive 90/667/EEC and that the used water is submitted to a treatment which inactivates any pathogens it may contain;

—
after removal of the fish, eggs and gametes, ponds, equipment and any material liable to be contaminated must be cleaned and disinfected as soon as possible following the instructions established by the official service in such a way as to eliminate any risk of the agent of the disease spreading or surviving. The procedures for cleaning and disinfecting an infected farm shall be determined in accordance with the procedure laid down in Article 19;

—
any substances which might be contaminated, referred to in Article 5 (2)(d), must be destroyed or treated in such a way as to ensure the destruction of any pathogen present;

—
an epizootic investigation must be carried out in accordance with Article 8(1) and the provisions of Article 8(4) must be applied; this investigation must include the taking of samples for laboratory examination;

(b)

all farms situated in the water catchment area or in the coastal zone in which the infected farm is situated shall undergo health inspections; if these inspections reveal positive cases, the measures provided for under (a) of this paragraph shall be applied;

(c)

the repopulation of the farm shall be authorised by the official service following satisfactory inspection of the cleaning and disinfection operations and at the end of a period deemed adequate by the official service to ensure eradication of the pathogen, and of other possible infections in the same water catchment area;

(d)

[if] application of the measures laid down under (a), (b), (c) and (d) of Article 5(2) requires the cooperation of the official services of other Member States, the official services of the Member States concerned shall collaborate to ensure compliance with the measures laid down in this Article.

Where necessary, appropriate additional measures shall be adopted in accordance with the procedure laid down in Article 19.

18

Article 9 of Directive 93/53 provides:

1.

Where a List II disease is suspected and/or confirmed in an approved zone or on an approved farm situated in a non-approved zone, an epizootic investigation shall be carried out in accordance with Article 8. Member States wishing to regain their status defined in accordance with Directive 91/67/EEC must comply with the provisions of Annexes B and C to that Directive.

2.

If the epizootic investigation reveals that the disease could have been introduced from an approved zone or from another approved farm, or could have been transferred to another approved farm as a result of the movement of fish, eggs or gametes, vehicles or persons, or in any other way, those zones or farms shall be considered suspect and the appropriate measures shall apply.

3.

The official service may, however, authorise the fattening of fish to be slaughtered until they reach commercial size.

19

The provisions of Annex B to Directive 91/67, as amended, mentioned in Article 9(1) of Directive 93/53 provide that the approval of a zone may be restored provided that, among other things, all fish in the infected farms have been slaughtered, and infected or contaminated fish have been destroyed.

20

Under Article 17 of Directive 93/53: The conditions governing the Community's financial contribution to the measures connected with the application of this Directive are laid down in Decision 90/424/EEC.

21

Article 20(2) of that directive provides: However, from the date laid down in paragraph 1, Member States may, subject to the general rules of the Treaty, maintain or apply in their territory stricter provisions than those laid down by this Directive. They shall notify the Commission of any such measure.

Decision 90/424/EEC

22

Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field (OJ 1990 L 224, p. 19), lays down, among other things, detailed financial rules governing the Community's contribution towards emergency measures which are necessary in the case of outbreaks of the diseases listed in Article 3(1) thereof and towards programmes for the eradication and monitoring of certain diseases listed in the Annex thereto. It provides, in each case, for a financial contribution by the Community to national compensation programmes for farmers.

23

The list of diseases in Article 3(1) of Decision 90/424 does not include any fish disease. It may, however, as Article 5(2) of that decision expressly provides, be added to so as to include diseases which can be transmitted to fish.

24

In addition, by virtue of Article 3(2) of Decision 90/424, a Member State may obtain a financial contribution from the Community towards emergency measures which are necessary in the case of outbreaks of the diseases listed in paragraph 1 of that article, only on condition that the measures immediately applied by it include, at least, in particular, swift and adequate compensation of the livestock farmers.

25

The only fish disease which is mentioned in the list in the Annex to Decision 90/424 is infectious haematopoietic necrosis, which was added to that list by Council Decision 94/370/EC of 21 June 1994 (OJ 1994 L 168, p. 31).

National legislation

26

Directive 91/67 was implemented in the United Kingdom by the Fish Health Regulations 1992 (S.I. 1992 No 3300).

27

Directive 93/53 was implemented in the United Kingdom by the Diseases of Fish (Control) Regulations 1994 (S.I. 1994 No 1447). Regulations 4 and 5 thereof brought into effect the minimum Community measures for the control of List I diseases. They oblige the minister responsible to adopt orders requiring the application of measures prescribed by Directive 93/53.

28

When the Diseases of Fish (Control) Regulations 1994 were made, no clinical or other signs of List II diseases had been observed in the United Kingdom, entitling it, therefore, in that regard to the status of an approved zone. That Member State decided that an outbreak of such a disease called for the application of the same measures as the Community had laid down for List I diseases.

29

Regulation 7 of the Diseases of Fish (Control) Regulations 1994 therefore obliges the minister responsible to adopt orders imposing the same measures in respect of List II diseases as those intended to control List I diseases. The measures which the minister is bound to adopt by order in the case of a confirmed epidemic of VHS in an approved zone thus comprise:

(iii)

the destruction of all eggs, gametes, dead fish, and fish showing clinical signs of disease, under the supervision of the Minister and in accordance with the provisions of Directive 90/667/EEC;

(iv)

(aa)

the killing and destruction of all live fish, under the supervision of the Minister and in accordance with the provisions of Directive 90/667/EEC; or

(bb)

the slaughter of all live fish, for marketing or processing for human consumption, under the supervision of the Minister, but only if the fish have reached commercial size and show no clinical signs of disease

.

3.7.2. The questions referred

Case C-20/00

30

McConnell Salmon Limited (MSL) was acquired by Booker in 1995 and 1996. MSL had entered into a lease of a turbot farm on the Isle of Gigha (United Kingdom) in 1993. At the same time it had purchased a turbot stock of year classes 1991 and 1993. It subsequently introduced further turbot to the farm, of year class 1994. The farm was, at that time, situated in an approved zone under Directive 91/67, as amended.

31

In August 1994, an outbreak of VHS was confirmed at that farm, and, in September 1994, the Secretary of State for Scotland served a notice (hereinafter the 1994 Notice) on MSL under Regulation 7 of the Diseases of Fish (Control) Regulations 1994.

32

Under Article 4 of the 1994 Notice: Subject to paragraph 5 hereof, all fish will be killed and their carcasses destroyed in accordance with the provisions of Council Directive 90/667/EEC provided that the carcasses or remains of those fish shall be disposed of in such a manner or to such a place as shall be previously approved by the Secretary of State.

33

Article 5 of the 1994 Notice provides: Any fish which, at the date of this Notice, are of commercial size may be slaughtered for marketing or processing for human consumption provided that:

(a)

in the opinion of an inspector they show no clinical signs of disease;

(b)

they are first eviscerated;

(c)

their slaughter, evisceration and preparation for marketing or processing for human consumption is carried out in accordance with any rule of law relating to those matters;

...

34

The fish in year classes 1993 and 1994 were not of a commercial size when the 1994 Notice was served and thus had to be killed and destroyed in accordance with paragraph 4 thereof. The fish in year class 1991, which were then of commercial size, were slaughtered for marketing or processing for human consumption, in accordance with paragraph 5 of that notice.

35

As a result of that outbreak of VHS, Decision 92/538 was amended by Commission Decision 94/817/EC of 15 December 1994 (OJ 1994 L 337, p. 88), so as to redefine the approved zones with regard to VHS as including [t]he territory of Great Britain except the island of Gigha.

36

MSL claimed compensation from the Secretary of State for the loss it had allegedly suffered as a result of the slaughter and destruction of the 1993 and 1994 fish, and the slaughter and forced early marketing of the 1991 fish. In May 1996, the Secretary of State informed the petitioner in the main proceedings that he considered that it had no legal right to compensation, and, moreover, that it would be inappropriate to make an ex gratia payment, on

the ground that the Government had a long-established policy of not paying compensation to those subjected to measures taken for the control of fish diseases.

37

Booker commenced an action against the Secretary of State seeking judicial review of Regulation 7 of the Diseases of Fish (Control) Regulations 1994 and of the decision refusing compensation taken by the Secretary of State in May 1996. At first instance, the Lord Ordinary in the Court of Session (Scotland) (United Kingdom) found that the Secretary of State had acted illegally by failing to provide either legislative or administrative means for payment of any compensation where slaughter orders were made under that regulation.

38

The Secretary of State appealed against that decision. The Scottish Ministers, who had in law succeeded the Secretary of State, adopted his position in relation to the claim for compensation and proceeded with the appeal.

39

Since it took the view that the outcome of the main proceedings depended on the interpretation of Community law, the Court of Session (Scotland) decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

1.

Where, in implement of an obligation under Directive 93/53/EEC to provide control measures for an outbreak of a List II disease on an approved farm or in an approved zone, a Member State adopts a domestic measure the application of which results in the destruction and slaughter of fish, are the principles of Community law relating to the protection of fundamental rights, in particular the right to property, to be interpreted as having placed on a Member State the obligation to adopt measures providing for the payment of compensation:

(a)

to an owner of fish which are destroyed; and

(b)

to an owner of fish which are required to be slaughtered immediately, thereby necessitating the immediate sale of those fish by that owner?

2.

If the Member State is required to adopt such measures, what are the criteria of interpretation needed by a national court to determine whether the measures that are adopted are compatible with the fundamental rights, in particular the right to property, which the Court ensures and which derive in particular from the European Convention on Human Rights?

3.

In particular, do the criteria require that the measures differentiate between the situation where the outbreak of the disease was due to the fault of the owner of the fish concerned and the situation where the owner was not at fault?

Case C-64/00

40

Hydro Seafood operates several salmon farms in western Scotland. In 1998, those farms were affected by an outbreak of ISA. Pursuant to Regulation 5 of the Diseases of Fish (Control) Regulations 1994, the Secretary of State served several notices (hereinafter the 1998 Notices) on Hydro Seafood between May and July 1998 requiring the slaughter of its stocks of fish which were not yet of marketable size and the marketing of its stocks which were of such size.

41

Hydro Seafood complied with the 1998 Notices. It claimed however that, besides the loss resulting directly from the destruction and early sale of its fish stocks, it had incurred further significant costs through the stringent practical measures imposed by the 1998 Notices. Hydro Seafood therefore claimed compensation from the Secretary of State for its losses, which it estimated at GBP 14 million. The latter rejected the claim and refused any compensation.

42

In March 1999, Hydro Seafood commenced an action against the Secretary of State for judicial review of that decision refusing compensation. Having succeeded the Secretary of State, the Scottish Ministers adopted the same position.

43

Since it took the view that the main action raised similar but not identical questions to those referred to the Court in Case C-20/00, the Court of Session (Scotland) decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

1.

Where, in implement of an obligation under Directive 93/53/EEC to provide control measures for an outbreak of a List I disease, a Member State adopts a domestic measure the application of which results in the destruction and slaughter of fish, are the principles of Community law relating to the protection of fundamental rights, in particular the right to property, to be interpreted as having placed on a Member State the obligation to adopt measures providing for the payment of compensation:

(a)

to an owner of fish which are destroyed; and

(b)

to an owner of fish which are required to be slaughtered immediately, thereby necessitating the immediate sale of those fish by that owner?

2.

If the Member State is required to adopt such measures, what are the criteria of interpretation needed by a national court to determine whether the measures that are adopted are compatible with the fundamental rights, in particular the right to property, which the Court ensures and which derive in particular from the European Convention on Human Rights?

3.

In particular, do the criteria require that the measures differentiate between the situation where the outbreak of the disease was due to the fault of the owner of the fish concerned and the situation where the owner was not at fault?

4

Is Directive 93/53/EEC invalid as being in breach of the fundamental right to property in not making provision for the payment of compensation to (a) an owner of fish which are destroyed and (b) to an owner of fish which are required to be slaughtered immediately, thereby necessitating the immediate sale of those fish by that owner, in circumstances where an outbreak of ISA has been confirmed?

The first and second questions in Cases C-20/00 and C-64/00 and the fourth question in Case C-64/00

44

It should be noted, at the outset, that Directive 93/53 provides that, at farms infected by certain diseases, Member States are to adopt, among others, the following measures:

—

in relation to List I diseases, all fish showing clinical signs of disease are to be regarded as high-risk material and must be destroyed under the supervision of the official service. All live fish must be killed and destroyed under the supervision of the official service, or, in the case of fish which are of marketable size and show no clinical signs of disease, be slaughtered under the supervision of the official service with a view to their marketing or processing for human consumption (first paragraph of Article 6, subparagraph (a), of Directive 93/53);

—

in relation to List II diseases, the restoration of a zone's approval under Directive 91/67, as amended, is subject to fulfilment of the requirements of Annex B to that directive, particularly the slaughter of all fish at the infected farms and the destruction of the infected or contaminated fish. The official service may, however, authorise the fattening of fish to be slaughtered until they reach commercial size (Article 9 of Directive 93/53).

In that context, the first two questions referred for a preliminary ruling in both Case C-20/00 and Case C-64/00, as well as the fourth question referred in Case C-64/00, are intended to ascertain, firstly, whether Directive 93/53, in so far as it imposes minimum control measures for List I diseases, is invalid because it infringes the fundamental right to property and, secondly, whether the measures adopted by a Member State against List I and List II diseases in implementing that directive are incompatible with that right, where neither the directive nor the national implementing measures provides for the award of compensation to affected owners. Observations submitted to the Court All the interested parties which have submitted observations to the Court point out that fundamental rights are an integral part of the general principles of Community law. They state, further, that the requirements arising from the protection of fundamental rights in the Community legal order are also binding on the Member States when they implement Community legislation and that such rights include the right to property, which is also enshrined in Article 1 of the First Protocol to the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed at Rome on 4 November 1950 (hereinafter the ECHR).

Booker and Hydro Seafood submit that the principles of Community law on the protection of fundamental rights, in particular of the right to property, are to be interpreted as meaning that they require compensation to be paid to owners whose fish have been destroyed, either by being killed and destroyed or by being slaughtered in circumstances such as those in the main proceedings. They cite in that regard, in particular, the case-law of the European Court of Human Rights (*Sporrong and Lönnroth v. Sweden* , judgment of 23 September 1982, Series A No 52; *James and Others v. United Kingdom* , judgment of 21 February 1986, Series A No 98, and *Pressos Compania Naviera SA and Others v. Belgium* , judgment of 20 November 1995, Series A No 332).

According to the petitioners in the main proceedings, the existence and extent of the right to compensation are important elements in the balance between the general public interest and private rights so as to ensure that the protection accorded by Article 1 of the First Protocol of

the ECHR against expropriation and deprivation of use of property is not illusory or wholly ineffective.

49

They state that they do not contend that the restrictions placed, in the circumstances of the main proceedings, on their right to property run counter to objectives of general interest pursued by the Community in the context of the common organisation of the aquaculture market. However, in the absence of any form of compensation, they submit that the measures taken by the United Kingdom Government constitute a disproportionate and intolerable interference impairing the very substance of that right.

50

Booker and Hydro Seafood submit also that, in so far as it affects a fundamental right such as the right to property, the complete absence of compensation for persons affected by national measures implementing a directive infringes the principle of proportionality.

51

Hydro Seafood also submits that there are no exceptional circumstances such as might justify an absolute refusal to compensate it for the losses suffered as a result of the measures in issue in the main proceedings.

52

The Scottish Ministers, the United Kingdom, French, Italian, Netherlands and Norwegian Governments as well as the Council and the Commission contend, on the contrary, firstly, that the Court of Justice has never held that the general principles of Community law require the payment of compensation in circumstances such as those in the main proceedings and, secondly, that such an absence of compensation is compatible with the case-law of the European Court of Human Rights.

53

The Scottish Ministers, the Netherlands Government and the Commission submit further that the losses suffered by the petitioners in the main proceedings result not from the destruction and slaughter ordered but from the outbreak of diseases regarding which the Community is justified in taking measures to control.

54

According to the French, Italian, Netherlands and Norwegian Governments as well as the Council and the Commission, where the destruction and slaughter of fish are justified by a Community objective of general interest and such measures are not so disproportionate in relation to the objective pursued as to impair the very substance of the right to property, they do not require the payment of compensation.

55

In relation to the validity of Directive 93/53, Hydro Seafood submits that, while that directive does not expressly provide for a system of compensation for farmers affected by measures which it imposes, it impliedly envisages one. If the Member States have neither the power nor the obligation to establish a system of compensation for such farmers, the relevant provisions of the directive should be held to be unlawful.

56

According to the Italian and Netherlands Governments as well as the Council and the Commission, the fact that Directive 93/53 makes no provision for compensating farmers does not mean that it infringes the right to property and thus is tainted by illegality.

57

The Netherlands Government also submits that, in the absence of Community provisions regulating the question, the principle and the form of such compensation are matters for each Member State.

Findings of the Court

58

By adopting Directive 93/53, the Community legislature laid down animal health and preventive measures which Member States must take to prevent and to eliminate certain fish diseases in their territory.

59

It must be stated at the outset that no right of compensation for the benefit of owners whose fish have been destroyed or slaughtered following the implementation of such measures follows either from the scheme or from the terms of Directive 93/53.

60

It is true that Article 17 of Directive 93/53 provides that the conditions governing the Community's financial contribution towards the measures connected with the application of that directive are laid down in Decision 90/424. That decision makes provision for a financial contribution by the Community for the benefit of Member States which have, in particular, incurred costs in compensating owners whose animals have been slaughtered or destroyed in order to control certain diseases, within the framework of either emergency measures or eradication and monitoring programmes.

61

However, the list in Article 3(1) of Decision 90/424, which sets out the diseases subject to emergency measures, does not mention any fish disease.

62

Furthermore, by virtue of Article 3(2) of Decision 90/424, a Member State may obtain a financial contribution from the Community for emergency measures which are necessary in the case of outbreaks of the diseases listed in Article 3(1) only on condition that the measures immediately applied by it include, at least, in particular, swift and adequate compensation for farmers. It is therefore only if the Member State decides to pay such compensation and satisfies those requirements that it may obtain the financial contribution from the Community.

63

The Community financial measure which Article 24 of Decision 90/424 provides for the eradication and monitoring of diseases can apply only to the diseases listed in the annex to that decision. Since Decision 94/370 came into force, the only fish disease on that list has been infectious haematopoietic necrosis.

64

It is therefore necessary to determine whether, in the absence of compensation for affected farmers, Directive 93/53 is compatible with the fundamental right to property.

65

In that regard, according to settled case-law, fundamental rights form an integral part of the general principles of law, whose observance the Court ensures. For that purpose, the Court draws inspiration from the constitutional traditions common to the Member States and from the guidelines supplied by international treaties for the protection of human rights on which the Member States have collaborated or to which they are signatories (see, to that effect, Case 44/79 Hauer [1979] ECR 3727, paragraph 15). The ECHR has special significance in that respect (see, among others, Case C-274/99 P Connolly v Commission [2001] ECR I-1611, paragraph 37, and Case C-94/00 Roquette Frères [2002] ECR I-9011, paragraph 25).

66

The principles established by that case-law have been reaffirmed in the preamble to the Single European Act and in Article F(2) of the Treaty on European Union (Case C-415/93 Bosman [1995] ECR I-4921, paragraph 79). They are now set out in Article 6(2) EU pursuant to which the Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms ... and as they result from the constitutional traditions common to the Member States, as general principles of Community law.

67

The right to property is one of the fundamental rights protected by the Court (Hauer , cited above, paragraph 17).

68

However, fundamental rights are not absolute rights but must be considered in relation to their social function. Consequently, restrictions may be imposed on the exercise of those rights, in particular in the context of a common organisation of the markets, provided that those restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute, with regard to the aim pursued, a disproportionate and intolerable

interference, impairing the very substance of those rights (Case 5/88 Wachauf [1989] ECR 2609, paragraph 18; Case C-177/90 Kühn [1992] ECR I-35, paragraph 16, and Case C-22/94 The Irish Farmers' Association and Others [1997] ECR I-1809, paragraph 27).

69

It is in the light of those criteria that the Court must assess the compatibility of the regime in issue in the main proceedings with the requirements arising from the protection of the fundamental right to property.

70

It is necessary, firstly, to identify the objectives pursued by Directive 93/53 and, secondly, to determine whether, taking account of such objectives, the destruction and slaughter measures provided for by that directive constitute, in the absence of compensation for affected owners, a disproportionate and intolerable interference impairing the very substance of the right to property.

71

The provisions of Directive 93/53 must be seen against the background of the common organisation of the market in aquaculture animals and products, which is closely connected with the structural policy of the Community in that field. Certain objectives pursued in that regard are apparent from Directive 91/67, as amended.

72

It follows from the entirety of Directive 91/67, as amended, that the policy implemented by the Community is intended to contribute to the completion of the internal market in aquaculture animals and products while avoiding the spread of contagious diseases of fish.

73

That directive therefore seeks to attain, within the framework of the guidelines laid down in Article 39 of the EC Treaty (now, after amendment, Article 33 EC), a double objective which is, firstly, to ensure, by the completion of the internal market, the rational development of the aquaculture sector and to increase its productivity and, secondly, to lay down, at Community level, health rules for that sector.

74

In order to attain that double objective, Directive 91/67, as amended, lays down general requirements relating to the placing on the market of aquaculture animals, including the species susceptible to List I and II diseases. It establishes a broad range of rules which apply both to the approval of zones and farms considered to be completely or partially clear of List II diseases, including VHS, and to the placing on the market of aquaculture animals and products.

75

In relation to List II diseases, Articles 5 to 7 and 9 of, as well as Annex A to, Directive 91/67, as amended, should be noted. Since the health situation of aquaculture animals is not the same throughout the territory of the Community, those provisions define and govern approved zones and approved farms which are entitled to a special animal health status, in order to facilitate the placing on the market of fish from such zones and farms.

76

In particular, Article 7 of Directive 91/67, as amended, provides that species of fish susceptible to List II diseases may be freely transported alive and placed on the market in the Community if they come from an approved zone or farm. In order to allow such placing on the market, that directive defines the conditions and the procedure which apply to the approval of a zone or farm and to the maintenance, suspension, restoration and withdrawal of approval.

77

It was in that context that Directive 93/53 was adopted. It is apparent from its preamble that it too fulfils a double function. Firstly, it enables the taking of control measures as soon as the presence, on a farm, of a List I or II disease is suspected, so that immediate and effective action can be implemented once the presence of the disease is confirmed. Secondly, as an outbreak of disease can quickly spread and become epizootic, causing the death of numerous fish as well as disturbances on such a scale that the profitability of aquaculture can be seriously reduced, that directive seeks to prevent the spread of the disease, in particular by carefully monitoring movements of fish and products liable to spread the infection.

78

Directive 93/53 therefore seeks to contribute to the completion of the internal market in aquaculture animals and products and forms part of a regime intended to introduce minimum Community measures for the control of certain fish diseases. Accordingly, the measures which that directive imposes are in conformity with objectives of general interest pursued by the Community.

79

As to whether, taking into account the objective sought and in the absence of compensation, the restrictions on the right to property resulting from those measures constitute a disproportionate and intolerable interference impairing the very substance of the right to property, it must be observed that those measures are urgent and are intended to guarantee that effective action is implemented as soon as the presence of a disease is confirmed and to eliminate any risk of the spread or survival of the pathogen.

80

Further, the measures referred to do not deprive farm owners of the use of their fish farms, but enable them to continue to carry on their activities there.

81

In effect, the immediate destruction and slaughter of all the fish enable owners to restock the affected farms as soon as possible.

82

Those measures therefore enable the resumption of the transportation and placing on the market in the Community of species of live fish susceptible to List I and II diseases, with the result that all interested parties, including fish farm owners, may benefit as a result.

83

Finally, as Booker itself acknowledged, the business which it carries on as an owner of a fish farm carries commercial risks. As the Scottish Ministers, the United Kingdom and Netherlands Governments and the Commission correctly maintained, the petitioners in the main proceedings can expect, as farmers, that a fish disease may break out at any moment and

cause them loss. Such risk is inherent in the business of raising and selling livestock and is the consequence of a natural occurrence, so far as both List I and II diseases are concerned.

84

As to the extent of any loss, by reason of their condition, fish which show clinical signs of disease have no marketable value. So far as concerns fish which have reached a commercial size and could have been marketed or processed for human consumption since they were not showing, when slaughtered, any clinical sign of disease, any loss eventually suffered by farmers by reason of the immediate slaughter of that kind of fish arises from the fact that they have been unable to choose the most advantageous time for their sale. In fact, because of the risk of their presenting clinical signs of disease in future, it is impossible to determine a more advantageous time for their sale. So far as all other types of fish are concerned, it is not possible to establish whether they have any marketable value either, because of the risk that in the future they will develop clinical signs of disease.

85

Admittedly, the Community legislature may consider, in the context of its broad discretion in the field of agricultural policy (see Case C-315/93 *Flip and Verdegem* [1995] ECR I-913, paragraph 26), that full or partial compensation is appropriate for owners of farms on which animals have been destroyed and slaughtered. Nonetheless, the existence, in Community law, of a general principle requiring compensation to be paid in all circumstances cannot be inferred from that fact.

86

It follows from all the preceding considerations that the minimum measures of immediate destruction and slaughter laid down by Directive 93/53 in order to control List I diseases do not constitute, in the absence of compensation for affected owners, a disproportionate and intolerable interference impairing the very substance of the right to property.

87

Therefore, the reply to the fourth question referred in Case C-64/00 must be that examination of that question has disclosed no factor of such a kind as to affect the validity of Directive 93/53 by reason of its laying down minimum measures to control List I diseases without providing for compensation for owners affected by those measures.

88

As regards the application of Directive 93/53 by the Member States, it is settled case-law (see, in particular, Wachauf , cited above, paragraph 19, and Case C-2/92 Bostock [1994] ECR I-955, paragraph 16), that the requirements flowing from the protection of fundamental rights in the Community legal order are also binding on Member States when they implement Community rules. Consequently, Member States must, as far as possible, apply those rules in accordance with those requirements.

89

The United Kingdom adopted the minimum measures to control List I diseases required by Directive 93/53. It did not make use of the power accorded to the Member States by Article 9(3) of that directive permitting the fattening of fish infected by a List II disease until they reach commercial size, but imposed, with regard to List II diseases, measures equivalent to those required by the directive in respect of List I diseases.

90

In circumstances such as those in the main proceedings, on the one hand, the implementation by a Member State of compulsory control measures against List I diseases, which are identical to the minimum measures which the Community has imposed for those diseases and do not provide for compensation, does not constitute, having regard to the considerations set out in paragraphs 79 to 85 of this judgment, a disproportionate and intolerable interference impairing the very substance of the right to property.

91

On the other hand, the immediate destruction and slaughter of fish on a farm infected by a List II disease enable the restoration in a Member State, as quickly as possible, of the approval of a zone in a part of the territory of the Community in which that disease is not present. Such restoration enables species of live fish susceptible to those diseases to be placed on the market freely in the Community at the earliest opportunity and the prohibition, in an approved zone, of the placing on the market of those species of live fish which do not come from an approved zone or farm.

92

For the same reasons as those mentioned in paragraphs 79 to 85 and 91 of this judgment, in circumstances such as those in the main proceedings, the implementation by a Member State of control measures against List II diseases, which are similar to the minimum measures which the Community has laid down for List I diseases and which do not provide for compensation, corresponds to objectives of general interest pursued by the Community and does not constitute a disproportionate and intolerable interference impairing the very substance of the right to property.

93

Therefore, the reply to the first two questions referred in Cases C-20/00 and C-64/00 must be that measures for the immediate destruction and slaughter of fish implemented by a Member State in order to control List I and II diseases in the context of the application of Directive 93/53, which are, respectively, identical and similar to the minimum measures which the Community has laid down for List I diseases and which do not provide for compensation, are not, in circumstances such as those in the main proceedings, incompatible with the fundamental right to property.

The third question referred in Cases C-20/00 and C-64/00

94

By the third question referred in Cases C-20/00 and C-64/00, the national court asks whether the determination of the compatibility with the fundamental right to property of the measures adopted by a Member State in order to control List I and II diseases in the context of the application of Directive 93/53 may differ, depending on whether or not the outbreak of the disease is due to the fault of the fish owner.

95

Having regard to the replies given to the first and second questions in Cases C-20/00 and C-64/00, the reply to the third question in those cases must be that, in circumstances such as those in the main proceedings, the fact that the outbreak of the disease is due or not due to the fish owner's fault has no bearing on the compatibility with the fundamental right to property of the measures imposed by a Member State in order to control List I and II diseases in the context of the application of Directive 93/53.

3.7.3. Costs

96

The costs incurred by the United Kingdom, French, Italian, Netherlands and Norwegian Governments and by the Council and the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

3.7.4. The Court's decision

On those grounds,

THE COURT,

in answer to the questions referred to it by the Court of Session (Scotland) by orders of 11 January and 18 February 2000, hereby rules:

1.

Examination of the fourth question referred for a preliminary ruling in Case C-64/00 has disclosed no factor of such a kind as to affect the validity of Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases, by reason of its laying down minimum measures to control diseases in List I in Annex A to Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products, as amended by Council Directive 93/54/EEC of 24 June 1993, without providing for compensation for owners affected by those measures.

2.

The measures for the immediate destruction and slaughter of fish implemented by a Member State in order to control List I and II diseases in the context of the application of Directive 93/53, which are, respectively, identical and similar to the minimum measures which the Community has laid down for List I diseases and which do not provide for compensation, are

not, in circumstances such as those in the main proceedings, incompatible with the fundamental right to property.

3.

In circumstances such as those in the main proceedings, the fact that the outbreak of the disease is due or not due to the fish owner's fault has no bearing on the compatibility with the fundamental right to property of the measures imposed by a Member State in order to control List I and II diseases in the context of the application of Directive 93/53.

4. **"Abortion tourism" - a comparison of the judgments of the Court of Justice of the European Union and the European Court of Human Rights.**

4.1. The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan and Others¹⁸

4.1.1. Judgment

Grounds

1 By order dated 5 March 1990, which was received at the Court on 23 May 1990, the High Court of Ireland referred to the Court for a preliminary ruling under Article 177¹⁰ of the EEC Treaty three questions on the interpretation of Community law, in particular Article 60¹² of the EEC Treaty.

¹⁸ In Case C-159/90, *The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan and Others*

2 The questions arose in proceedings brought by the Society for the Protection of Unborn Children Ireland Ltd ("SPUC") against Stephen Grogan and fourteen other officers of students associations in connection with the distribution in Ireland of specific information relating to the identity and location of clinics in another Member State where medical termination of pregnancy is carried out.

3 Abortion has always been prohibited in Ireland, first of all at common law, then by statute. The relevant provisions at present in force are Sections 58 and 59 of the Offences Against the Person Act 1861, as reaffirmed in the Health (Family Planning) Act 1979.

4 In 1983 a constitutional amendment approved by referendum inserted in Article 40, Section 3, of the Irish Constitution a third subsection worded as follows: "The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right."

5 According to the Irish courts (High Court, judgment of 19 December 1986, and Supreme Court, judgment of 16 March 1988, *The Attorney General (at the relation of the Society for the Protection of Unborn Children Ireland Ltd) v Open Door Counselling Ltd and Dublin Wellwoman Centre Ltd* [1988] Irish Reports 593), to assist pregnant women in Ireland to travel abroad to obtain abortions, inter alia by informing them of the identity and location of a specific clinic or clinics where abortions are performed and how to contact such clinics, is prohibited under Article 40.3.3 of the Irish Constitution.

6 SPUC, the plaintiff in the main proceedings, is a company incorporated under Irish law whose purpose is to prevent the decriminalization of abortion and to affirm, defend and promote human life from the moment of conception. In 1989/90 Stephen Grogan and the other defendants in the main proceedings were officers of students associations which issued certain publications for students. Those publications contained information about the availability of legal abortion in the United Kingdom, the identity and location of a number of abortion clinics in that country and how to contact them. It is undisputed that the students associations had no links with clinics in another Member State.

7 In September 1989 SPUC requested the defendants, in their capacity as officers of their respective associations, to undertake not to publish information of the kind described above during the academic year 1989/90. The defendants did not reply, and SPUC then brought

proceedings in the High Court for a declaration that the distribution of such information was unlawful and for an injunction restraining its distribution.

8 By a judgment of 11 October 1989 the High Court decided to refer certain questions to the Court of Justice for a preliminary ruling under Article 177 of the EEC Treaty before ruling on the injunction applied for by the plaintiff. An appeal was brought against that judgment and, on 19 December 1989, the Supreme Court granted the injunction applied for but did not overturn the High Court's decision to refer questions to the Court of Justice for a preliminary ruling. Moreover, each of the parties was given leave to apply to the High Court in order to vary the decision of the Supreme Court in the light of the preliminary ruling to be given by the Court of Justice.

9 As it had already indicated in its judgment of 11 October 1989, the High Court considered that the case raised problems of interpretation of Community law; it therefore stayed the proceedings and referred the following questions to the Court of Justice for a preliminary ruling:

"1. Does the organized activity or process of carrying out an abortion or the medical termination of pregnancy come within the definition of 'services' provided for in Article 60 of the Treaty establishing the European Economic Community?

2. In the absence of any measures providing for the approximation of the laws of Member States concerning the organized activity or process of carrying out an abortion or the medical termination of pregnancy, can a Member State prohibit the distribution of specific information about the identity, location and means of communication with a specified clinic or clinics in another Member State where abortions are performed?

3. Is there a right at Community law in a person in Member State A to distribute specific information about the identity, location and means of communication with a specified clinic or clinics in Member State B where abortions are performed, where the provision of abortion is prohibited under both the Constitution and the criminal law of Member State A but is lawful under certain conditions in Member State B?"

10 Reference is made to the Report for the Hearing for a fuller account of the facts of the case, the course of the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

4.1.2. Jurisdiction of the Court

11 In its written observations, the Commission states that it is not clear whether the order referring the questions for a preliminary ruling was delivered in the context of the main action or in that of the proceedings for the grant of the injunction.

12 As the Court held in the judgment in *Pardini* (Case 338/85 *Pardini v Ministero del commercio con l' estero* [1988] ECR 2041, paragraph 11), a national court or tribunal is not empowered to bring a matter before the Court by way of a reference for a preliminary ruling under Article 177 of the Treaty unless a dispute is pending before it in the context of which it is called upon to give a decision which could take into account the preliminary ruling. Conversely, the Court of Justice has no jurisdiction to hear a reference for a preliminary ruling when at the time it is made the procedure before the court making it has already been terminated.

13 As far as these proceedings are concerned, if the High Court made the reference to this Court in the context of the interlocutory proceedings, it should be observed that the Supreme Court expressly authorized it to vary the injunction granted in the light of the preliminary ruling to be given by the Court of Justice. If, on the other hand, the request for a preliminary ruling was made in the context of the main proceedings, the High Court will have to give a decision on the substance of the case. This means that in either case the court making the reference is called upon to give a decision which could take into account the preliminary ruling. Consequently, it is entitled to refer questions to the Court under Article 177 of the Treaty and the Court has jurisdiction to entertain them.

14 SPUC, for its part, argues that no question of Community law arises in these proceedings and that the Court should refuse to give a ruling on the questions referred. First, the defendants in the main proceedings did not distribute the information in question in the context of any economic activity, which precludes the application of the Treaty rules on the freedom to provide services whose interpretation is sought. Secondly, as the provision of information took place entirely in Ireland and involved no other Member State, those provisions of the Treaty cannot apply.

15 In this regard, it is sufficient to observe that the circumstances referred to by SPUC go to the substance of the national court's questions. Consequently, whilst they may be taken into account in answering those questions, they are not relevant in determining whether the Court has jurisdiction to rule on the request for a preliminary ruling (see the judgment in Case 180/83 Moser v Land Baden-Wuerttemberg [1984] ECR 2539). As a result, it is necessary to proceed to examine the national court's questions.

First question

16 In its first question, the national court essentially seeks to establish whether medical termination of pregnancy, performed in accordance with the law of the State where it is carried out, constitutes a service within the meaning of Article 60 of the EEC Treaty.

17 According to the first paragraph of that provision, services are to be considered to be "services" within the meaning of the Treaty where they are normally provided for remuneration, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital or persons. Indent (d) of the second paragraph of Article 60 expressly states that activities of the professions fall within the definition of services.

18 It must be held that termination of pregnancy, as lawfully practised in several Member States, is a medical activity which is normally provided for remuneration and may be carried out as part of a professional activity. In any event, the Court has already held in the judgment in *Luisi and Carbone* (Joined Cases 286/82 and 26/83 *Luisi and Carbone v Ministero del Tesoro* [1984] ECR 377, paragraph 16) that medical activities fall within the scope of Article 60 of the Treaty.

19 SPUC, however, maintains that the provision of abortion cannot be regarded as being a service, on the grounds that it is grossly immoral and involves the destruction of the life of a human being, namely the unborn child.

20 Whatever the merits of those arguments on the moral plane, they cannot influence the answer to the national court's first question. It is not for the Court to substitute its assessment for that of the legislature in those Member States where the activities in question are practised legally.

21 Consequently, the answer to the national court's first question must be that medical termination of pregnancy, performed in accordance with the law of the State in which it is carried out, constitutes a service within the meaning of Article 60 of the Treaty.

Second and third questions

22 Having regard to the facts of the case, it must be considered that, in its second and third questions, the national court seeks essentially to establish whether it is contrary to Community law for a Member State in which medical termination of pregnancy is forbidden to prohibit students associations from distributing information about the identity and location of clinics in another Member State where medical termination of pregnancy is lawfully carried out and the means of communicating with those clinics, where the clinics in question have no involvement in the distribution of the said information.

23 Although the national court's questions refer to Community law in general, the Court takes the view that its attention should be focused on the provisions of Article 59 et seq. of the EEC Treaty, which deal with the freedom to provide services, and the argument concerning human rights, which has been treated extensively in the observations submitted to the Court.

24 As regards, first, the provisions of Article 59 of the Treaty, which prohibit any restriction on the freedom to supply services, it is apparent from the facts of the case that the link between the activity of the students associations of which Mr Grogan and the other defendants are officers and medical terminations of pregnancies carried out in clinics in another Member State is too tenuous for the prohibition on the distribution of information to be capable of being regarded as a restriction within the meaning of Article 59 of the Treaty.

25 The situation in which students associations distributing the information at issue in the main proceedings are not in cooperation with the clinics whose addresses they publish can be distinguished from the situation which gave rise to the judgment in *GB-INNO-BM* (Case C-362/88 *GB-INNO-BM v Confédération du Commerce Luxembourgeois* [1990] I-667), in which the Court held that a prohibition on the distribution of advertising was capable of constituting a barrier to the free movement of goods and therefore had to be examined in the light of Articles 30, 31 and 36 of the EEC Treaty.

26 The information to which the national court's questions refer is not distributed on behalf of an economic operator established in another Member State. On the contrary, the information constitutes a manifestation of freedom of expression and of the freedom to impart and receive

information which is independent of the economic activity carried on by clinics established in another Member State.

27 It follows that, in any event, a prohibition on the distribution of information in circumstances such as those which are the subject of the main proceedings cannot be regarded as a restriction within the meaning of Article 59 of the Treaty.

28 Secondly, it is necessary to consider the argument of the defendants in the main proceedings to the effect that the prohibition in question, inasmuch as it is based on a constitutional amendment approved in 1983, is contrary to Article 62 of the EEC Treaty, which provides that Member States are not to introduce any new restrictions on the freedom to provide services in fact attained at the date when the Treaty entered into force.

29 It is sufficient to observe, as far as that argument is concerned, that Article 62, which is complementary to Article 59, cannot prohibit restrictions which do not fall within the scope of Article 59.

30 Thirdly and lastly, the defendants in the main proceedings maintain that a prohibition such as the one at issue is in breach of fundamental rights, especially of freedom of expression and the freedom to receive and impart information, enshrined in particular in Article 10(1) of the European Convention on Human Rights.

31 According to, *inter alia*, the judgment of 18 June 1991 in *Elliniki Radiophonia Tileorasi* (Case C-260/89 *Elliniki Radiophonia Tileorasi v Dimotiki Etairia Pliroforissis* [1991] ECR I-2951, paragraph 42), where national legislation falls within the field of application of Community law the Court, when requested to give a preliminary ruling, must provide the national court with all the elements of interpretation which are necessary in order to enable it to assess the compatibility of that legislation with the fundamental rights - as laid down in particular in the European Convention on Human Rights - the observance of which the Court ensures. However, the Court has no such jurisdiction with regard to national legislation lying outside the scope of Community law. In view of the facts of the case and of the conclusions which the Court has reached above with regard to the scope of Articles 59 and 62 of the Treaty, that would appear to be true of the prohibition at issue before the national court.

32 The reply to the national court's second and third questions must therefore be that it is not contrary to Community law for a Member State in which medical termination of pregnancy is forbidden to prohibit students associations from distributing information about the identity

and location of clinics in another Member State where voluntary termination of pregnancy is lawfully carried out and the means of communicating with those clinics, where the clinics in question have no involvement in the distribution of the said information.

4.1.3. Costs

Decision on costs

The costs incurred by Ireland and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, in so far as the parties to the main proceedings are concerned, in the nature of a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

Operative part

4.1.4. The Court's decision

On those grounds,

THE COURT,

in reply to the questions submitted to it by the High Court of Ireland, by order of 5 March 1990, hereby rules:

1. Medical termination of pregnancy, performed in accordance with the law of the State in which it is carried out, constitutes a service within the meaning of Article 60¹² of the Treaty;
2. It is not contrary to Community law for a Member State in which medical termination of pregnancy is forbidden to prohibit students associations from distributing information about the identity and location of clinics in another Member State where voluntary termination of pregnancy is lawfully carried out and the means of communicating with those clinics, where the clinics in question have no involvement in the distribution of the said information.

4.2. Case Of A, B and C v. Ireland¹⁹

4.2.1. The procedure

1. The case originated in an application (no. 25579/05) against Ireland lodged with the Court under Article 34³² of the Convention for the Protection of Human Rights and Fundamental Freedoms (“the Convention”) by two Irish nationals, Ms A and Ms B, and by a Lithuanian national, Ms C, (“the applicants”), on 15 July 2005. The President of the Chamber acceded to the applicants’ request not to have their names disclosed (Rule 47 § 3³³ of the Rules of Court).
2. The applicants were represented by Ms J. Kay, a lawyer with the Irish Family Planning Association, a non-governmental organisation based in Dublin. The Irish Government (“the Government”) were represented by their Agents, Ms P. O’Brien and, subsequently, Mr P. White, both of the Department of Foreign Affairs, Dublin.
3. The first two applicants principally complained under Article 8 about, inter alia, the prohibition of abortion for health and well-being reasons in Ireland and the third applicant’s main complaint concerned the same Article and the alleged failure to implement the constitutional right to an abortion in Ireland in the case of a risk to the life of the woman.
4. The application was allocated to the Third Section of the Court (Rule 52 § 1³⁴ of the Rules of Court). On 6 May 2008 a Chamber of that Section, composed of the following judges: Josep Casadevall, President, Elisabet Fura, Boštjan Zupančič, Alvin Gyulumyan, Egbert Myjer, Ineta Ziemele, Luis López Guerra, judges, and also of Santiago Quesada, Section Registrar, communicated the case to the respondent Government.
5. The applicants and the Government each filed written observations on the admissibility and merits. Third-party comments were also received from the Lithuanian Government which had exercised their right to intervene (Article 36 § 1³⁵ of the Convention and Rule 44 § 1 (b)³⁶). Leave having been accorded by the President of the Section to intervene in the written procedure (Article 36 § 2³⁵ of the Convention and Rule 44 § 2³⁶), numerous third party

¹⁹ Judgment Strasbourg 16 December 2010; Application no. 25579/05; Case Of A, B and C v. Ireland

submissions were also received: joint observations from the European Centre for Law and Justice in association with Kathy Sinnott (Member of the European Parliament), the Family Research Council (Washington D.C.) and the Society for the Protection of Unborn Children (London); observations from the Pro-Life Campaign; joint observations from Doctors for Choice (Ireland) and the British Pregnancy Advisory Service; and joint observations from the Center for Reproductive Rights and the International Reproductive and Sexual Health Law Programme.

6. On 7 July 2009 the Chamber relinquished jurisdiction in favour of the Grand Chamber, none of the parties having objected to relinquishment (Article 30³⁷ of the Convention and Rule 72³⁸). The composition of the Grand Chamber was determined according to the provisions of Article 27 §§ 2 and 3³⁹ of the Convention and Rule 24⁴⁰ of the Rules of Court.

7. Judge Ann Power, the judge elected in respect of Ireland, withdrew from sitting in the Grand Chamber (Rule 28). The Government appointed Mr Justice Nicolas Kearns and, following his withdrawal due to a judicial appointment in Ireland, Ms Justice Mary Finlay Geoghegan to sit as an ad hoc judge (former Article 27 § 2³⁹, now Article 26 § 4⁴¹, of the Convention, and Rule 29 § 1 of the Rules of Court). At the first deliberations, Judge George Nicolaou replaced Judge Peer Lorenzen, who was unable to take part in the further consideration of the case (Rule 24 § 3⁴⁰).

8. The applicants and the Government each filed a memorial on the admissibility and on the merits with the Grand Chamber. The Lithuanian Government did not make further observations before the Grand Chamber and their, as well as the above-described other third party submissions to the Chamber, were included in the Grand Chamber's file.

9. A hearing took place in public in the Human Rights Building, Strasbourg, on 9 December 2009 (Rule 59 § 3). There appeared before the Court:

(a) for the Government

Mr P. White, Agent,

Mr P. Gallagher, Attorney General,

Mr D. O'Donnell, Senior Counsel,

Mr B. Murray, Senior Counsel, Counsel

Ms C. O'Rourke,

Ms G. Luddy,

Ms S. Farrell,

Ms B. McDonnell, Advisers.

(b) for the applicants

Ms J. Kay,

Ms C. Stewart, Senior Counsel, Counsel.

10. The Court heard addresses by Messrs Gallagher S.C. and O'Donnell S.C. for the Government and by Ms Kay and Ms Stewart S.C for the applicants.

4.2.2. The Facts

11. The applicants reside in Ireland and are women over 18 years of age.

12. The facts, as submitted by the applicants, are summarised immediately below. The Government's position was that these factual submissions were general, unsubstantiated and untested either by a domestic court, or through any other form of interaction with the Irish State, and they made further factual submissions as regards each applicant (summarised at paragraphs 115-118 and 122 below).

I THE CIRCUMSTANCES OF THE CASE

A. The first applicant (A)

13. On 28 February 2005 the first applicant travelled to England for an abortion as she believed that she was not entitled to an abortion in Ireland. She was 9½ weeks pregnant.

14. She had become pregnant unintentionally, believing her partner to be infertile. At the time she was unmarried, unemployed and living in poverty. She had four young children. The

youngest was disabled and all children were in foster care as a result of problems she had experienced as an alcoholic. She had a history of depression during her first four pregnancies, and was battling depression at the time of her fifth pregnancy. During the year preceding her fifth pregnancy, she had remained sober and had been in constant contact with social workers with a view to regaining custody of her children. She considered that a further child at that moment of her life (with its attendant risk of post-natal depression and to her sobriety) would jeopardise her health and the successful reunification of her family. She decided to travel to England to have an abortion.

15. Delaying the abortion for three weeks, the first applicant borrowed the minimum amount of money for treatment in a private clinic and travel from a money lender (650 euros, “EUR”) at a high interest rate. She felt she had to travel to England alone and in secrecy, without alerting the social workers and without missing a contact visit with her children.

16. She travelled back to Ireland by plane the day after the abortion for her contact visit with her youngest child. While she had initially submitted that she was afraid to seek medical advice on return to Ireland, she subsequently clarified that, on the train returning from Dublin she began to bleed profusely, and an ambulance met the train. At a nearby hospital she underwent a dilation and curettage. She claims she experienced pain, nausea and bleeding for weeks thereafter but did not seek further medical advice.

17. Following the introduction of the present application, the first applicant became pregnant again and gave birth to her fifth child. She is struggling with depression, has custody of three of her children and two (including the disabled child) remain in care. She maintained that an abortion was the correct decision for her in 2005.

B. The second applicant (B)

18. On 17 January 2005 the second applicant travelled to England for an abortion believing that she was not entitled to an abortion in Ireland. She was 7 weeks pregnant.

19. The second applicant became pregnant unintentionally. She had taken the “morning-after pill” and was advised by two different doctors that there was a substantial risk of an ectopic pregnancy (a condition which cannot be diagnosed until 6-10 weeks of pregnancy). She was certain of her decision to travel to England for an abortion since she could not care for a child on her own at that time of her life. She waited several weeks until the counselling centre in Dublin opened after Christmas. She had difficulty meeting the costs of the travel and, not

having a credit card, used a friend's credit card to book the flights. She accepted that, by the time she travelled to England, it had been confirmed that it was not an ectopic pregnancy.

20. Once in England she did not list anyone as her next of kin or give an Irish address so as to be sure her family would not learn of the abortion. She travelled alone and stayed in London the night before the procedure to avoid missing her appointment as well as the night of the procedure, as she would have arrived back in Dublin too late for public transport and the medication rendered her unfit to drive home from Dublin airport. The clinic advised her to inform Irish doctors that she had had a miscarriage.

21. On her return to Ireland she started passing blood clots and two weeks later, being unsure of the legality of having travelled for an abortion, sought follow-up care in a clinic in Dublin affiliated to the English clinic.

C. The third applicant (C)

22. On 3 March 2005 the third applicant had an abortion in England believing that she could not establish her right to an abortion in Ireland. She was in her first trimester of pregnancy at the time.

23. Prior to that, she had been treated for 3 years with chemotherapy for a rare form of cancer. She had asked her doctor before the treatment about the implications of her illness as regards her desire to have children and was advised that it was not possible to predict the effect of pregnancy on her cancer and that, if she did become pregnant, it would be dangerous for the foetus if she were to have chemotherapy during the first trimester.

24. The cancer went into remission and the applicant unintentionally became pregnant. She was unaware of this fact when she underwent a series of tests for cancer, contraindicated during pregnancy. When she discovered she was pregnant, the first applicant consulted her General Practitioner ("GP") as well as several medical consultants. She alleged that, as a result of the chilling effect of the Irish legal framework, she received insufficient information as to the impact of the pregnancy on her health and life and of her prior tests for cancer on the foetus.

25. She therefore researched the risks on the internet. Given the uncertainty about the risks involved, the third applicant travelled to England for an abortion. She maintained that she wanted a medical abortion (drugs to induce a miscarriage) as her pregnancy was at an early

stage but that she could not find a clinic which would provide this treatment as she was a non-resident and because of the need for follow-up. She therefore alleged she had to wait a further 8 weeks until a surgical abortion was possible.

26. On returning to Ireland after the abortion, the third applicant suffered complications of an incomplete abortion, including prolonged bleeding and infection. She alleges that doctors provided inadequate medical care. She consulted her own GP several months after the abortion and her GP made no reference to the fact that she was visibly no longer pregnant.

II. RELEVANT LAW AND PRACTICE

A. Article 40.3.3 of the Irish Constitution

27. The courts are the custodians of the rights set out in the Constitution and their powers are as ample as the defence of the Constitution requires (*The State (Quinn) v. Ryan* [1965] IR 70). In his judgment in *The People v. Shaw* ([1982] IR 1), Mr Justice Kenny also observed:

“The obligation to implement [the guarantee of Article 40.3] is imposed not on the Oireachtas [Parliament] only, but on each branch of the State which exercises the powers of legislating, executing and giving judgment on those laws: Article 6. The word ‘laws’ in Article [40.3] is not confined to laws which have been enacted by the Oireachtas, but comprehends the laws made by judges and by ministers of State when they make statutory instruments or regulations.”

1. The legal position prior to the Eighth Amendment of the Constitution

28. Prior to the adoption of the Eighth Amendment to the Constitution in 1983, Article 40.3 of the Constitution read as follows:

“1 The State guarantees in its laws to respect and, as far as practicable, by its laws to defend and vindicate the personal rights of the citizen.

2 The State shall, in particular, by its laws protect as best it may from unjust attack and, in the case of injustice done, vindicate the life, person, good name and property rights of every citizen.”

29. Certain judgments relied upon Article 40.3 and other Articles of the Constitution to recognise the right to life of the unborn and to suggest that the Constitution implicitly

prohibited abortion (*McGee v. Attorney General* [1974] IR 284; *G v. An Bord Uchtála* [1980] IR 32; and *Finn v. Attorney General* [1983] IR 154).

30. Abortion is also prohibited under the criminal law by section 58 (as amended) of the Offences Against the Person Act 1861 (“the 1861 Act”):

“Every woman, being with child, who, with intent to procure her own miscarriage, shall unlawfully administer to herself any poison or other noxious thing or shall unlawfully use any instrument or other means whatsoever with the like intent, and whosoever, with intent to procure the miscarriage of any woman, whether she be or not be with child, shall unlawfully administer to her or cause to be taken by her any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, shall be guilty of a felony, and being convicted thereof shall be liable to be kept in penal servitude for life.”

Section 59 of the 1861 Act states that:

“Whoever shall unlawfully supply or procure any poison or other noxious thing, or any instrument or thing whatsoever, knowing that the same is intended to be unlawfully used or employed with intent to procure the miscarriage of any woman, whether she be or be not with child, shall be guilty of a misdemeanour ...”

31. Section 58 of the Civil Liability Act 1961 (“the 1961 Act”) provides that “the law relating to wrongs shall apply to an unborn child for his protection in like manner as if the child were born, provided the child is subsequently born alive”.

32. Section 10 of the Health (Family Planning) Act 1979 re-affirms the statutory prohibition of abortion and stated as follows:

“Nothing in this Act shall be construed as authorising -

(a) the procuring of abortion,

(b) the doing of any other thing the doing of which is prohibited by section 58 or 59 of the Offences Against the Person Act, 1861 (which sections prohibit the administering of drugs or the use of any instruments to procure abortion)

or,

(c) the sale, importation into the State, manufacture, advertising or display of abortifacients.”

33. Article 50.1 of the Irish Constitution makes provision for the continuation of laws, such as the 1861 Act, which were in force on the adoption of the Constitution in 1937 as follows:

“Subject to this Constitution and to the extent to which they are not inconsistent therewith, the laws in force in [Ireland] immediately prior to the date of the coming into operation of this Constitution shall continue to be of full force and effect until the same or any of them shall have been repealed or amended by enactment of [Parliament].”

34. The meaning of section 58 of the 1861 Act was considered in England and Wales in *R. v. Bourne* ([1939] 1 KB 687), where the defendant had carried out an abortion on a minor, pregnant as a result of multiple rape. Macnaghten J. accepted that abortion to preserve the life of a pregnant woman was not unlawful and, further, where a doctor was of the opinion that the woman’s physical or mental health would be seriously harmed by continuing with the pregnancy, he could properly be said to be operating for the purpose of preserving the life of the mother. This principle was not, however, applied by the Irish courts. In the case of *Society for the Protection of the Unborn Child (Ireland) Ltd (S.P.U.C.) v. Grogan and Others* ([1989] I.R. 753), Keane J. maintained that “the preponderance of judicial opinion in this country would suggest that the Bourne approach could not have been adopted ... consistently with the Constitution prior to the Eighth Amendment”.

2. The Eighth Amendment to the Constitution (1983)

35. From the early 1980s there was some concern about the adequacy of existing provisions concerning abortion and the possibility of abortion being deemed lawful by judicial interpretation. There was some debate as to whether the Supreme Court would follow the course adopted in England and Wales in *Bourne* (cited above) or in the United States of America in *Roe v. Wade* (410 US 113 (1973)).

36. A referendum was held in 1983, resulting in the adoption of a provision which became Article 40.3.3 of the Irish Constitution, the Eighth Amendment (53.67% of the electorate voted with 841,233 votes in favour and 416,136 against). Article 40.3.3 reads as follows:

“The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.”

3. *Attorney General v. X and Others* [1992] 1 IR 1 (“the X case”)

(a) Prior to the X case

37. A number of cases then came before the courts concerning the interpretation of the Eighth Amendment and the provision of information on or referral to abortion services available in other countries.

38. In 1986 the S.P.U.C. obtained an injunction restraining two organisations (Open Door Counselling and the Dublin Well Woman Centre) from furnishing women with information which encouraged or facilitated an abortion. The Supreme Court held (*Attorney General (S.P.U.C.) v. Open Door Counselling* [1988] I.R. 593) that it was unlawful to disseminate information, including contact information, about foreign abortion services, which had the effect of facilitating the commission of an abortion (see also, *S.P.U.C. (Ireland) v. Grogan and Others*, cited above). These two organisations then complained about restraints on their freedom to impart and receive information and a violation of Article 10 of the Convention was established by this Court (*Open Door and Dublin Well Woman v. Ireland*, judgment of 29 October 1992, Series A no. 246-A, cited below as the “Open Door” case).

(b) Judgment of the Supreme Court in the X case

39. The interpretation of the Eighth Amendment was considered in the seminal judgment in the X case. X was fourteen years of age when she became pregnant as a result of rape. Her parents arranged for her to have an abortion in the United Kingdom and asked the Irish police whether it would be possible to have scientific tests carried out on retrieved foetal tissue with a view to determining the identity of the rapist. The Director of Public Prosecutions was consulted who, in turn, informed the Attorney General. On 7 February 1992 an interim injunction was granted ex parte on the application of the Attorney General restraining X from leaving the jurisdiction or from arranging or carrying out a termination of the pregnancy. X and her parents returned from the United Kingdom to contest the injunction.

40. On 26 February 1992, on appeal, a majority (Finlay C.J., McCarthy J., Egan J. and O’Flaherty J., with Hederman J. dissenting) of the Supreme Court discharged the injunction.

41. The Chief Justice noted that no interpretation of the Constitution was intended to be final for all time (citing *McGee v. the Attorney General* [1974] IR 284), which statement was “peculiarly appropriate and illuminating in the interpretation of [the Eighth Amendment] which deals with the intimate human problem of the right of the unborn to life and its relationship to the right of the mother of an unborn child to her life.” He went on:

“36. Such a harmonious interpretation of the Constitution carried out in accordance with concepts of prudence, justice and charity, ... leads me to the conclusion that in vindicating and defending as far as practicable the right of the unborn to life but at the same time giving due regard to the right of the mother to life, the Court must, amongst the matters to be so regarded, concern itself with the position of the mother within a family group, with persons on whom she is dependent, with, in other instances, persons who are dependent upon her and her interaction with other citizens and members of society in the areas in which her activities occur. Having regard to that conclusion, I am satisfied that the test proposed on behalf of the Attorney General that the life of the unborn could only be terminated if it were established that an inevitable or immediate risk to the life of the mother existed, for the avoidance of which a termination of the pregnancy was necessary, insufficiently vindicates the mother’s right to life.

37. I, therefore, conclude that the proper test to be applied is that if it is established as a matter of probability that there is a real and substantial risk to the life, as distinct from the health, of the mother, which can only be avoided by the termination of her pregnancy, such termination is permissible, having regard to the true interpretation of Article [40.3.3] of the Constitution.

42. Considering that a suicide risk had to be taken into account in reconciling the right to life of the mother and the unborn, the Chief Justice continued:

“44. I am, therefore, satisfied that on the evidence before the learned trial judge, which was in no way contested, and on the findings which he has made, that the defendants have satisfied the test which I have laid down as being appropriate and have established, as a matter of probability, that there is a real and substantial risk to the life of the mother by self-destruction which can only be avoided by termination of her pregnancy.”

43. Similar judgments on the substantive issue were delivered by three other judges. McCarthy J. noted that “the right of the girl here is a right to a life in being; the right of the unborn is to a life contingent; contingent on survival in the womb until successful delivery”. He went on:

141. ... In my view, the true construction of the [Eighth] Amendment ... is that, paying due regard to the equal right to life of the mother, when there is a real and substantial risk attached to her survival not merely at the time of application but in contemplation at least throughout the pregnancy, then it may not be practicable to vindicate the right to life of the unborn. It is

not a question of a risk of a different order of magnitude; it can never be otherwise than a risk of a different order of magnitude.

142. On the facts of the case, which are not in contest, I am wholly satisfied that a real and substantial risk that the girl might take her own life was established; it follows that she should not be prevented from having a medical termination of pregnancy.”

44. McCarthy J. commented in some detail on the lack of legislation implementing Article 40.3.3. He noted in the above-cited Grogan case, that he had already pointed out that no relevant legislation had been enacted since the Eighth Amendment came into force, the direct criminal law ban on abortion still deriving from the 1861 Act. He also noted that the Chief Justice had pointed out in the above-cited Open Door case that it was “unfortunate that the [Parliament] has not enacted any legislation at all in respect of this constitutionally guaranteed right.”

Having noted that Article 40.3.3 envisaged a lawful abortion in the State and thereby qualified section 58 of the 1861 Act (which had made abortion for any purpose unlawful), he continued:

“... I agree with the Chief Justice that the want of legislation pursuant to the amendment does not in any way inhibit the courts from exercising a function to vindicate and defend the right to life of the unborn. I think it reasonable, however, to hold that the People when enacting the Amendment were entitled to believe that legislation would be introduced so as to regulate the manner in which the right to life of the unborn and the right to life of the mother could be reconciled.

147. In the context of the eight years that have passed since the Amendment was adopted and the two years since Grogan’s case the failure by the legislature to enact the appropriate legislation is no longer just unfortunate; it is inexcusable. What are pregnant women to do? What are the parents of a pregnant girl under age to do? What are the medical profession to do? They have no guidelines save what may be gleaned from the judgments in this case. What additional considerations are there? Is the victim of rape, statutory or otherwise, or the victim of incest, finding herself pregnant, to be assessed in a manner different from others? The Amendment, born of public disquiet, historically divisive of our people, guaranteeing in its laws to respect and by its laws to defend the right to life of the unborn, remains bare of legislative direction...

148. ... The State may fulfil its role by providing necessary agencies to help, to counsel, to encourage, to comfort, to plan for the pregnant woman, the pregnant girl or her family. It is not for the courts to programme society; that is partly, at least, the role of the legislature. The courts are not equipped to regulate these procedures.”

4. The Thirteenth and Fourteenth Amendments (1992)

45. The judgment of the Supreme Court gave rise to a number of questions. Certain obiter dicta of the majority in the Supreme Court implied that the constitutional right to travel could be limited so as to prevent an abortion taking place where there was no threat to the life of the mother.

46. A further referendum, in which three separate proposals were put forward, was held in November 1992. 68.18% of the electorate voted.

47. The first was a proposal to amend the Constitution to provide for lawful abortion where there would otherwise be a real and substantial risk to the mother’s life, except a risk of suicide. Its acceptance would therefore have limited the impact of the X case: it was rejected (65.35% to 34.65%).

48. The second proposal was accepted and became the Thirteenth Amendment to the Constitution (added to Article 40.3.3). It was designed to ensure that a woman could not be prevented from leaving the jurisdiction for an abortion abroad and it reads as follows:

“This subsection shall not limit freedom to travel between the State and another state.”

49. The third proposal was also accepted and became the Fourteenth Amendment (also added to Article 40.3.3). It allows for the provision in Ireland of information on abortion services abroad and provides as follows:

“This subsection shall not limit freedom to obtain or make available, in the State, subject to such conditions as may be laid down by law, information relating to services lawfully available in another State.”

5. The proposed Twenty-fifth Amendment to the Constitution (2002)

50. Further to certain public reflection process (see paragraphs 62-76 below), in March 2002 a third referendum on abortion was held to resolve the legal uncertainty since the X case by

putting draft legislation (Protection of Human Life in Pregnancy Act, 2002) to the electorate. The intention was threefold.

51. The referendum was to ensure that the draft 2002 Act, once adopted by referendum, could only be changed by another referendum.

52. The proposed 2002 Act defined the crime of abortion (to replace sections 58 and 59 of the 1861 Act and to reduce the maximum penalty). It also removed the threat of suicide as a ground for a lawful abortion and thereby restricted the grounds recognised in the X case. The definition of abortion excluded “the carrying out of a medical procedure by a medical practitioner at an approved place in the course of which or as a result of which unborn human life is ended where that procedure is, in the reasonable opinion of the practitioner, necessary to prevent a real and substantial risk of loss of the woman’s life other than by self-destruction”.

53. The proposed 2002 Act also provided safeguards to medical procedures to protect the life of the mother by setting out the conditions which such procedures were to meet in order to be lawful: the procedures had, inter alia, to be carried out by a medical practitioner at an approved place; the practitioner had to form a reasonable opinion that the procedure was necessary to save the life of the mother; the practitioner had also to make and sign a written record of the basis for the opinion; and there would be no obligation on anyone to carry out or assist in carrying out a procedure.

54. The referendum resulted in the lowest turnout in all three abortion referenda (42.89% of the electorate) and the proposal was defeated (50.42% against and 49.58% in favour). The Referendum Commission had earlier explained that a negative vote would mean that Article 40.3.3 would remain in place as it was. Any legislation introduced thereafter would have to accord with the present interpretation of the Constitution which would mean a threat of suicide would continue to be a ground for a legal abortion.

6. Current text of Article 40.3 of the Constitution

55. Following the above-described amendments, Article 40.3 of the Constitution reads as follows:

“1o The State guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate the personal rights of the citizen.

2o The State shall, in particular, by its laws protect as best it may from unjust attack and, in the case of injustice done, vindicate the life, person, good name, and property rights of every citizen.

3o The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.

This subsection shall not limit freedom to travel between the State and another state.

This subsection shall not limit freedom to obtain or make available, in the State, subject to such conditions as may be laid down by law, information relating to services lawfully available in another state.”

B. Information in Ireland as regards abortion services abroad

1. The Regulation of Information (Services outside the State for Termination of Pregnancies) Act 1995 (“the 1995 Act”)

56. The 1995 Act was the legislation envisaged by the Fourteenth Amendment and constituted a response to the above-cited judgment of this Court in the Open Door case. That Act defines the conditions under which information relating to abortion services lawfully available in another State might be made available in Ireland.

57. Section 2 defines “Act information” as information that (a) is likely to be required by a woman for the purpose of availing herself of services provided outside the State for the termination of pregnancies; and (b) relates to such services or to persons who provide them.

58. Section 1 confirms that a “person to whom section 5 applies” means a person who engages in, or holds himself, herself or itself out as engaging in, the activity of giving information, advice or counselling to individual members of the public in relation to pregnancy. Section 5 of the Act provides as follows:

“Where a person to whom section 5 applies is requested, by or on behalf of an individual woman who indicates or on whose behalf it is indicated that she is or may be pregnant, to give information, advice or counselling in relation to her particular circumstances having regard to the fact that it is indicated by her or on her behalf that she is or may be pregnant-

(a) it shall not be lawful for the person or the employer or principal of the person to advocate or promote the termination of pregnancy to the woman or to any person on her behalf,

(b) it shall not be lawful for the person or the employer or principal of the person to give Act information to the woman or to any person on her behalf unless—

(i) the information and the method and manner of its publication are in compliance with subparagraphs (I) and (II) of section 3 (1) (a) and the information is given in a form and manner which do not advocate or promote the termination of pregnancy,

(ii) at the same time, information (other than Act information), counselling and advice are given directly to the woman in relation to all the courses of action that are open to her in relation to her particular circumstances aforesaid, and

(iii) the information, counselling and advice referred to in subparagraph (ii) are truthful and objective, fully inform the woman of all the courses of action that are open to her in relation to her particular circumstances aforesaid and do not advocate or promote, and are not accompanied by any advocacy or promotion of, the termination of pregnancy.”

59. Section 8 of the 1995 Act reads as follows:

“(1) It shall not be lawful for a person to whom section 5 applies or the employer or principal of the person to make an appointment or any other arrangement for or on behalf of a woman with a person who provides services outside the State for the termination of pregnancies.

(2) Nothing in subsection (1) shall be construed as prohibiting the giving to a woman by a person to whom section 5 applies ... of any medical, surgical, clinical, social or other like records or notes relating to the woman”

2. Article 26 and the Regulation of Information (Services outside the State for the Termination of Pregnancies) Bill 1995, In Re [1995] IESC 9

60. Before its enactment, the 1995 Act was referred by the President to the Supreme Court for a review of its constitutionality. The Supreme Court found it to be constitutional so that the 1995 Act thereby became immune from future constitutional challenge (Article 34.3.3 of the Constitution). In so concluding, the Supreme Court examined, inter alia, whether the provisions of Articles 5 and 8 were repugnant to the Constitution namely, whether, from an objective point of view, those provisions represented “a fair and reasonable balancing by

[Parliament] of the various conflicting rights and was not so contrary to reason and fairness as to constitute an unjust attack on the constitutional rights of the unborn or on the constitutional rights of the mother or any other person or persons.” In this respect, the Supreme Court noted that:

“The [1995 Act] merely deals with information relating to services lawfully available outside the State for the termination of pregnancies and the persons who provide such services.

The condition subject to which such information may be provided to a woman who indicates or on whose behalf it is indicated that she is or may be pregnant is that the person giving such information is

(i) not permitted to advocate or promote the termination of pregnancy to the woman or any person on her behalf;

(ii) not permitted to give the information unless it is given in a form and manner which do not advocate or promote the termination of pregnancy

and is only permitted to give information relating to services which are lawfully available in the other State and to persons, who in providing them are acting lawfully in that place if

(a) the information and the method and manner of its publication are in compliance with the law of that place, and

(b) the information is truthful and objective and does not advocate or promote, and is not accompanied by any advocacy or promotion of the termination of pregnancy.

At the same time information, counselling and advice must be given directly to the woman in relation to all the courses of action that are open to her in relation to her particular circumstances and such information, counselling and advice must not advocate or promote and must not be accompanied by any advocacy or promotion of, the termination of pregnancy.

Subject to such restrictions, all information relating to services lawfully available outside the State and the persons who provide them is available to her.”

61. The Supreme Court considered that the submission, that a woman’s life and/or health might be placed at serious risk in the event that a doctor was unable to send a letter referring her to another doctor for the purposes of having her pregnancy terminated, was based on a misinterpretation of the provisions of section 8 of the 1995 Act:

“This section prohibits a doctor or any person to whom Section 5 of the [1995 Act] relates from making an appointment or any other arrangement for or on behalf of a woman with a person who provides services outside the State for the termination of pregnancies.

It does not preclude him, once such appointment is made, from communicating in the normal way with such other doctor with regard to the condition of his patient provided that such communication does not in any way advocate or promote and is not accompanied by any advocacy of the termination of pregnancy.

While a doctor is precluded by the terms of the [1995 Act] from advocating or promoting the termination of pregnancy, he is not in any way precluded from giving full information to a woman with regard to her state of health, the effect of the pregnancy thereon and the consequences to her health and life if the pregnancy continues and leaving to the mother the decision whether in all the circumstances the pregnancy should be terminated. The doctor is not in any way prohibited from giving to his pregnant patient all the information necessary to enable her to make an informed decision provided that he does not advocate or promote the termination of pregnancy.

In addition, Section 8(2) does not prohibit or in any way prevent the giving to a woman of any medical, surgical, clinical, social or other like records relating to her. ...

Having regard to the obligation on [Parliament] to respect, and so far as practicable, to defend and vindicate the right to life of the unborn having regard to the equal right to life of the mother, the prohibition against the advocacy or promotion of the termination of pregnancy and the prohibition against any person to whom Section 5 of the Bill applies making an appointment or any other arrangement for and on behalf of a woman with a person who provides services outside the State for the termination of pregnancies does not constitute an unjust attack on the rights of the pregnant woman. These conditions represent a fair and reasonable balancing of the rights involved and consequently Sections 5 and 8 of the Bill are not repugnant to the Constitution on these grounds.”

C. Public Reflection Processes

1. The Constitution Review Group Report 1996 (“the Review Group Report 1996”)

62. Established in April 1995, the Review Group's terms of reference were to review the Constitution and to establish those areas where constitutional change might be necessary with a view to assisting the governmental committees in their constitutional review work.

63. In its 1996 report, the Review Group considered the substantive law on abortion in Ireland following the X case and the rejection of the Twelfth Amendment to be unclear (for example, the definition of the unborn, the scope of the admissibility of the suicidal disposition as a ground for abortion and the absence of any statutory time-limit on lawful abortion following the X case criteria). The Review Group considered the option of amending Article 40.3.3 to legalise abortion in constitutionally defined circumstances:

“Although thousands of women go abroad annually for abortions without breach of domestic law, there appears to be strong opposition to any extensive legalisation of abortion in the State. There might be some disposition to concede limited permissibility in extreme cases, such, perhaps, as those of rape, incest or other grave circumstances. On the other hand, particularly difficult problems would be posed for those committed in principle to the preservation of life from its earliest stage.”

64. The Review Group concluded that, while in principle the major issues should ideally be tackled by constitutional amendment, there was no consensus as to what that amendment should be and no certainty of success for any referendum proposal for substantive constitutional change in relation to Article 40.3.3. The Review Group therefore considered that the only practical possibility at that time was the introduction of legislation to regulate the application of Article 40.3.3. Such legislation could, inter alia, include definitions (for example of the “unborn”); afford express protection for appropriate medical intervention necessary to protect the life of the mother, require written certification by appropriate medical specialists of “real and substantial risk to the life of the mother” and impose a time-limit on lawful abortion namely, in circumstances permitted by the X case.

2. The Interdepartmental Working Group Green Paper on Abortion, 1999 (“the Green Paper 1999”)

65. A cabinet committee was established to supervise the drafting of a Green Paper on abortion and the preparatory work was carried out by an Interdepartmental Working Group of officials. In drawing up the Green Paper, submissions were invited from the public, from professional and voluntary organisations and any other parties who wished to contribute. Over

10,000 such submissions were received, as well as petitions containing 36,500 signatures. The introduction to the Green Paper 1999 noted that:

“The current situation ... is that, constitutionally, termination of pregnancy is not legal in this country unless it meets the conditions laid down by the Supreme Court in the X case; information on abortion services abroad can be provided within the terms of the [1995 Act]; and, in general, women can travel abroad for an abortion.

There are strong bodies of opinion which express dissatisfaction with the current situation, whether in relation to the permissibility of abortion in the State or to the numbers of women travelling abroad for abortion.

Various options have been proposed to resolve what is termed the “substantive issue” of abortion but there is a wide diversity of views on how to proceed. The Taoiseach indicated shortly after the Government took office in 1997 that it was intended to issue a Green Paper on the subject. The implications of the X case were again brought sharply into focus in November 1997 as a result of the C Case, and a Cabinet Committee was established to oversee the drafting of this Green Paper, the preparatory work on which was carried out by an interdepartmental group of officials. (for a description of the C case, see paragraphs 95-96 below)

While the issues surrounding abortion are extremely complex, the objective of this Green Paper is to set out the issues, to provide a brief analysis of them and to consider possible options for the resolution of the problem. The Paper does not attempt to address every single issue in relation to abortion, nor to give an exhaustive analysis of each. Every effort has been made to concentrate on the main issues and to discuss them in a clear, concise and objective way.

Submissions were invited from interested members of the public, professional and voluntary organisations and any other parties who wished to contribute. ...”

66. Paragraph 1.09 noted that there was no medical evidence to suggest that doctors in Ireland did not treat women with cancer or other illnesses on the grounds that the treatment would damage the unborn.

67. Chapter 7 of the paper comprised a discussion of seven possible constitutional and legislative solutions:

- an absolute constitutional ban on abortion;
- an amendment of the Constitution so as to restrict the application of the X case;
- the retention of the current position;
- the retention of the constitutional status quo with a legislative restatement of the prohibition of abortion;
- legislation to regulate abortion as defined in the X case;
- a reversion to the pre-1983 position; and
- permitting abortion beyond the grounds specified in the X case.

68. As to the fifth option (legislation to regulate abortion as defined in the X case), the Green Paper 1999 noted as follows:

“7.48 The objective of this approach would be to implement the X case decision by means of legislation ... This approach assumes that there would be no change in the existing wording of Article 40.3.3.

7.49 In formulating such legislation a possible approach may be not to restate the prohibition on abortion, which is already contained in section 58 of the Offences Against the Person Act, 1861, but instead to provide that a termination carried out in accordance with the legislation would not be an offence.

7.50 The detail of such legislation would require careful consideration but it could be along the lines of that discussed under the previous option (retention of the constitutional status quo with legislative restatement of the prohibition on abortion).

Discussion

7.51 Since this option does not provide for a regime more liberal than the X case formulation, no constitutional amendment would be required. This option would, however, provide for abortion in defined circumstances and as such, would be certain to encounter criticism from those who are opposed to abortion on any grounds and who disagreed with the decision in the X case. Central to the criticism would be the inclusion of the threat of suicide as a ground and the difficulties inherent in assessing same.

7.52 The main advantage of this approach is that it would provide a framework within which the need for an abortion could be assessed, rather than resolving the question on a case-by-case basis before the courts, with all the attendant publicity and debate. It would allow pregnant women who establish that there is a real and substantial risk to their life to have an abortion in Ireland rather than travelling out of the jurisdiction and would provide legal protection for medical and other personnel, such as nurses, involved in the procedure to terminate the pregnancy. The current medical ethical guidelines would not be consistent with such legislation.

7.53 It must be pointed out however that the problems of definition in the text of Article 40.3.3 would remain. A decision would be necessary on whether the proposed legislation would provide the definitions necessary to remove the current ambiguity surrounding the text of that Article. There is however a limit to what legislation can achieve by way of definitions as ultimately the interpretation of Article 40.3.3 is a matter for the Courts.”

69. As to the Seventh option (permitting abortion beyond the grounds specified in the X case), the Green Paper 1999 noted as follows:

“7.65 In Chapter 4, other possible grounds for abortion are examined and set where possible in an international context. As indicated earlier, a number of submissions also sought the introduction of abortion on some or all of these grounds. Each of the possible types of provision identified has been considered separately. This does not rule out consideration of a combination of some or all of these options if this approach were to be pursued. Were this to be done, some of the difficulties identified when options are considered separately might not arise.

7.66 In all of the cases discussed in this section, abortion would be permissible only if Article 40.3.3 of the Constitution were amended. Sections 58 and 59 of the Offences Against the Person Act, 1861 may also need to be reviewed and new legislation to regulate any new arrangement would be necessary. The type of legislative model referred to in the discussion on the option of retention of the constitutional status quo with legislative restatement of the prohibition on abortion (see paragraphs 7.42 - 7.47) might, with appropriate adaptations, serve as a basis for regulation in other circumstances also. Issues such as criteria under which an abortion would be permissible, gestational limits, certification and counselling requirements, and possibly a waiting period after counselling, would be among the matters which legislation

might address. The provisions in force in some other countries are also discussed in Chapter 4.

Discussion

(a) Risk to Physical/mental health of mother

7.67 This option would provide for abortion on grounds of risk to a woman's physical and/or mental health.

7.68 In 1992 the proposed Twelfth Amendment to the Constitution was the subject of some criticism on the grounds that it specifically excluded risk to health as grounds for termination of a pregnancy. The English Bourne case of 1938 involved interpretation of the Offences Against the Person Act, 1861 to permit termination of a pregnancy where a doctor thought that the probable consequence of continuing a pregnancy would be to make the woman a physical or mental wreck.

7.69 As stated earlier, this case has not been specifically followed in any decision of the Irish courts. Article 40.3.3 of the Constitution would rule out an interpretation of the Offences Against the Person Act, 1861 in the manner of the Bourne judgement. Therefore any proposal to permit abortion on the grounds of danger to a woman's health would require amendment of this Article and possibly a review of the Sections 58 and 59 of the Offences Against the Person Act, 1861. A legislative framework to regulate the operation of such arrangements would also be required.

7.70 As discussed in Chapter 4, 'Other Grounds for Abortion, set in an International Context', the concept of physical health used in other countries for the purposes of abortion law tends not to be very specific. If it were intended to permit abortion on grounds of risk to a woman's health, but to confine the operation of such a provision to cases where there was a grave risk of serious and permanent damage, it would be necessary to circumscribe the provisions in an appropriate manner. The usual practice in other countries is for the issue to be treated as a medical matter. It could be anticipated that it might be difficult to arrive at provisions which would allow clinical independence and at the same time be guaranteed to operate in a very strict manner so as not to permit abortion other than on a very limited basis."

3. The Oireachtas Committee on the Constitution Fifth Progress Report 2000 ("the Fifth Progress Report on Abortion 2000")

70. The Green Paper 1999 was then referred to this Committee. The Committee consulted widely, initially seeking submissions on the options discussed in the Green Paper 1999. Over 100,000 submissions were received from individuals and organisations. Approximately 92% of these communications took the form of signatures to petitions (over 80,000 signatures were contained in one petition alone). The vast majority of communications were in favour of the first option in the Green Paper 1999 (an absolute constitutional ban on abortion).

71. Since very few medical organisations had made submissions during the preparation of the Green Paper 1999, the Committee was concerned to establish authoritatively the current medical practice in Irish hospitals as regards medical intervention during pregnancies. The Committee therefore heard the views and opinions of experts in the fields of obstetrics, gynaecology and psychiatry through public (and recorded) hearings.

72. The Chairman of the Institute of Obstetricians and Gynaecologists, which represents 90%-95% of the obstetricians and gynaecologists in Ireland, gave written evidence, inter alia, that:

“In current obstetrical practice rare complications can arise where therapeutic intervention is required at a stage in pregnancy when there will be little or no prospect for the survival of the baby, due to extreme immaturity. In these exceptional situations failure to intervene may result in the death of both the mother and baby. We consider that there is a fundamental difference between abortion carried out with the intention of taking the life of the baby, for example for social reasons, and the unavoidable death of the baby resulting from essential treatment to protect the life of the mother.

We recognise our responsibility to provide after care for women who decide to leave the State for a termination of pregnancy. We recommend that full support and follow-up services be made available for all women whose pregnancies have been terminated, whatever the circumstances”.

73. In oral evidence, the Chairman also noted that:

“We have never regarded these interventions as abortion. It would never cross an obstetrician’s mind that intervening in a case of pre-eclampsia, cancer of the cervix or ectopic pregnancy is abortion. They are not abortion as far as the professional is concerned, these are medical treatments that are essential to protect the life of the mother. So when we interfere in the best interests of protecting a mother, and not allowing her to succumb, and we are faced

with a foetus that dies, we don't regard that as something that we have, as it were, achieved by an abortion. Abortion in the professional view to my mind is something entirely different. It is actually intervening, usually in a normal pregnancy, to get rid of the pregnancy, to get rid of the foetus. That is what we would consider the direct procurement of an abortion. In other words, it's an unwanted baby and, therefore, you intervene to end its life. That has never been a part of the practice of Irish obstetrics and I hope it never will be. ...

In dealing with complex rare situations, where there is a direct physical threat to the life of the pregnant mother, we will intervene always.”

74. In 2000 the Committee issued its Fifth Progress Report on Abortion. The Report explained that was not a comprehensive analysis of the matters discussed in the Green Paper 1999 but rather a political assessment of questions which arose from it in the context of the submissions received and the hearings conducted.

75. The Committee on the Constitution agreed that a specific agency should be put in place to implement a strategy to reduce the number of crisis pregnancies by the provision of preventative services, to reduce the number of women with crisis pregnancies who opt for abortion by offering services which make other options more attractive and to provide post-abortion services consisting of counselling and medical check-ups. There was agreement on other matters including on the need for the Government to prepare a public memorandum outlining the State's precise responsibilities under all relevant international and European Union (“EU”) instruments.

76. The Committee agreed that clarity in legal provisions was essential for the guidance of the medical profession so that any legal framework should ensure that doctors could carry out best medical practice necessary to save the life of the mother. However, the Committee found that none of the seven options canvassed in the Green Paper 1999 commanded unanimous support of the Committee. Three approaches commanded substantial but not majority support: the first was to concentrate on the plan to reduce the number of crisis pregnancies and the rate of abortion and to leave the legal position unchanged; the second approach would add legislation which would protect medical intervention to safeguard the life of the mother within the existing constitutional framework; and the third approach was in addition to accommodate such legislation with a Constitutional amendment. The Committee did not therefore reach agreement on a single course of reform action.

D. Crisis Pregnancy Agency (“the CPA”)

1. The objectives of the CPA

77. Further to the Fifth Progress Report on Abortion 2000, the CPA was established by the Crisis Pregnancy Agency (Establishment) Order 2001 (S.I. No. 446 of 2001). Section 4 of that Order described the functions of the Agency, in so far as relevant, as follows (prior to its amendment in 2007):

“(i) ... to prepare a strategy to address the issue of crisis pregnancy, this strategy to provide, inter alia, for:

(a) a reduction in the number of crisis pregnancies by the provision of education, advice and contraceptive services;

(b) a reduction in the number of women with crisis pregnancies who opt for abortion by offering services and supports which make other options more attractive;

(c) the provision of counselling and medical services after crisis pregnancy ...”

78. The CPA implemented its first Strategy (2004-2006) and is in the process of implementing its second one (2007-2011). It achieves its objectives mainly through its communications programme (including media campaigns and resource materials), its research programme (promoting evidence-based practice and policy development) and its funding programme which funds projects ranging from personal development to counselling, parent supports and medical and health services.

79. Further to the Health (Miscellaneous Provisions) Act 2009, the CPA was integrated into the Health Service Executive (HSE) from 1 January 2010. Funding of the crisis pregnancy function was also transferred to the HSE.

2. Primary Care Guidelines for the Prevention and Management of Crisis Pregnancy (“CPA Guidelines”)

80. The CPA Guidelines, developed in association with the Irish College of General Practitioners, outline the role of GPs in the management of crisis pregnancy. The Guidelines detail the role of GPs in the prevention of crisis pregnancies, in assisting the woman in making decisions about the outcome of her crisis pregnancy (by, inter alia, counselling on all options available to her including pregnancy, adoption and abortion) and assisting her in

safely carrying out her decision (by, inter alia, advising on the importance of follow-up care, including medical care, after any abortion). GPs are advised on the importance of providing sensitive counselling to assist the decision-making process (“to minimize the risk of emotional disturbance, whatever decision is reached”) and of pre- and post-abortion counselling and medical care. GPs are reminded of their duty of care to the patient, that they should never refuse treatment on the basis of moral disapproval of the patient’s behaviour and that, where they have a conscientious objection to providing care, they should make the names of other GPs available to the patient.

The Guidelines went on to note that “Irrespective of what decision a woman makes in the crisis pregnancy situation, follow-up care will be important. This may include antenatal care, counselling, future contraception or medical care after abortion. The GP’s response to the initial consultation will have a profound influence on her willingness to attend for further care”. If a woman decides to proceed with an abortion, it is the GP’s main concern to ensure that she does so safely, receives proper medical care, and returns for appropriate follow-up. GPs are advised to supplement verbal advice with a written handout.

81. A Patient Information Leaflet is attached to the Guidelines. It informs women that, should they choose an abortion, they should plan to visit their GP at least three weeks after the termination to allow the GP to carry out a full check-up and allow the woman to express any questions or concerns she may have.

3. “Understanding how sexually active women think about fertility, sex, and motherhood”, CPA Report No. 6 (2004)

82. The subject of this report was the perceptions of Irish women in the general age range of 20-30 about fertility, sex, and motherhood. The report captured the meanings young women attributed to their fertility and fertility-related decisions in relation to life objectives and women’s changing roles in education, careers, relationships, and motherhood. The report uses data drawn from qualitative interviews (twenty individual case studies and twelve focus groups; the total sample was 66 women with an age range of 19-34). The research reflected the views of a diverse group of women by socio-economic status, geographic location, and relationship history. The data demonstrated a need for greater support for young Irish women in the range and variety of their decision-making about fertility, sex and motherhood.

83. The significant findings included that the X case and the declining role of the Catholic Church were major events in the lives of young women and shaped their attitudes and experiences. Young women had moved into adulthood more firmly convinced that sexual and reproductive decisions should be part of a person's private actions, with the freedom to decide as they think best.

4. "Irish Contraception and Crisis Pregnancy Study: A Survey of the General Population", CPA Report No. 7 (2004)

84. The aim of the study was to establish nationally representative data on current attitudes, knowledge and experience of contraception, crisis pregnancy and related services in Ireland. It carried out a cross-sectional national survey of the young adult population using a telephone interview (in 2003) of 3000 members of the public to include equal numbers of women and men and people aged 18-45 in order to focus on those for whom contraceptive practices, service perceptions and service usage were considered most relevant. It was also considered that the age profile of the sample meant that the results would be particularly relevant to contemporary evaluation of services and in planning for the future.

85. Public attitudes to aspects of crisis-pregnancy outcomes were assessed to evaluate the acceptability of alternative outcomes (lone parenting, adoption and abortion). The questions were adapted from a prior survey in 1986 and the replication of these questions in the CPA study provided an opportunity to measure any changes in attitudes to abortion. In the 1986 survey, over 38% of participants indicated that they believed abortion should not be permissible under any circumstances while 58% felt that it should be allowed in certain circumstances. 4% did not express a view.

86. In the CPA study, the question was extended to include the option that a woman 'should always have a choice to have an abortion, regardless of the circumstances': 8% of participants felt that abortion should not be permissible under any circumstances, 39% felt that it should be allowed under certain circumstances, 51% felt women should always have a choice to have an abortion and 2% were unsure.

"Thus, a notable change in attitudes towards abortion was observed over the seventeen-year period (1986-2003), with a substantially higher proportion of the population supporting a choice of abortion in some or all circumstances in the more recent [CPA] survey".

87. Since many participants, who thought that a woman should have a choice in certain circumstances or who did not know, were considered to hold qualified views concerning the acceptability of abortion, those participants were asked whether they agreed or disagreed that a woman should have a choice to have an abortion in specific circumstances (based on the 1986 survey). The Report described the results as follows:

“The level of agreement reported across possible circumstances under which an abortion may be acceptable varied greatly across circumstance. The majority of these participants agreed that a woman should have a choice to have an abortion if the pregnancy seriously endangered her life (96%) or her health (87%). Additionally, most agreed that a woman should have a choice to have an abortion if the pregnancy was a result of rape (87%) or incest (85%). Less than half (46%) of participant’s felt that a woman should have a choice if there was evidence that the child would be seriously deformed. Furthermore, the majority of participants disagreed that a woman should have a choice if she was not married (79%) or if the couple cannot afford another child (80%). There were no significant variations in attitude across gender or educational level for any of the statements. There were small but significant age differences across two items. Firstly, younger participants were more likely to favour abortion as a choice for rape victims (92% of 18-25 year olds vs. 87% of 26-35 year olds and 83% of 36-45 year olds) ... The reverse pattern was evident in the case of pregnancy where there is evidence that the baby will be seriously deformed. Here older participants were more likely to favour having the choice to have an abortion (fewer (42%) of 18-25 year olds agreed vs. 49% of 26-35 year olds and 48% of 36-45 year olds)”

88. The findings as to the circumstances in which abortion was acceptable were compared with those reported from the 1986 survey. The percentages of those who agreed that abortion was acceptable in various circumstances were reported as a proportion of all those interviewed for the relevant study. This showed that the acceptability of abortion in various circumstances “had increased substantially in the population over time”:

- if the pregnancy seriously endangered the woman’s life (57% agreement in 1986; 90% agreement in 2003);
- if the pregnancy seriously endangered the woman’s health (46% in 1986; 86% in 2003);
- if the pregnancy is the result of rape (51% in 1986; 86% in 2003) or incest (52% in 1986; 86% in 2003); and

- where there is evidence that the child will be deformed (31% in 1986 and 70% in 2003).

E. Medical Council Guidelines 2004

89. The Medical Practitioners Act 1978 gives the Medical Council of Ireland responsibility for providing guidance to the medical profession on all matters relating to ethical conduct and behaviour.

90. Its Guide to Ethical Conduct and Behaviour (6th Edition 2004) provides (paragraph 2.5) that “treatment must never be refused on grounds of moral disapproval of the patient’s behaviour”. The Guide recognises that an abortion may be lawfully carried out in Ireland in accordance with the criteria in X case, and provides as follows:

“The Council recognises that termination of pregnancy can occur where there is real and substantial risk to the life of the mother and subscribes to the view expressed in Part 2 of the written submission of the Institute of Obstetricians and Gynaecologists to the All-Party Oireachtas Committee on the Constitution as contained in its Fifth Progress Report ..”

91. This latter written submission is Appendix C to the Guide and contains three paragraphs. In the first paragraph, the Institute of Obstetricians and Gynaecologists welcomes the Green Paper 1999 and notes that its comments were confined to the medical aspects of the question. The submission continued as cited at paragraph 72 above.

F. European Convention on Human Rights Act 2003 (“the 2003 Act”)

92. The 2003 Act came into force on 31 December 2003. Its long title described it as an Act to enable further effect to be given “subject to the constitution” to certain provisions of the Convention.

93. Section 5 of the 2003 Act reads, in so far as relevant, as follows:

“(1) In any proceedings, the High Court, or the Supreme Court when exercising its appellate jurisdiction, may, having regard to the provisions of section 2, on application to it in that behalf by a party, or of its own motion, and where no other legal remedy is adequate and available, make a declaration (referred to in this Act as “a declaration of incompatibility”) that a statutory provision or rule of law is incompatible with the State’s obligations under the Convention provisions.

(2) A declaration of incompatibility—

(a) shall not affect the validity, continuing operation or enforcement of the statutory provision or rule of law in respect of which it is made, and

(b) shall not prevent a party to the proceedings concerned from making submissions or representations in relation to matters to which the declaration relates in any proceedings before the European Court of Human Rights.

(3) The Taoiseach shall cause a copy of any order containing a declaration of incompatibility to be laid before each House of the Oireachtas within the next 21 days on which that House has sat after the making of the order.

(4) Where—

(a) a declaration of incompatibility is made,

(b) a party to the proceedings concerned makes an application in writing to the Attorney General for compensation in respect of an injury or loss or damage suffered by him or her as a result of the incompatibility concerned, and

(c) the Government, in their discretion, consider that it may be appropriate to make an ex gratia payment of compensation to that party (“a payment”),

the Government may request an adviser appointed by them to advise them as to the amount of such compensation (if any) and may, in their discretion, make a payment of the amount aforesaid or of such other amount as they consider appropriate in the circumstances.

(5) In advising the Government on the amount of compensation for the purposes of subsection (4), an adviser shall take appropriate account of the principles and practice applied by the European Court of Human Rights in relation to affording just satisfaction to an injured party under Article 41 of the Convention.”

94. The Supreme Court (Carmody -v- Minister for Justice Equality and Law Reform and others 2009 IESC 71) made the following comments on an application for a declaration under section 5 of the 2003 Act:

“As can be seen from the foregoing the nature of the remedy, such as it is, provided by s. 5 of the Act of 2003 is both limited and sui generis. It does not accord to a plaintiff any direct or enforceable judicial remedy. There are extra-judicial consequences whereby the [Prime Minister] is obliged to lay a copy of the order containing a declaration before each House of

the Oireachtas within 21 days. That is the only step which is required to be taken under national law in relation to the provisions concerned. Otherwise it rests with the plaintiff who obtained the declaration to initiate an application for compensation in writing to the Attorney General for any alleged injury or loss or damage suffered by him or her as a result of the incompatibility and then it is a matter for the discretion of the Government as to whether or not they should pay any such compensation on an *ex gratia* basis. ...

.. the Court is satisfied that when a party makes a claim that an Act or any of its provisions is invalid for being repugnant to the Constitution and at the same time makes an application for a declaration of incompatibility of such Act or some of its provisions with the State's obligations under the Convention, the issue of constitutionality must first be decided."

G. Other domestic jurisprudence concerning abortion

1. *A and B v. Eastern Health Board, Judge Mary Fahy and C, and the Attorney General* (notice party), [1998] 1 IR 464 ("the C case")

95. This case concerned a thirteen-year-old girl ("C") who became pregnant following a rape. The Health Board, which had taken the girl into its care, became aware that she was pregnant and, in accordance with her wishes, obtained an interim care order (under the Child Care Act 1991) from the District Court allowing the Health Board to facilitate a termination of her pregnancy. C's parents sought to challenge that order by judicial review. On appeal C, her parents and the Health Board were each represented by a Senior and Junior Counsel, and the Attorney General was represented by two Senior and two Junior Counsel.

96. On 28 November 1997 the High Court accepted that, where evidence had been given to the effect that the pregnant young woman might commit suicide unless allowed to terminate her pregnancy, there was a real and substantial risk to her life and such termination was therefore a permissible medical treatment of her condition where abortion was the only means of avoiding such a risk. An abortion was therefore lawful in Ireland in C's case and the travel issue became unnecessary to resolve. It rejected the appeal on this basis. In rejecting the parents' argument that the District Court was not competent given, *inter alia*, the reconciliation of constitutional rights required, the High Court found:

"Furthermore, I think it highly undesirable for the courts to develop a jurisprudence under which questions of disputed rights to have a termination of pregnancy can only be determined by plenary action in the High Court. The High Court undoubtedly has a function in granting

injunctions to prevent unlawful terminations taking place and it may in certain circumstances properly entertain an action brought for declarations and consequential orders if somebody is being physically prevented without just cause from having a termination. But it would be wrong to turn the High Court into some kind of licensing authority for abortions and indeed it was for this reason that I have rejected a suggestion made by counsel for C. in this case that I should effectively convert the judicial review proceedings into an independent application invoking the inherent jurisdiction of the High Court and grant leave for such a termination to take place. I took the view that the case should continue in the form of a judicial review and nothing more. The Child Care Act, 1991 is a perfectly appropriate umbrella under which these questions can be determined.”

2. MR v. TR and Others

97. The parties disputed the ‘ownership’ of embryos fertilised in vitro. The High Court ([2006] IEHC 359) analysed at some length the decision of the Supreme Court in X which it found equated “unborn” with an embryo which was implanted in the womb or a foetus. The High Court concluded that there was no evidence that it was ever in the mind of the people voting on the Eighth Amendment to the Constitution that “unborn meant anything other than a foetus or child within the womb”. Accordingly, it could not be concluded that embryos outside the womb or in-vitro fell within the scope of Article 40.3.3. As regards the Medical Council Guidelines 2004, the High Court noted as follows:

“These ethical guidelines do not have the force of law and offer only such limited protection as derives from the fear on the part of a doctor that he might be found guilty of professional misconduct with all the professional consequences that might follow”.

98. The appeal to the Supreme Court ([2009] IESC 82) was unanimously dismissed, the five judges each finding that frozen embryos did not enjoy the protection of the unborn in Article 40.3.3 of the Constitution. Hardiman and Fennelly J.J. also expressed concern about the absence of any form of statutory regulation of in vitro fertilisation in Ireland.

3. D (A Minor) v. District Judge Brennan, the Health Services Executive, Ireland and the Attorney General, unreported judgment of the High Court , 9 May 2007

99. D was a minor in care who had been prevented by the local authority from going abroad for an abortion. Her foetus had been diagnosed with anencephaly, which diagnosis was accepted as being incompatible with life outside the uterus. According to a transcript of its ex

tempore oral judgment, the High Court clarified that the case was “not about abortion or termination of pregnancy. It is about the right to travel, admittedly for the purposes of a pregnancy termination, but that does not convert it into an abortion case.” Accordingly, the legal circumstances in which a termination of pregnancy was available in Ireland were not in issue, and this “judgment expressly disavows any intention to interfere, whether by enlargement or curtailment, with such circumstances”. The High Court held that the right to travel guaranteed by the Thirteenth Amendment took precedence over the right of the unborn guaranteed by Article 40.3.3. There was no statutory or constitutional impediment preventing Ms D from travelling to the United Kingdom for an abortion.

H. Relevant European and international material

1. The Maastricht and Lisbon Treaties

100. Efforts to preserve, inter alia, the existing Irish prohibition on abortion gave rise to Protocol No. 17 to the Maastricht Treaty on European Union which was signed in February 1992. It reads as follows:

“Nothing in the Treaty on European Union, or in the treaties establishing the European Communities, or in the Treaties or Acts modifying or supplementing those treaties, shall affect the application in Ireland of Article 40.3.3 of the Constitution of Ireland”

101. On 12 June 2008 the proposed constitutional amendment for the ratification of the Lisbon Treaty was rejected by referendum. The Government commissioned University College Dublin to conduct independent research into the behaviour and attitudes of the electorate and, notably, to analyse why the people voted for, against or abstained in the referendum. The Report (entitled “Attitudes and Behaviour in the Referendum on the Treaty of Lisbon” prepared by professionals with expertise in political science, quantitative research methods, economics and social science data) is dated March 2009. Fieldwork was completed in July 2008 and the sample size was 2,101. The Executive Summary concluded:

“The defeat by referendum of the proposal to ratify the Treaty of Lisbon ... was the product of a complex combination of factors. These included attitudes to Ireland’s membership of the EU, to Irish-only versus Irish-and-European identity and to neutrality. The defeat was heavily influenced by low levels of knowledge and by specific misperceptions in the areas of abortion, corporate taxation and conscription. Concerns about policy issues (the scope of EU decision-making and a belief in the importance of the country having a permanent

commissioner) also contributed significantly and substantially to the treaty's downfall, as did the perception that the EU means low wage rates. Social class and more specific socio-economic interests also played a role”

102. The Government sought and obtained a legally binding Decision of the Heads of State or Governments of the 27 Member States of the EU reflecting the Irish people's concerns that Article 40.3.3 would be unaffected by the Lisbon Treaty (The Presidency Conclusions of the European Council of 11/12 December 2008 and of 18/19 July 2009 (172171/1/08 and 11225/2/08). The relevant part of the Decision, which came into effect on the same date as the Lisbon Treaty, reads as follows:

“Nothing in the Treaty of Lisbon attributing legal status to the charter of fundamental rights of the European Union, or in the provisions of that Treaty and the area freedom, security and justice, affects in any way the scope and applicability of the protection of the right to life in Article 40.3.1, 40.3.4 and 40.3.3... provided by the Constitution of Ireland”.

103. On 2 October 2009 a referendum approved a constitutional amendment allowing for the ratification of the Treaty of Lisbon.

2. The International Conference on Population and Development (“the Cairo ICPD, 1994”)

(a) The Programme of Action of the Cairo ICPD, 1994

104. At this conference 179 countries adopted a twenty-year Programme of Action which focused on individuals' needs and rights rather than on achieving demographic targets. Article 8.25 of the programme provided, in so far as relevant, as follows:

“... All Governments ... are urged to strengthen their commitment to women's health, to deal with the health impact of unsafe abortion as a major public health concern and to reduce the recourse to abortion through expanded and improved family-planning services. ... Any measures or changes related to abortion within the health system can only be determined at the national or local level according to the national legislative process.”

(b) The Fourth World Conference on Women, Beijing 1995

105. The Platform for Action adopted at this conference recalled the above-noted paragraph 8.25 of the Programme of Action of the Cairo ICPD 1994 and the Governments resolved to

consider reviewing laws containing punitive measures against women who have undergone illegal abortions.

(c) Parliamentary Assembly of the Council of Europe (“PACE”) Recommendation 1903(2010) entitled: Fifteen years since the International Conference on Population and Development Programme of Action

106. The PACE noted some progress has been made since the Cairo ICPD 1994. However, “achievements on education enrolment, gender equity and equality, infant child and maternal mortality and morbidity and the provision of universal access to sexual and reproductive health services, including family planning and safe abortion services, remain mixed”. The PACE called on European governments to “review, update and compare Council of Europe members states’ national and international population and sexual and reproductive health and rights policies and strategies”, as well as to review and compare funding to ensure the full implementation of the Programme of Action of the Cairo ICPD 1994 by 2015.

3. PACE Resolution 1607 (2008) entitled “Access to safe and legal abortion in Europe”

107. This resolution was adopted by 102 votes to 69. The 4 Irish representatives to the PACE voted against it, two of the members urging the PACE to apply the Programme of Action of the Cairo ICPD 1994.

108. The Resolution reads, in so far as relevant, as follows:

“2. In most of the Council of Europe member states the law permits abortion in order to save the expectant mother’s life. Abortion is permitted in the majority of European countries for a number of reasons, mainly to preserve the mother’s physical and mental health, but also in cases of rape or incest, of foetal impairment or for economic and social reasons and, in some countries, on request. The Assembly is nonetheless concerned that, in many of these states, numerous conditions are imposed and restrict the effective access to safe, affordable, acceptable and appropriate abortion services. These restrictions have discriminatory effects, since women who are well informed and possess adequate financial means can often obtain legal and safe abortions more easily.

3. The Assembly also notes that, in member states where abortion is permitted for a number of reasons, conditions are not always such as to guarantee women effective access to this right: the lack of local health care facilities, the lack of doctors willing to carry out abortions,

the repeated medical consultations required, the time allowed for changing one's mind and the waiting time for the abortion all have the potential to make access to safe, affordable, acceptable and appropriate abortion services more difficult, or even impossible in practice.

4. The Assembly takes the view that abortion should not be banned within reasonable gestational limits. A ban on abortions does not result in fewer abortions but mainly leads to clandestine abortions, which are more traumatic and increase maternal mortality and/or lead to abortion "tourism" which is costly, and delays the timing of an abortion and results in social inequities. The lawfulness of abortion does not have an effect on a woman's need for an abortion, but only on her access to a safe abortion.

5. At the same time, evidence shows that appropriate sexual and reproductive health and rights strategies and policies, including compulsory age-appropriate, gender-sensitive sex and relationships education for young people, result in less recourse to abortion. This type of education should include teaching on self-esteem, healthy relationships, the freedom to delay sexual activity, avoiding peer pressure, contraceptive advice, and considering consequences and responsibilities.

6. The Assembly affirms the right of all human beings, in particular women, to respect for their physical integrity and to freedom to control their own bodies. In this context, the ultimate decision on whether or not to have an abortion should be a matter for the woman concerned, who should have the means of exercising this right in an effective way.

7. The Assembly invites the member states of the Council of Europe to:

7.1. decriminalise abortion within reasonable gestational limits, if they have not already done so;

7.2. guarantee women's effective exercise of their right of access to a safe and legal abortion;

7.3. allow women freedom of choice and offer the conditions for a free and enlightened choice without specifically promoting abortion;

7.4. lift restrictions which hinder, de jure or de facto, access to safe abortion, and, in particular, take the necessary steps to create the appropriate conditions for health, medical and psychological care and offer suitable financial cover ..."

4. Report of the Commissioner for Human Rights on his visit to Ireland, 26-30 November 2007, adopted on 30 April 2008, CommDH(2008)9

109. The Commissioner noted that there was still no legislation in place implementing the X judgment and, consequently, no legal certainty when a doctor might legally perform a life-saving abortion. He opined that, in practice, abortion was largely unavailable in Ireland in almost all circumstances. He recalled the *Tysi c v. Poland* judgment (no. 5410/03, ECHR 2007 IV) and urged the Irish authorities to ensure that legislation was enacted to resolve this problem.

5. Office of the High Commissioner for Human Rights, Committee on the Elimination of Discrimination Against Women (“CEDAW”)

110. The Report of the CEDAW of July 2005 (A/60/38(SUPP)) recorded Ireland’s introduction of its periodic report to the Committee as follows:

“365. Steps had been taken to integrate a gender dimension into the health service and to make it responsive to the particular needs of women. Additional funding had been provided for family planning and pregnancy counselling services. The [CPA] had been set up in 2001. Extensive national dialogue had occurred on the issue of abortion, with five separate referendums held on three separate occasions. The representative noted that the Government had no plans to put forward further proposals at the present time.”

In the Committee’s concluding comments, it responded as follows:

“396. While acknowledging positive developments ... the Committee reiterates its concern about the consequences of the very restrictive abortion laws, under which abortion is prohibited except where it is established as a matter of probability that there is a real and substantial risk to the life of the mother that can be averted only by the termination of her pregnancy.

397. The Committee urges the State party to continue to facilitate a national dialogue on women’s right to reproductive health, including on the very restrictive abortion laws ...”

6. The Human Rights Committee

111. In the Committee's Concluding Comments on the third periodic Report of Ireland on observance of the UN Covenant on Civil and Political Rights (CCPR/C/IRL/CO/3 dated 30 July 2008), it noted:

“13. The Committee reiterates its concern regarding the highly restrictive circumstances under which women can lawfully have an abortion in the State party. While noting the establishment of the [CPA], the Committee regrets that the progress in this regard is slow. ...

The State party should bring its abortion laws into line with the Covenant. It should take measures to help women avoid unwanted pregnancies so that they do not have to resort to illegal or unsafe abortions that could put their lives at risk ... or to abortions abroad (articles 26 and 6).”

7. Laws on abortion in Contracting States

112. Abortion is available on request (according to certain criteria including gestational limits) in some 30 Contracting States. An abortion justified on health grounds is available in some 40 Contracting States and justified on well-being grounds in some 35 such States. Three Contracting States prohibit abortion in all circumstances (Andorra, Malta and San Marino). In recent years, certain States have extended the grounds on which abortion can be obtained (Monaco, Montenegro, Portugal and Spain).

4.2.3. The Law

113. The first two applicants complained under Articles 3, 8, 13 and 14 of the Convention about the prohibition of abortion in Ireland on health and well-being grounds.

The third applicant complained under Articles 2, 3, 8, 13 and 14 of the Convention about the absence of legislative implementation of Article 40.3.3 of the Constitution which she argued meant that she had no appropriate means of establishing her right to a lawful abortion in Ireland on the grounds of a risk to her life.

I. ADMISSIBILITY

A. The relevant facts and scope of the case

114. The parties disputed the factual basis of the applications. Having regard to the Court's conclusions as regards the applicants' exhaustion of domestic remedies (paragraph 156), the Court has examined immediately below the relevant facts and, consequently, the scope of the case before it.

1. The submissions of the parties

115. The Government considered that the profoundly important issues in this case were based on subjective and general factual assertions which were unproven, disputed and not tested either by review by a domestic tribunal or through any other form of interaction with the State. No documentation was submitted, in contrast to the above-cited case of *Tysi c v. Poland*. Many of the alleged perceptions and assumptions (notably as regards information available and medical treatment) were countered by authoritative documents. It was a serious and unsubstantiated allegation to suggest that doctors and social workers would not carry out the duties imposed on them by law.

116. As to the first applicant, the Government did not accept that her health was adversely affected by travelling for an abortion (her alleged side effects were known complications of abortion) or that the stress which she allegedly suffered resulted from the Irish legal regime. If she received inadequate medical treatment on her return, this was due to her reluctance to see a doctor. Her suggestions that a social worker would have denied or reduced her access to her children and that she did not consult her doctor as he or she might disapprove, were unsubstantiated and, indeed, such alleged acts would have been unlawful.

117. As to the second applicant, the Government maintained that nothing demonstrated that her health and well-being were affected by having to travel for an abortion. Part of the distress she claimed to have suffered stemmed from her family's opinions and, if she were advised by the English clinic to lie to Irish doctors, that clinic misunderstood Irish law. The alleged "chilling effect" of Irish criminal law did not affect her factual situation. If she had an ectopic pregnancy, she would have been able to seek an abortion as well as the necessary follow-up care in Ireland.

118. As to the third applicant, the Government submitted that the asserted facts (her rare form of cancer) did not allow a determination of whether her pregnancy was life threatening or whether she was unable to obtain relevant advice to that effect. She had not demonstrated that her health and well-being were affected by a delay caused by travelling for a surgical abortion: she herself submitted that she chose an abortion provider who did not offer a medical abortion. It was equally unclear whether she suggested that she was not afforded the proper treatment due to some form of moral disapproval.

119. The applicants considered their factual submissions to be clear. The first two applicants travelled to England for abortions for reasons of health and/or well-being and the third applicant given her fear that her pregnancy posed a risk to her life. The third applicant also referred to a fear for the health of the foetus given the prior tests for cancer she had undertaken. They took issue with the Government's description of their seeking abortion for "social reasons", a vague term with no legal or human rights meaning. The Court should take note of the first applicant's concern about her mental health, alcoholism and custody of her children and it was understandable that the first applicant would prefer not to inform her social worker, given the possibility that the latter would disapprove and prejudice her chances of regaining custody of her children. The Court should also take note of the second applicant's concern about her well-being and of the third applicant's concern for her own life and for the health of her foetus. All felt stigmatised as they were going abroad to do something that was a criminal offence in their own country. The constitutional and criminal restrictions added to the difficulties and delays in accessing abortions and all applicants faced significant hardship as a result of having to travel abroad for an abortion.

2. Relevant submissions of the third parties

120. Joint observations were submitted by 'Doctors for Choice' (an Irish non-governmental organisation of approximately 200 doctors) and by the British Pregnancy Advisory Service ("BPAS", a British non-governmental organisation set up following the Abortion Act 1967 to provide non-profit services, to train doctors and to ensure premises for safe abortions).

They made detailed submissions as to the physiological and physical consequences for women of the restrictions on abortion in Ireland. Women had to bear the weight of abortions abroad. They had recourse to less safe abortions, inevitable delays in abortions abroad, de facto exclusion from early non-invasive medical abortion, "backstreet" illegal abortions in the country or abortions abroad in unsafe conditions. Continuing pregnancy was riskier than a

termination. Studies were not definitive about the negative psychological impact of an abortion, especially measured against the burden of an unwanted pregnancy. Nor was there evidence that abortion affected fertility.

121. The third parties also made the following additional submissions. They suggested that vital post-abortion medical care and counselling in Ireland were randomly available and of poor quality due to a lack of training and the reluctance of women to seek care. Women in Ireland were also being denied other medical care: life saving treatment was denied to pregnant women and women with a diagnosis of severe foetal abnormality were denied an abortion and necessary genetic analysis post-abortion in Ireland. Concealment of pregnancy and the abandonment of newborns were not unusual in Ireland. The restrictions on abortion also impacted on women's autonomy and rights: families suffered as a result of the unintended addition; women of already reduced resources found their lives disproportionately disadvantaged by abortion restrictions; women were entitled to confidentiality as regards their reproductive choices but feared that admitting an abortion would mean that their privacy would not be respected and, sometimes, it inevitably was not as, for example, in the case of female immigrants who had to apply for travel documents to travel for an abortion; and comforted, by the restrictions, treating health professionals pressured women against abortion.

122. The Government disputed these third party submissions. In particular, they considered unsubstantiated the suggestion that pre- and post-abortion care and counselling in Ireland was "randomly available or of poor quality". The CPA funded 14 service providers to offer non-judgmental crisis pregnancy and post-abortion counselling free of charge in 27 cities and towns in Ireland; some of the larger cities and towns had more than one service; the CPA funded 7 service providers to offer free post-termination medical checks, provided by the relevant service in family planning clinics or through a network of GPs in a number of locations around the country; GPs and family planning clinics which did not receive funding from the CPA also provided such services, which were either paid for, or subsidised through, the health service; the CPA had developed information resources on post-abortion care including an information leaflet published in 2006 and widely distributed throughout Ireland and in abortion clinics in the United Kingdom, a new website and a service providing messages to mobile telephones to raise awareness and provide clarity about the availability of free post-abortion medical care as well as counselling. The Irish College of GPs had reported that 95% of doctors provided medical care after abortion.

3. The Court's assessment

123. The Court would underline at the outset that it is not its role to examine submissions which do not concern the factual matrix of the case before it: rather it must examine the impugned legal position on abortion in Ireland in so far as it directly affected the applicants, in so far as they belonged to a class of persons who risked being directly affected by it or in so far as they were required to either modify their conduct or risk prosecution (*Burden v. the United Kingdom* [GC], no. 13378/05, §§ 33-34, 29 April 2008; and *Sejdić and Finci v. Bosnia and Herzegovina* [GC], nos. 27996/06 and 34836/06, § 28, 22 December 2009). In this respect, the present case is to be contrasted with the above-cited *Open Door* case where the interference in question was an injunction against the provision by the applicant non-governmental organisations of, inter alia, information to women about abortion services abroad so that the Court's response in that case necessarily involved consideration of the general impact on women of the injunction.

124. Turning therefore to the circumstances of the present applicants' cases, the Court notes that, although arguing that the facts were unsubstantiated and disputed, the Government did not seriously dispute (*Open Door*, § 76, cited above) the core factual submission that the applicants had travelled to England for abortions. Having regard also to the nature of the subject matter as well as the undoubted personal reticence associated with its disclosure in proceedings such as the present, the Court considers it reasonable to accept that each of the applicants travelled to England for an abortion in 2005.

125. As to their reasons for doing so, the Court notes the claimed involvement of a social worker and the fact that the first applicant's children had been in care, facts which were not specifically disputed by the State. It considers that it can reasonably rely on the related personal circumstances outlined by her (her history of alcoholism, post-natal depression and her difficult family circumstances) as her reasons for seeking an abortion abroad. The second applicant acknowledged that she knew her pregnancy was not ectopic before her abortion and the Court has accepted her core factual submission that she travelled for an abortion as she was not ready to have a child. Equally, it is reasonable to consider that the third applicant previously had cancer, this not being specifically disputed by the Government, so that she travelled abroad for an abortion because of a fear (whether founded or not) that her pregnancy constituted a risk to her life (that her cancer would return because of her pregnancy and that she would not be able to obtain treatment for cancer in Ireland if she was pregnant) and

because she would be unable to establish her right to an abortion in Ireland. She also suggested that her foetus might have been harmed by tests undergone for cancer but she did not indicate that she had undertaken the relevant clinical tests or established that this was an overriding reason for obtaining an abortion abroad.

Accordingly, the Court finds that the first applicant travelled for an abortion for reasons of health and well-being, the second applicant for well-being reasons and the third applicant as she mainly feared her pregnancy constituted a risk to her life. While the Government's use of the term "social reasons" is noted, the Court has considered it useful to distinguish between health (physical and mental) and other well-being reasons to describe why the applicants choose to obtain abortions.

126. As to the psychological impact on the applicants of their travelling abroad for an abortion, the Court considers that this is by its nature subjective, personal and not susceptible to clear documentary or objective proof. The Court considers it reasonable to find that each applicant felt the weight of a considerable stigma prior to, during and after their abortions: they travelled abroad to do something which, on the Government's own submissions, went against the profound moral values of the majority of the Irish people (see also paragraphs 222-227 below) and which was, or (in the case of the third applicant) could have been, a serious criminal offence in their own country punishable by penal servitude for life (paragraph 30 above). Moreover, obtaining an abortion abroad, rather than in the security of their own country and medical system, undoubtedly constituted a significant source of added anxiety. The Court considers it evident that travelling abroad for an abortion constituted a significant psychological burden on each applicant.

127. As to the physical impact of travelling for an abortion abroad, it is evident that an abortion would have been physically a less arduous process without the need to travel, notably after the procedure. However, the Court does not find it established that the present applicants lacked access to necessary medical treatment in Ireland before or after their abortions. The Court notes the professional requirements on doctors to provide medical treatment to women post-abortion (the CPA Guidelines and Medical Council Guidelines (paragraphs 80-81 and 89-91 above)). Against this, the first and second applicants accepted that they obtained medical treatment post-abortion when required. The third applicant's suggestions as to the inadequacy of medical treatment available to her for a relatively well-known condition (incomplete abortion) are too general and improbable to be considered substantiated.

128. As to the financial burden of travelling for an abortion abroad, it would be reasonable to consider that the costs of doing so constituted a significant financial burden on the first applicant (given her personal and family circumstances as accepted at paragraph 125 above) and constituted a considerable expense for the second and third applicants.

129. As to any delay (and the consequent physical and psychological impact on the applicants), the financial demands on the first applicant must be accepted as having delayed somewhat her abortion. The second applicant herself chose to delay her travel to consult further in Ireland. While the third applicant alleged she had to await 8 weeks for a surgical abortion (in addition to the time taken in making her earlier enquiries about her medical situation), she again remained vague on essential matters notably as to the precise stage of her pregnancy when she obtained her abortion: the Court considers she has not either demonstrated that she was excluded from an early medical abortion or established a specific period of delay in travelling for an abortion.

130. As to the first and second applicants' submissions that there was a lack of information on the options available to them and that this added to the burden of the impugned restrictions on abortion in Ireland, the Court finds these submissions to be general and unsubstantiated. While Doctors for Choice/BPAS maintained that information services in Ireland were inadequate, the Court has had regard to the developments in Ireland since the above-cited Open Door judgment including: the adoption of the 1995 Act (the breadth of which was explained by the Supreme Court during its review of its constitutionality) to ensure a right to provide and receive information about, inter alia, abortion services abroad (paragraphs 56-61 above); the establishment of the CPA in 2001, with the aims outlined in section 4 of the relevant establishing order, its first Strategy (2004-2006) and the Government's clarifications as regards care and counselling provided or facilitated by the CPA (paragraphs 77-79 and 122 above); and the adoption of the CPA Guidelines and Medical Council Guidelines (paragraphs 80-81 and 89-91 above). Against this, the first two applicants' core submission was that they understood that their only option for an abortion on health and/or well-being grounds was to travel abroad and, in that respect, neither indicated precisely what information they sought but could not obtain.

The third applicant's submission about a lack of information is different. She complained that she required a regulatory framework by which any risk to her life and her entitlement to a lawful abortion in Ireland could be established, so that any information provided outside such

a framework was insufficient. This submission will be examined as relevant on the merits of her complaints.

131. Finally, and as to the risk of criminal sanctions, the first and second applicants did not submit that they had considered an abortion in Ireland and Irish law clearly allowed them to travel for an abortion abroad (the Thirteenth Amendment to the Constitution and D(A Minor), paragraphs 48 and 99 above): apart from the psychological impact of the criminal regime in Ireland referred to above, the criminal sanctions had no direct relevance to their complaints. The risk of such sanctions will be examined on the merits of the third applicant's complaints in so far as she maintained that those sanctions had a chilling effect on the establishment of her qualification for a lawful abortion in Ireland.

B. Exhaustion of domestic remedies

1. The Government's submissions

132. The Government had two general observations. They noted the applicants' distinction between the relevant legal provisions, on the one hand, and the State's restrictive interpretation of those provisions, on the other. Since the applicants took issue with the latter, this underlined the need for them to have exhausted domestic remedies. The Government emphasised the consequences for the Convention system of this Court deciding on such vitally important issues when the underlying facts, as well as the application of the relevant domestic laws to each applicant's case, had not been determined by a domestic court.

133. The Government argued that there were effective remedies at the applicants' disposal. Supported by a Senior Counsel's Opinion, they relied on the principles outlined in the decision in *D v. Ireland* ((dec.), no. 26499/02, 6 September 2005) and, notably, underlined the need to test domestically, in a common law constitutional system, the meaning and potential of any alleged lack of clarity in domestic law so as to afford the State the opportunity to address breaches domestically. The Constitution provided remedies where there were constitutional rights and the domestic courts would make all rulings required to protect those rights.

134. The main remedies on which the Government relied, supported by the Opinion, were a challenge to the constitutionality or compatibility of the 1861 Act or, since the 1995 Act had been found to be constitutional, by taking an action for mandatory relief requiring the provision of information in compliance with that Act.

As to the merits of a constitutional action, they underlined the interpretative potential of Article 40.3.3 of the Constitution as confirmed by the admission of a risk of self-harm itself as a ground for lawful abortion in the X case and by two later domestic cases: the MR v. TR case raised the question of the point at which Article 40.3.3 would apply in the process of fertilisation and conception and demonstrated that it was possible to “raise arguments” in the Irish courts as to the breadth of Article 40.3.3; and in the case of D(A Minor), the High Court noted that the question of the minor’s right to an abortion in Ireland (given her foetus’ diagnosis) gave rise to “very important and very difficult and very significant issues”. This potential was such that it was difficult “to exclude on an a priori case basis many arguments in this area, particularly where the facts are compelling” and the domestic courts would be unlikely to interpret Article 40.3.3 with “remorseless logic”. However, the Government confirmed in their observations that on no analysis did Article 40.3.3 permit abortion in Ireland for social reasons.

As to seeking a post-abortion declaration of incompatibility under the 2003 Act and an ex gratia payment of damages from the Attorney General, the Government argued that it was incorrect to suggest that the 2003 Act afforded minimal weight to Convention rights. The courts were required to interpret statutes in a Convention compliant manner and, if that was not possible, to make a declaration of incompatibility (the above-cited Carmody case). While a declaration of incompatibility was not obligatory on the State, it would be formally put to the houses of the Oireachtas (parliament) and Ireland’s record of solemn compliance with its international obligations entitled it to a presumption that it would comply with those obligations and give effect to declarations of incompatibility.

135. As regards the first applicant specifically, the Government accepted that an abortion in Ireland in the circumstances outlined by her would have contravened domestic law and that “it was hard to see that she had any real prospects of succeeding on the merits of her claim to an entitlement to a termination”. Nevertheless, the domestic courts were deprived of the possibility of fact-finding and of determining the scope and application of the relevant legislative and constitutional provisions. Had the second applicant been diagnosed as suffering from an ectopic pregnancy, she would have been entitled to a therapeutic abortion in Ireland. In so far as the third applicant maintained that she was refused an abortion when her life was at risk, she could have sought mandatory orders from the courts requiring doctors to terminate her pregnancy in accordance with the X case criteria. In so far as she suggested that the 1861 Act produced a chilling effect precluding her from a lawful abortion in Ireland, she

could have brought proceedings to establish that the Act interfered with her constitutional rights and to have its offending provisions set aside. The suggestion that legislation, and not litigation, was required was inconsistent with the Commission's position in *Whiteside v. the United Kingdom* (no. 20357/92, (dec.) 7 March 1994).

136. The Government noted that the applicants had submitted no legal opinion or evidence that they had taken legal advice at the relevant time. The Government also responded in some detail to other effectiveness issues relied on by the applicants as regards the constitutional actions, notably the timing, speed, costs and confidentiality of those actions.

2. The applicants' submissions

137. The applicants maintained that the State had not demonstrated that an effective domestic remedy was available to any of them and they were not required to initiate ineffective actions simply to clarify facts. They underlined that it was not the law, but the State's interpretation of the law, which was overly restrictive. In addition, only remedies which could intervene prior to any necessary abortion could be considered effective.

138. Different submissions were made as regards the first and second applicants, on the one hand, and the third applicant, on the other.

139. The first and second applicants submitted that domestic entitlements to abortion remained general (Article 40.3.3 as clarified in the X case). While there had been numerous consultations and reports, the law had not changed since 1992 and certainly not towards allowing abortion in Ireland on the grounds of health or well-being. Moreover, even if the domestic courts could find in favour of these applicants, they would be unlikely to order the Government and/or a doctor to facilitate access by these applicants to abortion services in Ireland in a timely manner. Indeed, it would also be difficult to find a doctor to perform the procedure given the potential stigma and intimidation of a high profile case. This Court's decision in *D v. Ireland* was distinguishable from the present case since the conflicting interests in that case were entirely different from the present cases.

In addition, the 2003 Act did not require a balancing of the rights of the unborn and the mother or of the Convention and Constitutional rights and a constitutional prohibition would always trump Convention rights. A declaration of incompatibility created no legal obligation on the State and a successful applicant could only apply for an *ex gratia* award of damages. There had been only three declarations of incompatibility to date (concerning the Irish Civil

Registration Act 2004 and the Housing Act 1966) and these statutes remained in force pending ongoing current appeals.

140. As to the third applicant, there were no procedures at all to be followed by a woman and her advising doctor to determine her qualification for a life-saving abortion. Accordingly, the lack of such procedures constituted “special circumstances” absolving the third applicant from any obligation to exhaust domestic remedies (*Opuz v. Turkey*, no. 33401/02, § 201, ECHR 2009 ...). Even if she could have raised different arguments in a constitutional action about a risk to her life, it would have had little chance of success. In any event, legislation was required to clarify constitutional provisions not litigation.

141. The applicants also made detailed submissions on other effectiveness issues as regards the proposed constitutional actions and, notably, as regards the timing, speed, costs and confidentiality of such actions.

3. The Court’s assessment

142. The Court reiterates that under Article 35 § 1 it may only deal with a matter after all domestic remedies have been exhausted. The existence of such remedies must be sufficiently certain not only in theory but also in practice, failing which they will lack the requisite accessibility and effectiveness: it falls to the respondent State to establish that these conditions are satisfied (see, amongst many other authorities, *McFarlane v. Ireland* [GC], § 107, 10 September 2010). The Court also recalls the relevant principles set out at paragraphs 83-85 of its decision in the above-cited *D v. Ireland* case and, notably, the established principle that in a legal system providing constitutional protection for fundamental rights it is incumbent on the aggrieved individual to test the extent of that protection and, in a common law system, to allow the domestic courts to develop those rights by way of interpretation. In this respect, it is recalled that a declaratory action before the High Court, with a possibility of an appeal to the Supreme Court, constitutes the most appropriate method under Irish law of seeking to assert and vindicate constitutional rights (*D v. Ireland*, at § 85).

143. It is further recalled that the question of the applicants’ exhaustion of domestic remedies must be approached by considering the high threshold of protection of the unborn provided under Irish law by Article 40.3.3 as interpreted by the Supreme Court in the *X* case (*Open Door*, cited above, § 59). It is further recalled that the constitutional obligation that the State

defend and vindicate personal rights “by its laws” (Article 40.3.1 of the Constitution) has been interpreted by the courts as imposing an obligation on the Irish courts to defend and vindicate constitutionally protected personal rights.

144. While the Court has noted the applicants’ distinction between domestic law on abortion and what they described as the State’s interpretation of that law, the meaning of this submission is not entirely clear. The Court has had regard to the relevant Irish abortion laws namely, the constitutional and legislative provisions as interpreted by the Irish courts. It has examined whether the applicants had available to them any effective domestic remedies as regards their complaints about the prohibition in Ireland of abortion on health and well-being grounds (the first two applicants) and as regards a lack of legislative implementation of the right to abortion in Ireland in the case of a risk to the woman’s life (the third applicant).

(a) The first and second applicants

145. The Court notes that the prohibition of which the first two applicants complained comprised sections 58 and 59 of the 1861 Act (it being an offence to procure or attempt to procure an abortion, to administer an abortion or to assist in an abortion by supplying any noxious thing or instrument, punishable by penal servitude for life) as qualified by Article 40.3.3 of the Constitution as interpreted by the Supreme Court in the X case (see also Articles 40.3.1 and 50 of the Constitution).

146. The Court considers that the first remedy proposed by the Government (a constitutional action by these applicants seeking a declaration of unconstitutionality of sections 58 and 59 of the 1861 Act, with mandatory or other ancillary relief) would require demonstrating that those sections, in so far as they prohibit abortion on grounds of health and well-being of the woman, are inconsistent with the rights of the mother as guaranteed by Article 40.3 of the Constitution.

147. However, the Court does not consider that it has been demonstrated that such an action would have had any prospect of success, going against, as it would, the history, text and judicial interpretation of Article 40.3.3 of the Constitution. Prior to 1983, the 1861 Act constituted the only law prohibiting abortion in Ireland. Following the development of abortion rights in the England through, inter alia, judicial interpretation of the same 1861 Act, Article 40.3.3 was adopted by referendum in 1983. By that constitutional provision, the State acknowledged the right to life of the unborn and, with due regard to the equal right to life of

the mother, guaranteed in its laws to respect, and, as far as practicable, by its laws to defend and vindicate the right to life of the unborn. The Supreme Court then clarified, in the seminal X case, that the proper test for a lawful abortion in Ireland was as follows: if it was established as a matter of probability that there was “a real and substantial risk to the life, as distinct from the health, of the mother” (emphasis added) which could only be avoided by the termination of the pregnancy, a termination of a pregnancy was permissible in Ireland. The Supreme Court went on to accept that an established threat of suicide constituted a qualifying “real and substantial risk” to the life of the woman. Subsequent amendments to the Constitution did not extend the grounds for a lawful abortion in Ireland. None of the domestic case law subsequent to the X case, opened by the parties to this Court, concerned the right to an abortion in Ireland for reasons of health and well-being nor could they be considered to indicate any potential in this argument: the cases of “C” and of D(A Minor) concerned a suicide risk and a minor’s right to travel abroad for an abortion, respectively; and the case of MR v. TR concerned the question of whether the constitutional notion of “unborn” included an embryo fertilised extra-uterine.

148. In addition, it is evident from the public reflection processes (notably the Constitutional Review Group Report and the Green Paper 1999) that a termination of pregnancy was not considered legal in Ireland unless it met the conditions laid down in Article 40.3.3 as clarified by the X case and that to extend those conditions would require a constitutional amendment. Moreover, the Government acknowledged to the Grand Chamber that on no analysis did Article 40.3.3 permit abortion in Ireland for “social reasons” and that it was difficult to see how the first applicant would have had any real prospects of succeeding in such a constitutional claim. This latter submission would apply equally to the second applicant who obtained an abortion for reasons of well-being. Finally, the Court would agree that the balance of rights at issue in the D v. Ireland case were relevantly different from those at issue in the first and second applicants’ cases: in D v. Ireland the Court found that Ms D could have argued in the domestic courts, with some prospect of success, that the relevant balance of competing interests was in her favour since one of the twin foetuses she was carrying was already dead and the other had an accepted fatal foetal abnormality.

149. Accordingly, the Court concludes that it has not been demonstrated that an action by the first and second applicants seeking a declaration of a constitutional entitlement to an abortion in Ireland on health and/or well-being grounds and, consequently, of the unconstitutionality of sections 58 and 59 of the 1961 Act, would have had any prospect of success. It is not

therefore an effective remedy available both in theory and in practice which the first and second applicants were required to exhaust (see paragraph 142 above).

150. Moreover, and contrary to the Government's submissions at paragraph 134 above, the Court does not consider that an application under the 2003 Act for a declaration of incompatibility of the relevant provisions of the 1861 Act, and for an associated ex gratia award of damages, could be considered an effective remedy which had to be exhausted. The rights guaranteed by the 2003 Act would not prevail over the provisions of the Constitution (paragraphs 92-94 above). In any event, a declaration of incompatibility would place no legal obligation on the State to amend domestic law and, since it would not be binding on the parties to the relevant proceedings, it could not form the basis of an obligatory award of monetary compensation. In such circumstances, and given the relatively small number of declarations to date (paragraph 139 above) only one of which has recently become final, a request for such a declaration and for an ex gratia award of damages would not have provided an effective remedy to the first and second applicants (*Hobbs v. the United Kingdom* (dec.), no. 63684/00, 18 June 2002; and *Burden v. the United Kingdom* [GC], cited above, §§ 40-44).

151. Since these applicants' core complaints, on the facts accepted by the Court, did not concern or reveal a lack of information about the abortion options open to them (paragraph 130 above), it is not necessary to examine whether they had any remedies to exhaust in this regard and, notably, as regards the 1995 Act.

152. For these reasons, the Court considers that it has not been demonstrated that the first and second applicants had an effective domestic remedy available to them as regards their complaint about a lack of abortion in Ireland for reasons of health and/or well-being. The Court is not, therefore, required to address the parties' additional submissions concerning the timing, speed, costs and confidentiality of such domestic proceedings.

153. Moreover, when the proposed remedies have not been demonstrated to be effective, these applicants could not be required, nevertheless, to exhaust them solely with a view to establishing facts relevant to their applications to this Court.

(b) The third applicant

154. The third applicant feared her pregnancy constituted a risk to her life and complained under Article 8 about the lack of legislation implementing the constitutional right to an abortion in the case of such a risk. She argued that she therefore had no effective procedure by

which to establish her qualification for a lawful abortion in Ireland and that she should not be required to litigate to do so.

155. In those circumstances, the Court considers that the question of the need for the third applicant to exhaust judicial remedies is inextricably linked, and therefore should be joined, to the merits of her complaint under Article 8 of the Convention (*Tysi c v. Poland*, no. 5410/03 (dec.) 7 February 2006).

4. The Court's conclusion

156. Accordingly, the Court dismisses the Government's objection on grounds of a failure to exhaust domestic remedies as regards the first and second applicants and joins this objection to the merits of the third applicant's complaint under Article 8 of the Convention.

C. Article 2 of the Convention

157. The third applicant complained under Article 2 that abortion was not available in Ireland even in a life threatening situation because of the failure to implement Article 40.3.3 of the Constitution. The Government argued that no issue arose under Article 2 of the Convention.

158. The Court recalls that, just as for the first and second applicants, there was no legal impediment to the third applicant travelling for an abortion abroad (paragraph 131 above). The third applicant did not refer to any other impediment to her travelling to England for an abortion and none of her submissions about post-abortion complications concerned a risk to her life. In such circumstances, there is no evidence of any relevant risk to the third applicant's life (*L.C.B. v. the United Kingdom*, 9 June 1998, § 36, Reports of Judgments and Decisions 1998 III; and *Osman v. the United Kingdom*, 28 October 1998, § 116, Reports 1998 VIII). Her complaint that she was required to travel abroad for an abortion given her fear for her life falls to be examined under Article 8 of the Convention.

159. Accordingly, the third applicant's complaint under Article 2 of the Convention must be rejected as manifestly ill-founded pursuant to Article 35 §§ 3 and 4 of the Convention.

Since this complaint does not therefore give rise to an "arguable claim" of a breach of the Convention (*Boyle and Rice v. the United Kingdom*, judgment of 27 April 1988, Series A no.

131, § 52), her associated complaint under Article 13 of the Convention must also be rejected as manifestly ill-founded pursuant to Article 35 §§ 3 and 4 of the Convention.

D. Article 3 of the Convention

160. All three applicants complained that the restrictions on abortion in Ireland constituted treatment which breached Article 3 of the Convention.

161. The Government reiterated that relevant medical care and counselling were available to the applicants and, largely because of their failure to exhaust domestic remedies, they had not demonstrated any good reason for not availing themselves of these services. No act of the State prevented consultation and any perceived taboo or stigma causing the applicants' hesitation to consult did not flow from the impugned legal provisions. Even accepting a perceived stigma or taboo, the applicants had not demonstrated "beyond all reasonable doubt" treatment falling within the scope of Article 3 of the Convention.

162. The applicants complained of a violation of the positive and negative obligations in Article 3 of the Convention given the impact on them of the restrictions on abortion and of travelling for an abortion abroad. They maintained that the criminalisation of abortion was discriminatory (crude stereotyping and prejudice against women), caused an affront to women's dignity and stigmatised women, increasing feelings of anxiety. The applicants argued that the two options open to women - overcoming taboos to seek an abortion abroad and aftercare at home or maintaining the pregnancy in their situations - were degrading and a deliberate affront to their dignity. While the stigma and taboo effect of the criminalisation of abortion was denied by the Government, they submitted that there was much evidence confirming this effect on women. Indeed, the applicants contended that the State was under a positive obligation to protect the applicants from such hardship and degrading treatment.

163. The Court considers it evident, for the reasons set out at paragraphs 124-127 above, that travelling abroad for an abortion was both psychologically and physically arduous for each of the applicants. It was also financially burdensome for the first applicant (paragraph 128 above).

164. However, the Court reiterates its case-law to the effect that ill-treatment must attain a minimum level of severity if it is to fall within the scope of Article 3. The assessment of this

minimum depends on all the circumstances of the case, such as the duration of the treatment, its physical or mental effects and, in some cases, the sex, age and state of health of the victim (*Ireland v. the United Kingdom*, 18 January 1978, § 162, Series A no. 25; and, more recently, *Lotarev v. Ukraine*, no. 29447/04, § 79, 8 April 2010). In the above-described factual circumstances (paragraphs 124-129 above) and whether or not such treatment would be entirely attributable to the State, the Court considers that the facts alleged do not disclose a level of severity falling within the scope of Article 3 of the Convention.

165. In such circumstances, the Court rejects the applicants' complaints under Article 3 of the Convention as manifestly ill-founded pursuant to Article 35 §§ 3 and 4 of the Convention.

Since this complaint does not therefore give rise to an "arguable claim" of a breach of the Convention (*Boyle and Rice v. the United Kingdom*, cited above), their associated complaint under Article 13 of the Convention must also be rejected as manifestly ill-founded pursuant to Article 35 §§ 3 and 4 of the Convention.

E. The Court's conclusion on the admissibility of the applications

166. Accordingly, no ground having been established for declaring inadmissible the applicants' complaints under Article 8 or the associated complaints under Articles 13 and 14 of the Convention, the Court declares these complaints admissible and the remainder of the application inadmissible.

II. ALLEGED VIOLATION OF ARTICLE 8 OF THE CONVENTION

167. The first and second applicants complained under Article 8 about the restrictions on lawful abortion in Ireland which meant that they could not obtain an abortion for health and/or well-being reasons in Ireland and the third applicant complained under the same Article about the absence of any legislative implementation of Article 40.3.3 of the Constitution.

A. The observations of the applicants

168. The applicants maintained that Article 8 clearly applied to their complaints since the relevant restrictions on abortion interfered with the most intimate part of their family and private lives including their physical integrity.

169. They accepted that the restrictions were "in accordance with the law" but again referred to the Government's "interpretation" of the law (see paragraph 137 above).

170. While they accepted that the abortion restrictions pursued the aim of protecting foetal life, they took issue with a number of related matters.

They considered that it had not been shown that the restrictions were effective in achieving that aim: the abortion rate for women in Ireland was similar to States where abortion was legal since, *inter alia*, Irish women chose to travel abroad for abortions in any event.

Even if they were effective, the applicants questioned how the State could maintain the legitimacy of that aim given the opposite moral viewpoint espoused by human rights bodies worldwide.

The applicants also suggested that the current prohibition on abortion in Ireland (protecting foetal life unless the life of the woman was at risk) no longer reflected the position of the Irish people, arguing that there was evidence of greater support for broader access to legal abortion. Since 1983, each referendum proposed narrower access to abortion, each was rejected and no referendum had been proposed since 1983 to expand access to abortion. Research by the CPA showed that public support for legal access to abortion in Ireland had increased in the past two decades (CPA Report Nos. 6 and 7, paragraphs 82-88 above) and an opinion poll, conducted for “Safe and Legal (in Ireland) Abortion Rights Campaign” and reported in the Irish Examiner on 22 June 2007, found that 51% of respondents did not agree that a woman should have the right to abortion if she considered it ‘in her best interests’, while 43% agreed with abortion on these grounds. That the Government sought exceptions from the Maastricht and Lisbon Treaties was not relevant. In any event, popular opinion could not be used by a State to justify a failure to protect human rights, the European and international consensus outlined below being far more significant.

171. The applicants also maintained that the means chosen to achieve that aim was disproportionate.

172. While the State was entitled to a margin of appreciation to protect pre-natal life, it was not an absolute one. The Court could not give unqualified deference to the State’s interest in protecting pre-natal life as that would allow a State to employ any means necessary to restrict abortion without any regard to the mother’s life (*Open Door*, cited above, at §§ 68-69 and 73). The ruling requested of this Court was not, as the Government suggested, to mandate a particular abortion law for all Contracting States: the proportionality exercise did not preclude variation between States and it did not require deciding when life began (States, courts,

scientists, philosophers and religions had and would always disagree). However, this lack of agreement should not, of itself, deny women their Convention rights so that there was a need to express the minimum requirements to protect a woman's health and well-being under the Convention. Preserving pre-natal life was an acceptable goal only when the health and well-being of the mother were given proportionate value (*Vo v. France* [GC], no. 53924/00, § 80, ECHR 2004 VIII and *Tysi c v. Poland* judgment, § 113).

173. The restrictive nature of the legal regime in Ireland disproportionately harmed women. There was a medical risk due to a late, and therefore often surgical, abortion and an inevitable reduction in pre- and post-abortion medical support. The financial burden impacted more on poor women and, indirectly, on their families. Women experienced the stigma and psychological burden of doing something abroad which was a serious criminal offence in their own country.

The core Convention values necessitated that the State adopt alternative methods of protecting pre-natal life without criminalising necessary health care. Such methods existed and this was the approach favoured by human rights bodies (the Office of the Commissioner for Human Rights and the CEDAW). Instead of punitive criminal measures, State resources should be directed towards reproductive health and support. The establishment of the CPA was a positive but inadequate development in this direction.

174. Moreover, the extent of the prohibition on abortion in Ireland stood in stark contrast to more flexible regimes for which there was a clear European and international consensus. This Court's case law had previously found reliance on consensus instructive in considering the scope of Convention rights, including the consensus amongst Contracting States and the provisions in specialised international instruments and evolving norms and principles of international law (*Opuz v. Turkey*, no. 33401/02, §§ 164 and 184, ECHR 2009 ...; and *Christine Goodwin v. the United Kingdom* [GC], no. 28957/95, § 85, ECHR 2002 VI).

175. The current European consensus was clearly in favour of extending the right to abortion in Ireland and distinguished the earlier Commission case law on which the Government relied: the applicants relied in this respect on a report of the International Planned Parenthood Federation (*Abortion Legislation in Europe 2009*) and on certain third party submissions (at paragraphs 206-211 below). While there might be no European consensus on the scientific

and legal definition of the beginning of life (*Vo v. France*, cited above, at § 82), there was a clear consensus on the minimum standards for abortion services necessary to preserve a woman's health and well-being.

The PACE resolution (paragraphs 107-108 above) was indicative of this. In addition, the laws of the vast majority of the Contracting States also constituted strong evidence: 31 out of 47 States allowed abortion on request during the first trimester, 42 out of 47 States allowed abortion when the woman's health was at risk; and 32 out of 47 States expressly allowed the termination of pregnancy where there was a foetal abnormality. Ireland was in a small minority of 4 States that still enforced highly restrictive criminal abortion laws (with Malta, San Marino and Andorra). They further argued that the recent trend was towards further easing of restrictions on access to abortions including decriminalisation. The international human rights standards' consensus also tended to permitting legal abortion to protect the health and well-being of a woman (CEDAW and the Human Rights Committee, paragraphs 110-111 above) and to the decriminalising of abortion. The Cairo ICPD 1994 noted that an unsafe abortion could be a major public health concern.

176. While the above submissions were made by all applicants, the following were raised specifically as regards the third applicant.

177. The third applicant impugned the lack of a legal framework through which the relevant risk to her life and her entitlement to an abortion in Ireland could have been established which, she maintained, left her with no choice but to travel to England.

178. She underlined that Article 40.3.3, as interpreted by the *X* case, was a general provision. That provision did not define "unborn" and the *X* case did not define a real and substantial risk to life. A legal distinction, without more, between a woman's life and her health was also an unworkable distinction in practice. There were no legally binding and/or relevant professional guidelines and none of the professional bodies provided any clear guidance as to the precise steps to be taken or the criteria to be considered. Accordingly, none of her doctors could inform the third applicant of any official procedures to assist her. The doctors, who had treated her for cancer, were unable to offer her basic assistance as to the impact her pregnancy could have on her health. She stated that her own GP failed to advise her about abortion options and did not refer to the fact that she had been pregnant when she visited him several months later. This hesitancy on the part of doctors was explained by the chilling effect of a lack of clear legal procedures combined with the risk of serious criminal and professional

sanctions. It was not a problem that could be reduced, as the Government suggested, to the dereliction by doctors of their duties. Accordingly, the normal medical consultation process relied on by the Government to establish an entitlement to a lawful abortion was simply insufficient given the lack of clarity as to what constitutes a “real and substantial risk” to life combined with the chilling effect of severe criminal sanctions for doctors whose assessment could be considered *ex post facto* to fall outside that qualifying risk.

179. The third applicant also noted that domestic courts and many studies in Ireland clearly stated that Article 40.3.3 required implementation through legislation introducing a non-judicial certification procedure to establish a woman’s qualification for lawful abortion. Contracting States permitting abortion had such legal procedures in place enabling doctors to swiftly and confidentially make the relevant determinations. Ireland did not intend to introduce any such procedures. The Court required this in *Tysi c v. Poland* (indeed, in Poland there was already some legislative framework), a judgment recalled by the Commissioner for Human Rights during his visit to Ireland in 2007. International bodies had frequently criticised precisely this absence of legislation and the consequent negative impact on women.

B. The observations of the Irish Government

180. The Government argued that the Convention organs had never held that Article 8 was engaged where States failed to provide for certain types of abortion and any conclusion in that direction would raise serious issues for all Contracting States and, particularly for Ireland, where the prohibition was constitutionally enshrined. The Convention (see the *travaux pr paratoires*) did not intend to make this Court the arbiter of the substantive law of abortion. The issue attracted strong opinions in Contracting States and was resolved by domestic decision-making often following extensive political debate. The protection accorded under Irish law to the right to life of the unborn was based on profound moral values deeply embedded in the fabric of society in Ireland and the legal position was defined through equally intense debate. The Government accepted that no legislative proposal concerning abortion was currently under discussion in Ireland. The applicants were asking the Court to align varied abortion laws and thereby go against the recognised importance and fundamental role of the democratic process in each State and acceptance of a diversity of traditions and values in Contracting States (Article 53 of the Convention).

181. Even if Article 8 applied, the impugned restrictions satisfied the requirements of its second paragraph. In particular, Article 40.3.3, as interpreted in the X case, was a fundamental law of the State, was clear and foreseeable and pursued the legitimate aims of the protection of morals and the rights and freedoms of others including the protection of pre-natal life.

182. The Government underlined that the State was entitled to adopt the view, endorsed by the people, that the protection of pre-natal life, combined with the prohibition of direct destruction, was a legitimate goal and the Court should not scrutinise or measure the moral validity, legitimacy or success of this aim.

183. In any event, the Government disputed the applicants' suggestion that the current will of the Irish people was not reflected in the restrictions on abortion in Ireland: the opinion of the Irish people had been measured in referenda in 1983, 1992 and 2002. Its public representatives had actively sought, with detailed public reflection processes including extensive consultation, to consider the possible evolution of the laws and the recent public debates as to the possible impact of the Maastricht and Lisbon Treaties resulted in special Protocols to those Treaties.

The Government also underlined that the impugned restrictions had led to a significant reduction in Irish women travelling to the United Kingdom for an abortion (6673 women in 2001 travelled and 4686 women did so in 2007) and to one of the lowest levels of maternal deaths in the European Union and they disputed the assertion of Doctors for Choice/BPAS that the reduction in recent years in Irish women going to the United Kingdom for an abortion was explained by travel to other countries for an abortion. The Government maintained that CPA data from 2006 demonstrated relatively small numbers travelling to the 3 other countries most frequently cited (less than 10 women went to Spain and Belgium from 2005-2007 but significant numbers were going to the Netherlands namely, 42 in 2005, 461 in 2006 and 445 in 2007). Even taking account of these latter figures, there had been a clear reduction in the number of Irish women travelling abroad for an abortion.

184. Moreover, the impugned restrictions were proportionate.

185. The protection accorded under Irish domestic law to the right to life of the unborn and the restrictions on lawful abortion in Ireland were based on profound moral and ethical values to which the Convention afforded a significant margin of appreciation. A broad margin was

specifically accorded to determining what persons were protected by Article 2 of the Convention: the Court had conclusively answered in its judgments in *Vo v. France* and in *Evans v. the United Kingdom* ([GC], no. 6339/05, ECHR 2007 IV) that there was no European scientific or legal definition of the beginning of life so that the question of the legal protection of the right to life fell within the States' margin of appreciation. If States could have a different position on this point, they could have a different position as to limits on lawful abortion and the applicants were effectively asking the Court to leave out of the equation this fundamental legal foundation of the domestic position. The Court had not addressed the substantive issue of the regulation of abortion in the *Open Door* case on which the applicants relied.

In so far as the applicants' suggested that their situations must outweigh religious notions of morality, it was not clear whether the will of the Irish people was necessarily predicated on a particular religious view and, in any event, it was inappropriate to draw distinctions depending on whether a society's choices were based on religious or secular notions of morality.

186. As to the role of any consensus, the Government noted that it was not only the State's concern to protect pre-natal life that must be factored into the balance but also the legitimate choice made, in the absence of any European consensus on when life begins, that the unborn was deserving of protection. The Government did not accept the contention that there was a European and/or international consensus in favour of greater access to abortion, including for social reasons: while in some countries, access to abortion was indeed broader, the conditions of access greatly varied; the consensus upon which the applicants relied was irrelevant since it was based on legislation and not on the decisions of any constitutional court on the provisions of a constitution or the Convention; the applicants' reliance on random material, observations and recommendations was selective and futile; there was no discernible argument that the legislation in some or even most Contracting States was at some tipping point to be enforced on remaining States.

187. Indeed, even if there was such a consensus, determining the scope of fundamental rights based on such consensus was fraught with difficulty. The rights guaranteed by the Convention were not dependent upon the assessment of the popular will at any given time and, indeed, sometimes rights might have to be protected against the popular will. There were serious objections to attempting to deduce from the current position in Contracting States the

existence of a controversial Convention right which was not included in the Convention in the first place. Underlining the principle of subsidiarity and the respective roles of the State and the Court in such a particular context, the Government further maintained that the international consensus, if at all relevant, in fact pointed the other way namely, towards supporting a State's autonomy in determining its own abortion laws rather than leaving this to a supranational judicial-making body (the Cairo ICPD 1994, the Fourth World Conference on Women in Beijing in 1995 and the PACE Recommendation 1903(2010) as well as the Protocols to the Maastricht and Lisbon Treaties). The PACE Resolution 607(2008), relied on by the applicants, demonstrated the divergence of views in Contracting States as it was a resolution and not a recommendation and it was adopted by a split vote, the Irish MEPs voting against.

188. The ethical and moral issues to which abortion gave rise were to be distinguished from the scientific issues central to the *Christine Goodwin v. the United Kingdom* judgment (cited above). The violation of Article 8 in that case was based on a continuing international trend in favour of the legal recognition of the new sexual identity of post-operative transsexuals, even in the absence of European consensus, and on the fact that that no concrete or substantial hardship or detriment to the public would be likely to flow from a change in the status of transsexuals. A finding that a failure to provide abortion for social reasons breached Article 8 would bring a significant detriment to the Irish public which had sought to protect pre-natal life.

189. As regards the third applicant specifically, the Government made the following submissions.

In the first place, they maintained in response to a question from the Court, that the procedure for obtaining a lawful abortion in Ireland was clear. The decision was made, like any other major medical matter, by a patient in consultation with her doctor. On the rare occasion there was a possibility of a risk to the life of a woman, there was "a very clear and bright line rule provided by Irish law which is neither difficult to understand or to apply because it is the same law that has been applied under Section 58 of the 1861 Act, under Article 40.3.3 of the Irish Constitution and under the legislative provisions of every country which permits a pregnancy to be terminated on that ground". As to the precise procedures to be followed by a pregnant woman and her doctor where an issue arose as to such a possible risk, it was the responsibility of the doctor and a termination could occur when the risk was real and

substantial. If the patient did not agree with that advice, she was free to seek another medical opinion and, in the last resort, she could make an emergency application to the High Court (as outlined above). The grounds for lawful abortion in Ireland were well known and applied. Referring to the Medical Council Guidelines, the CPA Guidelines and the evidence of practitioners to the Committee on the Constitution, the Government considered it clear that, while there were issues regarding the characterisation of medical treatment essential to protect the life of the mother, medical intervention occurred when a mother's life was threatened, the refusal of treatment on grounds of moral disapproval was prohibited and a patient was entitled to a second opinion. While the Irish Institute of Obstetricians and Gynaecologists had no published guidelines concerning a pregnant woman presenting with life threatening conditions, that Institute would be in agreement with the Guidelines of the United Kingdom Royal College of Obstetricians and Gynaecologists concerning the management of ectopic pregnancies and it was probable that Irish gynaecologists would "by and large" follow the latter Guidelines with or without minor amendments or additions. This clear process of how a decision to terminate a pregnancy was taken in Ireland by the patient in consultation with the doctor was regularly followed in the case of ectopic pregnancies.

In response to a further question from the Court as to how many lawful abortions were carried out annually in Ireland, the Government referred to a database of the Economic and Social Research Institute on discharges and deaths from all public acute hospitals. The Department of Health and Children had analysed that database based on the conditions that might require termination of pregnancy referred to in the Fifth Progress Report on Abortion. The results presented by the Government concerned ectopic pregnancies only.

Secondly, the Government did not accept the conclusions drawn by the third applicant from the comment of McCarthy J. in the X case (paragraph 44 above) combined with the above-cited *Tysi ac v. Poland* judgment. McCarthy J. did not assert that legislation was required to operate Article 40.3.3 but rather that the courts had a duty to interpret and to apply Article 40.3.3.

Thirdly, since this Court in the Open Door case found that Article 40.3.3 was sufficiently clear and precise to be considered to be prescribed by law, it could not now find that it was not sufficiently clear and precise as regards the authorisation of an abortion which was the very focus of that constitutional provision.

Fourthly, the Government distinguished the *Tysic v. Poland* judgment. There was an undercurrent in that case that doctors were not operating procedures and this simply could not be sustained in the present case. In addition, there was a stark contrast between the wealth of medical evidence before the Court in the *Tysic v. Poland* case (notably, as regards the risk the pregnancy constituted for her health) and that in the case of the third applicant who presented no evidence of the life threatening nature of her condition. Moreover, the Government disputed whether the situation of patients and doctors would be improved by a certification process which applied in Poland. Furthermore, while in *Tysic v. Poland* the Court found that a State must not structure its legal framework so as to limit real possibilities to obtain a lawful abortion and should include a possibility of having a woman's views considered pre-partum, the third applicant had not demonstrated that she had considered legal action. Finally, the Government did not accept that the alleged chilling effect of the criminal sanctions in Irish law militated against obtaining an abortion in Ireland: there had been no criminal prosecution of a doctor in living memory, in the "C" case the High Court referred to doctors' support of C and to the fact that doctors would carry out the duties imposed on them by law and to suggest otherwise was serious and unsubstantiated.

190. Finally, the Government considered that the striking polarity of the third parties' submissions demonstrated the diversity of opinions and approaches on the subject of abortion throughout the Contracting States.

191. The Government concluded that, in the circumstances there was no basis for the applicants' claim that Article 40.3.3 was disproportionate. It would be inappropriate for this Court to attempt to balance the competing interests where striking that balance domestically has been a long, complex and delicate process, to which a broad margin of appreciation applied and in respect of which there was plainly no consensus in Member States of the Council of Europe.

C. The observations of the intervening Government to the Chamber

192. Since the third applicant is Lithuanian, that Government submitted observations to the Chamber (summarised below), although they did not make written or oral submissions to the Grand Chamber.

193. The Lithuanian Government reviewed the jurisprudence of the Convention organs: concerning the applicability of Article 2 to the foetus; concerning the compatibility of

restrictions on abortion with Article 8 and concerning the compatibility of restrictions on receiving and imparting information on abortion with Article 10. They pointed out that the Convention institutions had not, until the present case, had the opportunity to develop certain general Convention principles on the minimum degree of protection to which a woman seeking an abortion would be entitled, having regard to the right to protection of a foetus. They maintained that such clarification by this Court would be of great importance to all Contracting States.

194. Since the early Commission case law, the situation had evolved considerably and they referred, in particular to the PACE Resolution 1607, which Resolution responded to a perceived need to lay down standards in Europe as regards the rights of women seeking abortion. The explanatory memorandum to that Resolution noted that an abortion on request was at least in theory available in all Council of Europe Member States apart from Andorra, Ireland, Malta, Monaco and Poland and noted other commonalities and differences on the abortion issue in those States. They considered the situation in Council of Europe Member States to be diverse and that this sensitive question was still the subject of many debates in those States, often exposing conflicting moral positions: it was still not possible to find a uniform European conception of morals.

195. Accordingly, the Lithuanian Government considered that it would be of great importance for this Court to provide guidance on the question of the minimum degree of protection to which a woman requesting an abortion was to be accorded vis-à-vis her unborn child.

D. The observations of the third parties

1. Joint Observations of the European Centre for Law and Justice in association with Kathy Sinnott (Member of the European Parliament); of The Family Research Council, Washington D.C.; and of the Society for the Protection of Unborn Children, London.

196. These third parties described themselves as persons and bodies dedicated to the defence of the sanctity of human life.

197. As regards Article 2 of the Convention, Ireland had a sovereign right to determine when life began and the appropriate protections based on the paramount right to life, which right

outweighed other rights. Ireland's abortion regime was based on full and equal rights to life of the mother and of the unborn. It was against the paramount right to life of the unborn that the lesser rights to privacy and bodily integrity of the mother had to be measured. The primacy of the right to life came from the fact that the basic building block of the State was the individual and personal rights existed only because a human being existed from the moment of conception. This primacy was recognised by many international instruments. The principle of respect for national sovereignty formed the very basis for the Convention rights because those rights stemmed from treaty obligations. Recognising a right to abortion would create a new Convention right to which Ireland had never acceded. Ireland's position deserved special deference because of its longevity and consistency despite numerous domestic challenges and given its inscription in the Constitution ratified by the overwhelming majority of the Irish people. The Irish Government have always taken the firm position that their participation in the European political union would not impact on Article 40.3.3 of the Constitution.

198. The Convention organs recognised that Article 2 gave States the option of protecting the unborn (*H v. Norway*, cited above). The above-cited judgment of *Vo v. France* confirmed that the unborn belonged to the human race and that the highest deference had to be shown to States in determining the extent of that protection which amounted, indeed, to a higher measure of protection, inclusive of life, envisaged by Article 53 of the Convention. Since abortion in Ireland was lawful in case of a risk to life, it met any positive obligations under Article 2 of the Convention. Neither was there any negative aspect of Article 2 requiring States to deny life to the unborn to protect the life of women. Interpreting Article 2 in that manner would be tantamount to limiting the right to life by prohibiting States from recognising that right in the unborn and, indeed, creating a right to kill: the scope of Article 2 did not reach that far (*Pretty v. the United Kingdom*, no. 2346/02, § 39, ECHR 2002 III).

199. Just as Article 2 did not provide a right to abortion, Ireland's restrictions on abortion could not be said to unduly interfere with the Article 8 rights of women. A woman's right to privacy and bodily integrity in the context of pregnancy was not absolute, nor was pregnancy a purely private matter as it was to be analysed against the rights of the unborn and the State's right to choose when life began. In any event, the impugned restrictions were "prescribed by law". They were precise in their formulation, clearly defined in the case law (see the *X* case), codified by the Medical Council Guidelines and uniform in their application. In this latter respect, it was legitimate to rely on clinical judgments. The restrictions were also "proportionate" given the paramount right to life of the unborn. Deference to the fact that

Ireland was inclusive in recognising the right to life of the mother and the unborn outweighed any alleged conflict with the interests of the woman to health, privacy and bodily integrity. In fact, the restrictions also protected women: they avoided the selection of female children for abortion; Ireland's maternal mortality rate was the lowest in Europe; and abortion had negative effects on women's health, lives (the rate of death after abortion being higher than after childbirth) and on future pregnancies. The right to life of the unborn took precedence over any financial concerns of the mother.

200. That Irish women could travel for an abortion did not defeat the legitimacy of Ireland's abortion laws: that exception was imposed by the right to travel under the EC law and could not be used to justify an even wider exception to the restrictions.

201. There was no universal consensus towards recognising a right to abortion in international law: on the contrary, certain international instruments and 68 countries prohibited abortion entirely or allowed it to save the mother's life only.

2. The Pro-Life Campaign ("PLC")

202. The PLC described itself as an Irish non-governmental organisation which promoted pro-life education and defends human life from conception.

203. The PLC pointed out that the protection of the life of the unborn was fundamental to the Constitutional scheme of fundamental rights. That tradition of human rights protection via constitutional jurisprudence was a long, proud and praiseworthy one which had given Ireland an exemplary record before this Court as compared to other Contracting States.

204. The constitutional protection of the unborn was only capable of being curtailed in the limited circumstances outlined in the X case, in which circumstances abortion would be lawful in Ireland. Information on services abroad was available (the 1995 Act) and, in general, no one's travel was restricted. The Medical Council Guidelines made it clear that doctors should not refuse to treat any patient on grounds of moral disapproval.

205. The Irish courts had due regard to any decision or judgment of the Court but, despite the incorporation of the Convention into Irish law by the 2003 Act, the Constitution remained the paramount source of law in Ireland so that Convention argument could not be used to overthrow laws that were otherwise constitutional. The Contracting States had a margin of appreciation in relation to the implementation of the Convention since the national authorities

were, in principle, better placed than an international court to evaluate local needs and conditions. Any examination of the extent to which the Convention complimented, supplemented or deepened existing rights, should be addressed in the domestic courts prior to this Court.

3. Joint observations of Doctors for Choice, Ireland and BPAS

206. As well as the submissions outlined at paragraphs 120-121 above, they submitted figures as to the annual rates of abortion by Irish women in England and Wales published by the United Kingdom Department of Health (from the CPA Report no. 19) as follows: 1975 (1573); 1980 (3320); 1985 (3888); 1990 (4064); 1995 (4532); 2000 (6391); 2001 (6673); 2002 (6522); 2003 (6320); 2004 (6217); 2005 (5585); 2006 (5042); and 2007 (4686). However, they explained that Irish women give addresses in the United Kingdom to maintain confidentiality and/or to obtain British health cover. They argued that the reduction in the numbers of Irish women obtaining abortions in England and Wales in recent years could be explained by the availability of other more accessible options (abortions in other euro zone countries or greater use of abortion medication, “the abortion pill”). They also suggested that Irish women were statistically more likely to consult later for an abortion abroad and that there was no evidence that banning abortion in a country actually reduced the rate of abortion when other means were available.

207. Irish medical professionals were in an unclear position and unable to provide adequate medical services. Doctors advising a patient on the subject faced criminal charges, on the one hand, and an absence of clear legal, ethical or medical guidelines, on the other. The Medical Council Guidelines were of no assistance. They had never heard of any case where life-saving abortions had been performed in Ireland. Irish doctors did not receive any training on abortion techniques and were not therefore equipped to carry out an abortion or to provide adequate post-abortion care.

4. Joint Observations of the Centre for Reproductive Rights (“the Centre”) and International Reproductive and Sexual Health Law Programme (“the Programme”)

208. These third parties mainly argued that international human rights’ laws and comparative standards should inform the Court’s consideration and that the impugned Irish restrictions on abortion were inconsistent with such laws and standards for two reasons.

209. In the first place, they maintained that denying a lawful abortion to protect a woman's physical and mental health was inconsistent with international law and comparative standards. As to that international law, the UN human rights monitoring organs (inter alia, the Human Rights Committee and CEDAW) interpreted the human rights to life, health and non-discrimination, as well as the right to freedom from cruel, inhuman and degrading treatment or punishment, as requiring States to lawfully permit abortion where necessary to protect a woman's health. These bodies had consistently advised States to amend national abortion laws which prohibited abortion without exception or permitted abortion only where necessary to protect the woman's life. Laws permitted abortion to protect the health of the mother in all but 4 of the 47 Contracting States and 40 out of 47 allowed abortion for broader socio-economic reasons or on request within certain gestational limits. Constitutional courts in Europe, relying on women's rights to physical and mental health and personal autonomy, reflected these health-based exceptions to abortion restrictions.

Neither international law nor comparative standards supported a distinction between the right to life and health in abortion regulation. It was a basic principle of international human rights' law that no formal hierarchy could be drawn between life and health as interests equally deserving of State protection, so that a law which permitted abortion to protect life but not health would not be acceptable. International human rights' law also reflected an understanding in an abortion context that the protection of life was practically indistinguishable from the protection of health. A comparative review revealed that all Contracting States which permitted abortion to preserve life also admitted abortion to protect health: all except Ireland. This recognised that distinctions between life and health protection could not be meaningfully drawn in a clinical context.

210. Secondly, they submitted that international law and comparative standards recognised that the State should seek to protect pre-natal interests through proportionate means that give due consideration to the rights of pregnant women so that restrictive criminal abortion laws and harsh penalties were excessively burdensome on women and abortion providers. UN human rights monitoring bodies consistently called on States to amend and/or repeal legislation criminalising abortion to ensure access to lawful abortion. Criminal laws were considered not to restrict access to abortion but rather access to safe abortion. Certain of those UN human rights' monitoring bodies considered criminal restrictions on abortion discriminatory. While most Contracting States controlled abortion via criminal law, the majority did not have criminal punishment for women, the penalties were moderate and they

permitted lawful abortion in a broad set of circumstances. Ireland's criminal law was the harshest criminal penalty in abortion regulations across Europe. Equally, international and comparative standards supported the adoption by States of less restrictive measures that protected the State's interest in pre-natal life and guaranteed women's rights. International standards supported pre-natal life by ensuring safe pregnancies, welfare provisions and supporting family planning. Most Council of Europe Member States had procedural frameworks regulating access to abortion which balanced the State interest in protecting pre-natal life with a mother's rights.

211. In conclusion, the degree of conformity of the above-described international laws and comparative standards was such that it did not admit of a margin of appreciation being accorded to Ireland in this matter.

E. The Court's assessment

1. Whether Article 8 applied to the applicants' complaints

212. The Court recalls that the notion of "private life" within the meaning of Article 8 of the Convention is a broad concept which encompasses, inter alia, the right to personal autonomy and personal development (see *Pretty v. the United Kingdom*, cited above, § 61). It concerns subjects such as gender identification, sexual orientation and sexual life (for example, *Dudgeon v. the United Kingdom*, judgment of 22 October 1981, Series A no. 45, pp. 18-19, § 41; and *Laskey, Jaggard and Brown v. the United Kingdom*, judgment of 19 February 1997, Reports of Judgments and Decisions 1997-I, p. 131, § 36), a person's physical and psychological integrity (*Tysiąg v. Poland* judgment, cited above, § 107) as well as decisions both to have and not to have a child or to become genetic parents (*Evans v. the United Kingdom [GC]*, cited above, § 71).

213. The Court has also previously found, citing with approval the case-law of the former Commission, that legislation regulating the interruption of pregnancy touches upon the sphere of the private life of the woman, the Court emphasising that Article 8 cannot be interpreted as meaning that pregnancy and its termination pertain uniquely to the woman's private life as, whenever a woman is pregnant, her private life becomes closely connected with the developing foetus. The woman's right to respect for her private life must be weighed against

other competing rights and freedoms invoked including those of the unborn child (*Tysi c v. Poland* judgment, cited above, § 106; and *Vo v. France* [GC], cited above, §§ 76, 80 and 82).

214. While Article 8 cannot, accordingly, be interpreted as conferring a right to abortion, the Court finds that the prohibition in Ireland of abortion where sought for reasons of health and/or well-being about which the first and second applicants complained, and the third applicant's alleged inability to establish her qualification for a lawful abortion in Ireland, come within the scope of their right to respect for their private lives and accordingly Article 8. The difference in the substantive complaints of the first and second applicants, on the one hand, and that of the third applicant on the other, requires separate determination of the question whether there has been a breach of Article 8 of the Convention.

215. It is not, in these circumstances, necessary also to examine whether Article 8 applied as regards its family life component.

2. The first and second applicants

(a) Positive or negative obligations under Article 8 of the Convention?

216. While there are positive obligations inherent in effective respect for private life (see paragraphs 244-246 below), the Court considers it appropriate to analyse the first and second applicants' complaints as concerning negative obligations, their core argument being that the prohibition in Ireland of abortion where sought for health and/or well-being reasons disproportionately restricted their right to respect for their private lives. The Court has previously noted, citing with approval the case-law of the former Commission in *Bruggemann and Scheuten v. Germany*, that not every regulation of the termination of pregnancy constitutes an interference with the right to respect for the private life of the mother (*Vo v. France* [GC], cited above, § 76). Nevertheless, having regard to the broad concept of private life within the meaning of Article 8 including the right to personal autonomy and to physical and psychological integrity (see paragraphs 212-214 above), the Court finds that the prohibition of the termination of the first and second applicants' pregnancies sought for reasons of health and/or well being amounted to an interference with their right to respect for their private lives. The essential question which must be determined is whether the prohibition is an unjustified interference with their rights under Article 8 of the Convention.

217. As noted at paragraph 145 above, the impugned interference stemmed from sections 58 and 59 of the 1861 Act, as qualified by Article 40.3.3 of the Constitution as interpreted by the Supreme Court in the X case.

218. To determine whether this interference entailed a violation of Article 8, the Court must examine whether or not it was justified under the second paragraph of that Article namely, whether the interference was “in accordance with the law” and “necessary in a democratic society” for one of the “legitimate aims” specified in Article 8 of the Convention.

(b) Was the interference “in accordance with the law”?

219. The applicants accepted that the restriction was in accordance with the law and the Government recalled that the Court had found Article 40.3.3 to be “prescribed by law” in the above-cited Open Door case.

220. The Court recalls that an impugned interference must have some basis in domestic law, which law must be adequately accessible and be formulated with sufficient precision to enable the citizen to regulate his conduct, he or she being able - if need be with appropriate advice - to foresee, to a degree that is reasonable in the circumstances, the consequences which a given action may entail (for example, *Silver and Others v. the United Kingdom*, 25 March 1983, §§ 86-88, Series A no. 61).

221. The Court considers that the domestic legal provisions constituting the interference were clearly accessible. Having regard to paragraphs 147-149 above, the Court also considers that it was clearly foreseeable that the first and second applicants were not entitled to an abortion in Ireland for health and/or well-being reasons.

(c) Did the interference pursue a legitimate aim?

222. The Court recalls that, in the Open Door case, it found that the protection afforded under Irish law to the right to life of the unborn was based on profound moral values concerning the nature of life which were reflected in the stance of the majority of the Irish people against abortion during the 1983 referendum. The impugned restriction in that case was found to pursue the legitimate aim of the protection of morals of which the protection in Ireland of the right to life of the unborn was one aspect. This was confirmed by the Court’s finding in the above-cited *Vo v. France* case that it was neither desirable nor possible to answer the question of whether the unborn was a person for the purposes of Article 2 of the Convention, so that it

would be equally legitimate for a State to choose to consider the unborn to be such a person and to aim to protect that life.

223. However, the first and second applicants maintained that the will of the Irish people had changed since the 1983 referendum so that the legitimate aim accepted by the Court in its Open Door judgment was no longer a valid one. The Court recalls that it is not possible to find in the legal and social orders of the Contracting States a uniform European conception of morals including on the question of when life begins. By reason of their “direct and continuous contact with the vital forces of their countries”, State authorities are in principle in a better position than the international judge to give an opinion on the “exact content of the requirements of morals” in their country, as well as on the necessity of a restriction intended to meet them (*Handyside v. the United Kingdom* judgment of 7 December 1976, Series A no. 24, § 48; *Müller and Others v. Switzerland* judgment of 24 May 1988, Series A no. 133, § 35; *Open Door*, § 68; and *Vo v. France [GC]*, § 82).

224. The constitutional framework for the interference, Article 40.3.3, was adopted in referendum by a substantial majority in 1983. It is true that, since then, the population of Ireland has not been requested to vote in a referendum proposing any broader abortion rights in Ireland. In fact, in 1992 and 2002 the Irish people refused in referenda to restrict the existing grounds for lawful abortion in Ireland, on the one hand, and accorded in those referenda the right to travel abroad for an abortion and to have information about that option, on the other (paragraphs 45-54 above).

225. However, the Court recalls the public reflection processes prior to the adoption of the Constitution Review Group Report, the Green Paper and the Fifth Progress Report on Abortion (paragraphs 62-76 above). These processes, which involved significant consultation and considered numerous constitutional and/or legislative options, reflected profoundly differing opinions and demonstrated the sensitivity and complexity of the question of extending the grounds for lawful abortion in Ireland. The rejection by a further referendum of the Lisbon Treaty in 2008 is also important in this context. While it could not be said that this rejection was entirely due to concerns about maintaining Irish abortion laws, the Report commissioned by the Government found that the rejection was “heavily influenced by low levels of knowledge and specific misperceptions” as to the impact of the Treaty on Irish abortion laws. As with the Maastricht Treaty in 1992, a special Protocol to the Lisbon Treaty was granted confirming that nothing in the Treaty would affect, *inter alia*, the constitutional

protection of the right to life of the unborn and a further referendum in 2009 allowed the ratification of the Lisbon Treaty (paragraphs 100-103).

226. In light of the above, the Court does not consider that the limited opinion polls on which the first and second applicants relied (paragraphs 82-88 and 170 above) are sufficiently indicative of a change in the views of the Irish people, concerning the grounds for lawful abortion in Ireland, as to displace the State's opinion to the Court on the exact content of the requirements of morals in Ireland (*Handyside v. the United Kingdom* judgment and further references cited at 221 above). Accordingly, the Court finds that the impugned restrictions in the present case, albeit different from those at issue in the *Open Door* case, were based on profound moral values concerning the nature of life which were reflected in the stance of the majority of the Irish people against abortion during the 1983 referendum and which have not been demonstrated to have relevantly changed since then.

227. The Court concludes that the impugned restriction therefore pursued the legitimate aim of the protection of morals of which the protection in Ireland of the right to life of the unborn was one aspect.

228. The Court does not therefore consider it necessary to determine whether these are moral views stemming from religious or other beliefs or whether the term "others" in Article 8 § 2 extends to the unborn (*Open Door*, cited above, § 63; and *Vo v. France* [GC], cited above, § 85). The first and second applicants' submissions to the effect that the abortion restrictions in pursuance of that aim are ineffective and their reliance on the moral viewpoint of international bodies fall to be examined below under the necessity of the interference (*Open Door*, § 76).

(e) Was the interference "necessary in a democratic society"?

229. In this respect, the Court must examine whether there existed a pressing social need for the measure in question and, in particular, whether the interference was proportionate to the legitimate aim pursued, regard being had to the fair balance which has to be struck between the relevant competing interests in respect of which the State enjoys a margin of appreciation (*Open Door*, § 70; *Odièvre v. France* [GC], no. 42326/98, § 40, ECHR 2003 III; and *Evans v. the United Kingdom* [GC], § 75).

230. Accordingly, and as underlined at paragraph 213 above, in the present cases the Court must examine whether the prohibition of abortion in Ireland for health and/or well-being reasons struck a fair balance between, on the one hand, the first and second applicants' right

to respect for their private lives under Article 8 and, on the other, profound moral values of the Irish people as to the nature of life and consequently as to the need to protect the life of the unborn.

231. The Court considers that the breadth of the margin of appreciation to be accorded to the State is crucial to its conclusion as to whether the impugned prohibition struck that fair balance. The Government maintained that, in the context of abortion laws, the State's margin was significant and unaffected by any European or international consensus. The first and second applicants argued that, while a margin was to be accorded, the right to life of the unborn could not be accorded primacy to the exclusion of the proportionate protection of the rights of women and, further, that it was crucial to take account of the consensus outside of Ireland towards broader access to abortion.

232. The Court recalls that a number of factors must be taken into account when determining the breadth of the margin of appreciation to be enjoyed by the State when determining any case under Article 8 of the Convention. Where a particularly important facet of an individual's existence or identity is at stake, the margin allowed to the State will normally be restricted (see *Evans v. the United Kingdom* [GC], cited above, § 77). Where, however, there is no consensus within the Member States of the Council of Europe, either as to the relative importance of the interest at stake or as to the best means of protecting it, particularly where the case raises sensitive moral or ethical issues, the margin will be wider (*Evans v. the United Kingdom* [GC], cited above, § 77; *X., Y. and Z. v. the United Kingdom*, judgment of 22 April 1997, Reports of Judgments and Decisions 1997-II, § 44; *Frette v. France*, no. 36515/97, § 41, ECHR 2002-I; *Christine Goodwin*, cited above, § 85). As noted above, by reason of their direct and continuous contact with the vital forces of their countries, the State authorities are, in principle, in a better position than the international judge to give an opinion, not only on the "exact content of the requirements of morals" in their country, but also on the necessity of a restriction intended to meet them (*Handyside v. the United Kingdom* judgment and the other references cited at paragraph 223 above).

233. There can be no doubt as to the acute sensitivity of the moral and ethical issues raised by the question of abortion or as to the importance of the public interest at stake. A broad margin of appreciation is, therefore, in principle to be accorded to the Irish State in determining the question whether a fair balance was struck between the protection of that public interest,

notably the protection accorded under Irish law to the right to life of the unborn, and the conflicting rights of the first and second applicants to respect for their private lives under Article 8 of the Convention.

234. However, the question remains whether this wide margin of appreciation is narrowed by the existence of a relevant consensus.

The existence of a consensus has long played a role in the development and evolution of Convention protections beginning with *Tyrer v. the United Kingdom* (25 April 1978, § 31, Series A no. 26), the Convention being considered a “living instrument” to be interpreted in the light of present-day conditions. Consensus has therefore been invoked to justify a dynamic interpretation of the Convention (*Marckx v. Belgium*, judgment of 13 June 1979, Series A no. 31, § 41; *Dudgeon v. the United Kingdom*, judgment of 22 October 1981, Series A no. 45, § 60; *Soering v. the United Kingdom*, judgment of 7 July 1989, Series A no. 161, § 102; *L. and V. v. Austria*, nos. 39392/98 and 39829/98, § 50, ECHR 2003-I and *Christine Goodwin v. the United Kingdom* [GC], cited above, § 85).

235. In the present case, and contrary to the Government’s submission, the Court considers that there is indeed a consensus amongst a substantial majority of the Contracting States of the Council of Europe towards allowing abortion on broader grounds than accorded under Irish law. In particular, the Court notes that the first and second applicants could have obtained an abortion on request (according to certain criteria including gestational limits) in some 30 such States. The first applicant could have obtained an abortion justified on health and well-being grounds in approximately 40 Contracting States and the second applicant could have obtained an abortion justified on well-being grounds in some 35 Contracting States. Only 3 States have more restrictive access to abortion services than in Ireland namely, a prohibition on abortion regardless of the risk to the woman’s life. Certain States have in recent years extended the grounds on which abortion can be obtained (see paragraph 112 above). Ireland is the only State which allows abortion solely where there is a risk to the life (including self-destruction) of the expectant mother. Given this consensus amongst a substantial majority of the Contracting States, it is not necessary to look further to international trends and views which the first two applicants and certain of the third parties argued also leant in favour of broader access to abortion.

236. However, the Court does not consider that this consensus decisively narrows the broad margin of appreciation of the State.

237. Of central importance is the finding in the above-cited *Vo* case, referred to above, that the question of when the right to life begins came within the States' margin of appreciation because there was no European consensus on the scientific and legal definition of the beginning of life, so that it was impossible to answer the question whether the unborn was a person to be protected for the purposes of Article 2. Since the rights claimed on behalf of the foetus and those of the mother are inextricably interconnected (see the review of the Convention case law at paragraphs 75-80 in the above-cited *Vo v. France* [GC] judgment), the margin of appreciation accorded to a State's protection of the unborn necessarily translates into a margin of appreciation for that State as to how it balances the conflicting rights of the mother. It follows that, even if it appears from the national laws referred to that most Contracting Parties may in their legislation have resolved those conflicting rights and interests in favour of greater legal access to abortion, this consensus cannot be a decisive factor in the Court's examination of whether the impugned prohibition on abortion in Ireland for health and well-being reasons struck a fair balance between the conflicting rights and interests, notwithstanding an evolutive interpretation of the Convention (*Tyrer v. the United Kingdom*, § 31; and *Vo v. France* [GC], § 82, both cited above).

238. It is indeed the case that this margin of appreciation is not unlimited. The prohibition impugned by the first and second applicants must be compatible with a State's Convention obligations and, given the Court's responsibility under Article 19 of the Convention, the Court must supervise whether the interference constitutes a proportionate balancing of the competing interests involved (*Open Door*, § 68). A prohibition of abortion to protect unborn life is not therefore automatically justified under the Convention on the basis of unqualified deference to the protection of pre-natal life or on the basis that the expectant mother's right to respect for her private life is of a lesser stature. Nor is the regulation of abortion rights solely a matter for the Contracting States, as the Government maintained relying on certain international declarations (paragraph 187 above). However, and as explained above, the Court must decide on the compatibility with Article 8 of the Convention of the Irish State's prohibition of abortion on health and well-being grounds on the basis of the above-described fair balance test to which a broad margin of appreciation is applicable.

239. From the lengthy, complex and sensitive debate in Ireland (summarised at 28-76 above) as regards the content of its abortion laws, a choice has emerged. Irish law prohibits abortion in Ireland for health and well-being reasons but allows women, in the first and second

applicants' position who wish to have an abortion for those reasons (see paragraphs 123-130 above), the option of lawfully travelling to another State to do so.

On the one hand, the Thirteenth and Fourteenth Amendments to the Constitution removed any legal impediment to adult women travelling abroad for an abortion and to obtaining information in Ireland in that respect. Legislative measures were then adopted to ensure the provision of information and counselling about, *inter alia*, the options available including abortions services abroad, and to ensure any necessary medical treatment before, and more particularly after, an abortion. The importance of the role of doctors in providing information on all options available, including abortion abroad, and their obligation to provide all appropriate medical care, notably post-abortion, is emphasised in CPA work and documents and in professional medical guidelines (see generally paragraph 130 above). The Court has found that the first two applicants did not demonstrate that they lacked relevant information or necessary medical care as regards their abortions (paragraphs 127 and 130 above).

On the other hand, it is true that the process of travelling abroad for an abortion was psychologically and physically arduous for the first and second applicants, additionally so for the first applicant given her impoverished circumstances (paragraph 163 above). While this may not have amounted to treatment falling within the scope of Article 3 of the Convention (paragraph 164 above), the Court does not underestimate the serious impact of the impugned restriction on the first and second applicants. It may even be the case, as the first two applicants argued, that the impugned prohibition on abortion is to a large extent ineffective in protecting the unborn in the sense that a substantial number of women take the option open to them in law of travelling abroad for an abortion not available in Ireland: it is not possible to be more conclusive, given the disputed nature of the relevant statistics provided to the Court (paragraphs 170, 183 and 206 above).

240. It is with this choice that the first and second applicants take issue. However, it is equally to this choice that the broad margin of appreciation centrally applies. The Court would distinguish the prohibition on the provision of information about abortion services abroad at issue in the *Open Door* case and the finding in that case that the prohibition on information was ineffective to protect the right to life because women travelled abroad anyhow (§ 76 of that judgment). There is, in the Court's view, a clear distinction to be drawn between that prohibition and the more fundamental choice at issue in the present case as to the permitted

grounds for lawful abortion in Ireland to which the above-described margin of appreciation is accorded.

241. Accordingly, having regard to the right to lawfully travel abroad for an abortion with access to appropriate information and medical care in Ireland, the Court does not consider that the prohibition in Ireland of abortion for health and well-being reasons, based as it is on the profound moral views of the Irish people as to the nature of life (paragraphs 222-227 above) and as to the consequent protection to be accorded to the right to life of the unborn, exceeds the margin of appreciation accorded in that respect to the Irish State. In such circumstances, the Court finds that the impugned prohibition in Ireland struck a fair balance between the right of the first and second applicants to respect for their private lives and the rights invoked on behalf of the unborn.

(f) The Court's conclusion as regards the first and second applicants

242. It concludes that there has been no violation of Article 8 of the Convention as regards the first and second applicants.

3. The third applicant

243. The third applicant's complaint concerns the failure by the Irish State to implement Article 40.3.3 of the Constitution by legislation and, notably, to introduce a procedure by which she could have established whether she qualified for a lawful abortion in Ireland on grounds of the risk to her life of her pregnancy.

(a) Does her complaint fall to be examined under the positive or negative obligations of Article 8 of the Convention?

244. While the essential object of Article 8 is, as noted above, to protect individuals against arbitrary interference by public authorities, it may also impose on a State certain positive obligations to ensure effective respect for the rights protected by Article 8 (see, among other authorities, *X and Y v. the Netherlands*, judgment of 26 March 1985, Series A no. 91, § 23).

245. The Court has previously found States to be under a positive obligation to secure to its citizens their right to effective respect for their physical and psychological integrity (*Glass v. the United Kingdom*, no. 61827/00, §§ 74-83, ECHR 2004 II; *Sentges v. the Netherlands* (dec.) no. 27677/02, 8 July 2003; *Pentiacova and Others v. Moldova* (dec.), no. 14462/03, ECHR 2005-...; *Nitecki v. Poland* (dec.), no. 65653/01, 21 March 2002; *Odièvre v. France*

[GC], cited above, § 42). In addition, these obligations may involve the adoption of measures, including the provision of an effective and accessible means of protecting the right to respect for private life (*Airey v. Ireland*, 9 October 1979, § 33, Series A no. 32; *McGinley and Egan v. the United Kingdom*, 9 June 1998, § 101, Reports of Judgments and Decisions 1998 III; and *Roche v. the United Kingdom* [GC], no. 32555/96, § 162, ECHR 2005 X) including both the provision of a regulatory framework of adjudicatory and enforcement machinery protecting individuals' rights and the implementation, where appropriate, of specific measures in an abortion context (*Tysiąg v. Poland* judgment, cited above, § 110).

246. Accordingly, the Court considers that the third applicant's complaint falls to be analysed under the positive aspect of Article 8. In particular, the question to be determined by the Court is whether there is a positive obligation on the State to provide an effective and accessible procedure allowing the third applicant to establish her entitlement to a lawful abortion in Ireland and thereby affording due respect to her interests safeguarded by Article 8 of the Convention.

(b) General principles applicable to assessing a State's positive obligations

247. The principles applicable to assessing a State's positive and negative obligations under the Convention are similar. Regard must be had to the fair balance that has to be struck between the competing interests of the individual and of the community as a whole, the aims in the second paragraph of Article 8 being of a certain relevance (*Gaskin v. the United Kingdom*, 7 July 1989, § 42, Series A no. 160; and *Roche v. the United Kingdom* [GC], cited above, § 157).

248. The notion of "respect" is not clear cut especially as far as positive obligations are concerned: having regard to the diversity of the practices followed and the situations obtaining in the Contracting States, the notion's requirements will vary considerably from case to case (*Christine Goodwin v. the United Kingdom* [GC], cited above, § 72).

Nonetheless, certain factors have been considered relevant for the assessment of the content of those positive obligations on States. Some factors concern the applicant: the importance of the interest at stake and whether "fundamental values" or "essential aspects" of private life are in issue (*X and Y v. the Netherlands*, 26 March 1985, § 27, Series A no. 91; and *Gaskin v. the United Kingdom*, 7 July 1989, § 49, Series A no. 160); and the impact on an applicant of a discordance between the social reality and the law, the coherence of the administrative and

legal practices within the domestic system being regarded as an important factor in the assessment carried out under Article 8 (B. v. France, 25 March 1992, § 63, Series A no. 232 C; and Christine Goodwin v. the United Kingdom [GC], cited above, §§ 77-78). Some factors concern the position of the State: whether the alleged obligation is narrow and defined or broad and indeterminate (Botta v. Italy, 24 February 1998, § 35, Reports of Judgments and Decisions 1998 I); and the extent of any burden the obligation would impose on the State (Rees v. the United Kingdom, 17 October 1986, §§ 43-44, Series A no. 106; Christine Goodwin v. the United Kingdom [GC], cited above, §§ 86-88).

249. As in the negative obligation context, the State enjoys a certain margin of appreciation (see, among other authorities, Keegan v. Ireland, judgment of 26 May 1994, Series A no. 290, § 49). While a broad margin of appreciation is accorded to the State as to the decision about the circumstances in which an abortion will be permitted in a State (paragraphs 231-238 above), once that decision is taken the legal framework devised for this purpose should be “shaped in a coherent manner which allows the different legitimate interests involved to be taken into account adequately and in accordance with the obligations deriving from the Convention” (S.H. and Others v. Austria, no. 57813/00, § 74, 1 April 2010).

(c) Application of the general principles to the third applicant’s case

250. The third applicant had a rare form of cancer. When she discovered she was pregnant she feared for her life as she believed that her pregnancy increased the risk of her cancer returning and that she would not obtain treatment for that cancer in Ireland while pregnant (see paragraph 125 above). The Court considers that the establishment of any such relevant risk to her life caused by her pregnancy clearly concerned fundamental values and essential aspects of her right to respect for her private life (X and Y v. the Netherlands, 26 March 1985, cited above, § 27 and paragraph 248 above). Contrary to the Government’s submissions, it is not necessary for the applicant to further substantiate the alleged medical risk, her complaint concerning as it did the absence of any effective domestic procedure for establishing that risk.

251. The Government maintained that effective and accessible procedures existed whereby a woman could establish her entitlement to a lawful abortion in Ireland.

252. In the first place, the Court has examined the only non-judicial means on which the Government relied namely, the ordinary medical consultation process between a woman and her doctor.

253. However, the Court has a number of concerns as to the effectiveness of this consultation procedure as a means of establishing the third applicant's qualification for a lawful abortion in Ireland.

It is first noted that the ground upon which a woman can seek a lawful abortion in Ireland is expressed in broad terms: Article 40.3.3, as interpreted by the Supreme Court in the X case, provides that an abortion is available in Ireland if it is established as a matter of probability that there is a real and substantial risk to the life, as distinct from the health, of the mother, including a risk of self harm, which can only be avoided by a termination of the pregnancy (the X case, cited at paragraphs 39-44 above). While a constitutional provision of this scope is not unusual, no criteria or procedures have been subsequently laid down in Irish law, whether in legislation, case law or otherwise, by which that risk is to be measured or determined, leading to uncertainty as to its precise application. Indeed, while this constitutional provision (as interpreted by the Supreme Court in the X case) qualified sections 58 and 59 of the earlier 1861 Act (see paragraph 145 above), those sections have never been amended so that, on their face, they remain in force with their absolute prohibition on abortion and associated serious criminal offences thereby contributing to the lack of certainty for a woman seeking a lawful abortion in Ireland.

Moreover, whether or not the broad right to a lawful abortion in Ireland for which Article 40.3.3 provides could be clarified by Irish professional medical guidelines as suggested by the Government (and see the High Court judgment in MR v. TR and Others, at paragraph 97 above), the guidelines do not in any event provide any relevant precision as to the criteria by which a doctor is to assess that risk. The Court cannot accept the Government's argument that the oral submissions to the Committee on the Constitution, and still less obstetric guidelines on ectopic pregnancies from another State, could constitute relevant clarification of Irish law. In any event, the three conditions noted in those oral submissions as accepted conditions requiring medical intervention to save a woman's life (pre-eclampsia, cancer of the cervix and ectopic pregnancies) were not pertinent to the third applicant's case.

Furthermore, there is no framework whereby any difference of opinion between the woman and her doctor or between different doctors consulted, or whereby an understandable hesitancy on the part of a woman or doctor, could be examined and resolved through a decision which would establish as a matter of law whether a particular case presented a qualifying risk to a woman's life such that a lawful abortion might be performed.

254. Against this background of substantial uncertainty, the Court considers it evident that the criminal provisions of the 1861 Act would constitute a significant chilling factor for both women and doctors in the medical consultation process, regardless of whether or not prosecutions have in fact been pursued under that Act. Both the third applicant and any doctor ran a risk of a serious criminal conviction and imprisonment in the event that a decision taken in medical consultation, that the woman was entitled to an abortion in Ireland given the risk to her life, was later found not to accord with Article 40.3.3 of the Constitution. Doctors also risked professional disciplinary proceedings and serious sanctions. The Government have not indicated whether disciplinary action has ever been taken against a doctor in this regard. The Review Group Report 1996, the Green Paper 1999 and the Fifth Progress Report on Abortion 2000 each expressed concerns about the lack of legal protection for medical personnel. As to the Government's reliance on the C case, doctors consulted by women such as the third applicant were not in the same legal situation as those in the C case who were providing opinions as regards a rape victim who was a suicide risk, a situation falling clearly within the ambit of the X case.

255. Accordingly, and referring also to McCarthy J.'s judgment in the X case (paragraph 44 above), the Court does not consider that the normal process of medical consultation could be considered an effective means of determining whether an abortion may be lawfully performed in Ireland on the ground of a risk to life.

256. Secondly, the Government argued that her interests would be protected by the availability of judicial proceedings, submitting also that the third applicant had failed to exhaust domestic remedies, an argument which was joined to the merits of the present complaint (paragraph 155 above). They maintained that she could have initiated a constitutional action to determine her qualification for a lawful abortion in Ireland, in which action she could have obtained mandatory orders requiring doctors to terminate her pregnancy. In so far as she argued that the 1861 Act deterred doctors, she could also have established in such an action whether the 1861 Act interfered with her constitutional right in which case she could have obtained an order setting aside the offending provisions of the 1861 Act.

257. However, the Court does not consider that this action would be an effective means of protecting the third applicant's right to respect for her private life for the following reasons.

258. The Court does not consider that the constitutional courts are the appropriate fora for the primary determination as to whether a woman qualifies for an abortion which is lawfully available in a State. In particular, this process would amount to requiring the constitutional courts to set down on a case by case basis the legal criteria by which the relevant risk to a woman's life would be measured and, further, to resolve through evidence, largely of a medical nature, whether a woman had established that qualifying risk. However, the constitutional courts themselves have underlined that this should not be their role. Contrary to the Government's submission, McCarthy J. in the X case clearly referred to prior judicial expressions of regret that Article 40.3.3 had not been implemented by legislation and went on to state that, while the want of that legislation would not inhibit the courts from exercising their functions, it was reasonable to find that, when enacting that Amendment, the people were entitled to believe that legislation would be introduced so as to regulate the manner in which the right to life of the unborn and the right to life of the mother could be reconciled. In the view of McCarthy J., the failure to legislate was no longer just unfortunate, but it was "inexcusable" (paragraph 44 above). The High Court in the "C" case (paragraphs 95-96 above) referred to the same issue more succinctly, finding that it would be wrong to turn the High Court into a "licensing authority" for abortions.

259. In addition, it would be equally inappropriate to require women to take on such complex constitutional proceedings when their underlying constitutional right to an abortion in the case of a qualifying risk to life was not disputable (the Green Paper 1999, paragraph 68 above). The D v. Ireland decision is distinguishable for the reasons set out at paragraph 148 above and, notably, because D's constitutional right to an abortion in Ireland in the case of a fatal foetal abnormality was an open question.

260. Furthermore, it is not clear how the courts would enforce a mandatory order requiring doctors to carry out an abortion. The Government's statistical material provided in response to the Court's question (paragraph 189 above) concerned public acute hospitals and ectopic pregnancies only and thereby revealed a lack of knowledge on the part of the State as to, inter alia, who carries out lawful abortions in Ireland and where. It is also not clear on what basis a declaration of unconstitutionality of the provisions of the 1861 Act could have been made since those provisions have been already qualified by Article 40.3.3 and since the third applicant did not seek a right to abortion extending beyond the parameters of that Article.

261. Thirdly, the Court's findings as regards the 2003 Act outlined at paragraph 150 above are equally applicable to the third applicant. In addition, since her complaint does not concern a lack of information but rather the lack of a decision-making process, it is not necessary to examine whether she had any remedy to exhaust in this regard, in particular, in respect of the 1995 Act.

262. The above-noted factors distinguish the Whiteside decision on which the Government relied to suggest that the positive obligation could be fulfilled by litigation as opposed to legislation.

263. Consequently, the Court considers that neither the medical consultation nor litigation options relied on by the Government constituted effective and accessible procedures which allowed the third applicant to establish her right to a lawful abortion in Ireland. The Court is not, therefore, required to address the parties' additional submissions concerning the timing, speed, costs and confidentiality of such domestic proceedings.

264. The Court considers that the uncertainty generated by the lack of legislative implementation of Article 40.3.3, and more particularly by the lack of effective and accessible procedures to establish a right to an abortion under that provision, has resulted in a striking discordance between the theoretical right to a lawful abortion in Ireland on grounds of a relevant risk to a woman's life and the reality of its practical implementation (*Christine Goodwin v. the United Kingdom* [GC], cited above, at §§ 77-78; and *S. H. and Others v. Austria*, cited above, at § 74. See also the Commissioner for Human Rights, paragraph 110 above).

265. Moreover, the Government have not explained the failure to implement Article 40.3.3 and no convincing explanations can be discerned from the reports following the recent public reflection processes. The Review Group Report 1996 found the substantive law on abortion in Ireland to be unclear and recommended the adoption of legislation regulating the application of Article 40.3.3, by including a certification process by medical specialists and a time-limit for any certified termination in the case of an abortion considered lawful under Article 40.3.3. In discussing the option of such implementing legislation, the Green Paper 1999 noted that this would have several advantages: it would provide a "framework within which the need for an abortion could be assessed, rather than resolving the question on a case-by-case basis before the courts, with all the attendant publicity and debate"; it would allow "pregnant women who establish that there is a real and substantial risk to their life to have an

abortion in Ireland rather than travelling out of the jurisdiction”; and it would provide legal protection for medical and other personnel involved in a procedure to terminate the pregnancy in Ireland. The political assessment of that Paper by the Committee on the Constitution led to the Fifth Progress Report which found that clarity in legal provisions was essential for the guidance of the medical profession so that any legal framework should ensure that doctors could carry out best medical practice in saving the life of the mother.

Despite therefore the recognition by those bodies that further legal clarity was required as regards lawful abortions in Ireland, no agreement was reached on any reform proposals, no legislation and/or constitutional referenda were proposed and the Government confirmed to the Court that no legislative reform was envisaged.

266. As to the burden which implementation of Article 40.3.3 would impose on the State, the Court accepts that this would be a sensitive and complex task. However, while it is not for this Court to indicate the most appropriate means for the State to comply with its positive obligations (*Marckx v. Belgium* judgment, § 58; *Airey v. Ireland* judgment, § 26; and *B. v. France*, § 63, all cited above), the Court notes that legislation in many Contracting States has specified the conditions governing access to a lawful abortion and put in place various implementing procedural and institutional procedures (*Tysi c v. Poland* judgment, § 123). Equally, implementation could not be considered to involve significant detriment to the Irish public since it would amount to rendering effective a right already accorded, after referendum, by Article 40.3.3 of the Constitution.

(d) The Court’s conclusion as regards the third applicant

267. In such circumstances, the Court rejects the Government’s argument that the third applicant failed to exhaust domestic remedies. It also concludes that the authorities failed to comply with their positive obligation to secure to the third applicant effective respect for her private life by reason of the absence of any implementing legislative or regulatory regime providing an accessible and effective procedure by which the third applicant could have established whether she qualified for a lawful abortion in Ireland in accordance with Article 40.3.3 of the Constitution.

268. Accordingly, the Court finds that there has been a violation of Article 8 of the Convention.

III. ALLEGED VIOLATION OF ARTICLE 14 IN CONJUNCTION WITH ARTICLE 8 OF THE CONVENTION

269. The applicants also complained that the above-described restrictions and limitations on lawful abortion in Ireland were discriminatory and in breach of Article 14 in conjunction with Article 8 in that they placed an excessive burden on them as women and, in particular, on the first applicant as an impoverished woman. The Government argued that there was no basis for considering that the impugned legal framework discriminated against women on grounds of sex. Even if it did constitute a difference of treatment on that ground, it was justifiable and proportionate for the reasons referred to under Article 8 of the Convention. That the first applicant would have been adversely affected by virtue of her financial status was insufficient to ground a complaint under Article 14 of the Convention.

270. Having regard to the parties' submissions under Article 8 and to the reasons for its conclusions thereunder, the Court does not consider it necessary to examine the applicants' complaints separately under Article 14 of the Convention (*Open Door*, at § 83; and *Tysi c v. Poland* judgment, at § 144, both cited above).

IV. ALLEGED VIOLATION OF ARTICLE 13, IN CONJUNCTION WITH ARTICLES 8 AND 14 OF THE CONVENTION

271. The applicants also complained under Article 13, arguing that they had no effective domestic remedy as regards their complaints under Articles 8 and 14 of the Convention. The Government maintained that they had effective remedies available to them.

272. The Court recalls that Article 13 applies where an individual has an "arguable claim" that he or she has been the victim of a violation of a Convention right (*Boyle and Rice v. the United Kingdom*, cited above) and that complaints declared admissible, in the present case Articles 8 and 14, are considered "arguable".

273. The first and second applicants challenged the restrictions on abortion in Ireland, contained in the relevant provisions of the 1861 Act as qualified by Article 40.3.3. However, the Court recalls that Article 13 does not go so far as to guarantee a remedy allowing a Contracting State's primary legislation, let alone provisions of its Constitution, to be challenged before a national authority on grounds that it is contrary to the Convention (*James and Others v. the United Kingdom*, 21 February 1986, § 85, Series A no. 98; and *A. v. the United Kingdom*, no. 35373/97, § 112, ECHR 2002 X).

274. The third applicant's fundamental concern was the lack of implementation of Article 40.3.3 of the Constitution and therefore the lack of accessible and effective procedures in Ireland to allow her to establish her qualification for a lawful abortion in Ireland. Having regard to the overlap of this complaint and matters examined and found to violate Article 8 of the Convention, the Court finds that no separate issue arises under Article 13 of the Convention as regards the third applicant (*Tysi c v. Poland* judgment, § 135).

V. APPLICATION OF ARTICLE 41 OF THE CONVENTION

275. Article 41 of the Convention provides:

“If the Court finds that there has been a violation of the Convention or the Protocols thereto, and if the internal law of the High Contracting Party concerned allows only partial reparation to be made, the Court shall, if necessary, afford just satisfaction to the injured party.”

A. Damage

276. The third applicant claimed pecuniary damages as regards the costs of her abortion in England in the sum of EUR 1500, as she would not be eligible for reimbursement from the Irish State. She also claimed EUR 40,000 in non-pecuniary damages as regards the threat to her life, health and well-being and for the stigma, humiliation, harm and distress caused to her, which is continuing.

277. The Court has found that the failure by the State to implement Article 40.3.3 constituted a failure to respect the third applicant's right to respect for her private life in violation of Article 8 of the Convention.

However, the Court does not consider that there is an established causal link between the violation found and the third applicant's claim for pecuniary and non-pecuniary damage regarding her travel for an abortion to England. While it may be that the third applicant preferred the certainty of abortion services abroad to the uncertainty of a theoretical right to abortion in Ireland (paragraph 125 above), the Court cannot speculate on whether she would have qualified or not for an abortion in Ireland had she had access to the relevant regulatory procedures. It notes, in particular, the lack of any medical documentation submitted to the Court as regards her condition or its consequences, a point emphasised by the Government. Nor is it possible to speculate as to what the third applicant would have done had she not so qualified. It notes in this respect her submissions, albeit not developed, as to her concern

about the impact on the foetus of prior tests for cancer undertaken by her (*Tysiąg v. Poland* judgment, § 151)).

278. Consequently, the Court rejects the third applicant's claim for just satisfaction in so far as it is linked to her travelling abroad for an abortion.

279. However, the Court considers it evident that the lack of an effective procedure, which meant that she could not effectively determine her right to a lawful abortion in Ireland, caused considerable anxiety and suffering to the applicant, confronted as she was with a fear that her life was threatened by her pregnancy and an uncertain legal position, set against the highly sensitive backdrop of the abortion issue in Ireland. The Court considers that the damage suffered by the third applicant could not be satisfied by a mere finding of a violation of the Convention. Having regard to the circumstances of the case seen as a whole and deciding on equitable basis, the Court awards the third applicant EUR 15,000 in respect of non pecuniary damage, plus any tax that may be chargeable.

B. Costs and expenses

280. A global figure of EUR 50,000 was claimed as regards the costs and expenses of representation of all three applicants.

281. The Court reiterates that only legal costs and expenses found to have been actually and necessarily incurred and which are reasonable as to quantum are recoverable under Article 41 of the Convention (see, among other authorities, *Nikolova v. Bulgaria* [GC], no. 31195/96, 25 March 1999, § 79, and *Smith and Grady v. the United Kingdom* (just satisfaction), nos. 33985/96 and 33986/96, § 28, ECHR 2000 IX). In accordance with Rule 60 § 2 of the Rules of Court, itemised particulars of all claims must be submitted, failing which the Court may reject the claim in whole or in part (*Carabulea v. Romania*, no. 45661/99, § 179, 13 July 2010).

282. The Court notes that the fees are claimed in a global sum for all three applicants. In addition, no breakdown, of the costs referable to each applicant or of the tasks carried out for each, was submitted and no bills or vouchers were provided to support the amount claimed.

283. In such circumstances, the Court dismisses the applicant's claim under this head (see, for example, *Cudak v. Lithuania* [GC], no. 15869/02, § 82, ECHR 2010 ...).

C. Default interest

284. The Court considers it appropriate that the default interest should be based on the marginal lending rate of the European Central Bank, to which should be added three percentage points.

4.2.4. The Court's decision

1. Dismisses unanimously the Government's objection as to a failure to exhaust domestic remedies as regards the first and second applicants and joins this objection to the merits of the third applicant's complaint under Article 8⁴² of the Convention;
2. Declares unanimously the applicants' complaints concerning abortion laws in Ireland under Articles 8⁴², 13⁴³ and 14⁴⁴ admissible;
3. Declares by a majority the remainder of the application inadmissible;
4. Holds by eleven votes to six that there has been no violation of Article 8⁴² of the Convention, or of Article 13⁴³ taken in conjunction with Article 8, as regards the first and second applicants;
5. Holds unanimously that there has been a violation of Article 8⁴² of the Convention, and that no separate issue arises under Article 13 taken in conjunction with Article 8, as regards the third applicant;
6. Holds unanimously that no separate issue arises under Article 14⁴⁴ of the Convention in conjunction with Article 8 as regards all applicants;

7. Holds unanimously

(a) that the respondent State is to pay the third applicant, within three months, EUR 15,000 (fifteen thousand euros) in respect of non-pecuniary damage, plus any tax that may be chargeable;

(b) that from the expiry of the above-mentioned three months until settlement simple interest shall be payable on the above amounts at a rate equal to the marginal lending rate of the European Central Bank during the default period plus three percentage points;

8. Dismisses unanimously the remainder of the claims for just satisfaction.

4.3. D. v Ireland²⁰

4.3.1. The Facts

1. The applicant, D, is an Irish national who was born in 1961 and lives in Ireland. She is represented before the Court by Ms B. Hewson, a barrister practising in London. The Irish Government (“the Government”) are represented by their Agent, Ms P. O’Brien. At the oral hearing on 6 September 2005 the applicant was further represented by Mr M Forde S.C., counsel, and by Mr A. Qureshi, Adviser. The respondent Government were additionally represented by Mr B. McMahon, Co-Agent, by Mr D. O’Donnell, S.C. and Ms E. Barrington, B.L., both counsel and by Messrs C. O’Rourke and L. McCormack, Advisers.

A. The circumstances of the case

²⁰ The European Court of Human Rights (Fourth Section), sitting on 6 September 2005 and 27 June 2006; Application no. 26499/02; D. v Ireland

2. The facts of the case, as submitted by the parties, may be summarised as follows.

3. The applicant has two children and attended the same family doctor for all her pregnancies. In late 2001 she became pregnant with twins by her current partner. She received antenatal care as a private patient in Hospital A where she expected to give birth and under the care of a consultant obstetrician (Doctor X). On 7 January 2002 an amniocentesis was performed in Hospital B, the 14th week of pregnancy being the optimal time in terms of reducing risk to the foetus and obtaining reliable test results. On that day and following an ultrasound, she was informed that one foetus had “stopped developing” at 8 weeks gestation. The full results, communicated to Hospital B on 23 January 2002 (the applicant’s 17th week of pregnancy), confirmed that the second foetus had a severe chromosomal abnormality (Trisomy 18, known as Edward’s Syndrome). The clinical outcome of this condition is described, in a report submitted by the Government (and adopted by the applicant), as “a lethal genetic condition” and it is confirmed that “those affected will die from the condition” and that “the median survival age is approximately 6 days”. While there were rare reports of those surviving beyond one year, the report indicated this was “the exception rather than the rule”. Doctor Y in Hospital B gave the applicant the results on 24 January 2002 and explained the diagnosis (fatal). He also arranged for a further sample to be sent for a second test: on 25 January 2002 the second amniocentesis confirmed the diagnosis.

4. The applicant was devastated by the loss of her twins and dismayed by the prospect of carrying the pregnancy to term. She felt unable to tolerate the physical and mental toll of a further five months of pregnancy with one foetus dead and with the other dying. She did not consider any legal proceedings in Ireland at that point, but rather made arrangements to travel to the United Kingdom (“UK”) for an abortion. She felt unable to inform her family doctor and submitted that her health insurance did not cover the abortion costs. While she explained her wish to terminate the pregnancy to Doctors X and Y, they were “very guarded” in their responses indicating that they “appreciated that she was not eligible for an abortion in Ireland”. Hospital B “thought that she could not take her notes with her if she travelled abroad”. She did not clarify whether she brought a copy of her file and medical records to the UK or who made the appointment for her but confirmed that she had been “unable to obtain a referral”.

5. At that stage, the proposed Twenty-fifth Amendment of the Constitution was due to be voted upon in a referendum fixed for 6 March 2002 (see paragraphs 43-45 below).

6. On 28 January 2002 the applicant travelled to the UK. She did not say who made the appointment for her but indicated that she was relieved to see she was expected when she arrived at the relevant hospital in the UK. She was given an information booklet she found useful and consulted with a doctor. On 30 January 2002 the abortion was performed. The applicant chose the medical induction option (leading to 24 hours labour) as she felt it was the option most respectful of the second foetus. She felt that there was a culture of concern in this hospital which she found re-assuring. She did not have time to remain in the UK to have counselling on the genetic implications for future pregnancies, although she was given some statistical information about the recurrence of this abnormality. She transported the foetus to Ireland for a discrete burial by a sympathetic minister.

7. The applicant submitted that, when she discussed this experience with her consultant (Doctor X), he advised her to get over it and that, when she confided in a replacement doctor, the latter gave her a sympathetic nod but no counselling. A close friend who was also a doctor offered to prescribe anti-depressants. Further to complications following the abortion, the applicant attended at a hospital in Ireland in February 2002 (for a procedure known as dilation and curettage of the womb): she felt unable to explain to that hospital or to her family doctor that she had had an abortion so she said that she had had a miscarriage.

8. The applicant submitted that, as a result of the strain, she and her partner separated; she stopped working and re-studied; she took grief counselling, acupuncture, a holiday and genetic counselling. While Doctor X referred her to a psychiatrist in early 2003, she did not continue after the first visit for costs reasons and since “she had moved on”.

B. Relevant domestic law and practice

1. The legal position prior to the Eighth Amendment of the Constitution

9. Article 40.3 of the Constitution stated as follows:

“1 The State guarantees in its laws to respect and, as far as practicable, by its laws to defend and vindicate the personal rights of the citizen.

2 The State shall, in particular, by its laws protect as best it may from unjust attack and, in the case of injustice done, vindicate the life, person, good name and property rights of every citizen.”

10. The courts' judgments in certain cases relied upon these and other Articles of the Constitution to recognise the right to life of the unborn and to suggest that the Constitution implicitly prohibited abortion (McGee v. Attorney General [1974] IR 284; G v. An Bord Uchtála [1980] IR 32; Finn v. Attorney General [1983] I.R. 154 and Norris v. Attorney General [1984] IR 36).

11. Section 58 of the Offences Against the Person Act 1861 ("the 1861 Act") provides that:

"Every woman, being with child, who, with intent to procure her own miscarriage, shall unlawfully administer to herself any poison or other noxious thing or shall unlawfully use any instrument or other means whatsoever with the like intent, and whosoever, with intent to procure the miscarriage of any woman, whether she be or not be with child, shall unlawfully administer to her or cause to be taken by her any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, shall be guilty of a felony ..."

Section 59 of the 1861 Act states that:

"Whoever shall unlawfully supply or procure any poison or other noxious thing, or any instrument or thing whatsoever, knowing that the same is intended to be unlawfully used or employed with intent to procure the miscarriage of any woman, whether she be or be not with child, shall be guilty of a misdemeanour ..."

Section 58 of the Civil Liability Act 1961 provides that:

"The law relating to wrongs shall apply to an unborn child for his protection in like manner as if the child were born, provided the child is subsequently born alive".

12. Section 10 of the Health (Family Planning) Act 1979 re-affirms the statutory prohibition of abortion and states as follows:

"Nothing in this Act shall be construed as authorising -

(a) the procuring of abortion,

(b) the doing of any other thing the doing of which is prohibited by section 58 or 59 of the Offences Against the Person Act, 1861 (which sections prohibit the administering of drugs or the use of any instruments to procure abortion)

or,

(c) the sale, importation into the State, manufacture, advertising or display of abortifacients.”

The meaning of section 58 of the 1861 Act was considered in England and Wales in the case of *R-v- Bourne* [1939] 1 KB 687. This case involved a fourteen-year-old girl who had become pregnant as a result of multiple rape. An abortion was carried out by Dr. Bourne, who was then tried under the section. In his ruling, Macnaghten J. accepted that abortion to preserve the life of a pregnant woman was not unlawful and, further, where a doctor was of the opinion that the probable consequence of a pregnancy was to render a woman a mental and physical wreck, he could properly be said to be operating for the purpose of preserving the life of the mother.

The Abortion Act 1967 (as amended) now supercedes the Bourne case in England and Wales. The 1967 Act permits the termination of pregnancy on one or more of the following grounds:

A. the continuance of the pregnancy would involve risk to the life of the pregnant woman greater than if the pregnancy was terminated;

B. the termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman;

C. the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman;

D. the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of any existing child(ren) of the family of the pregnant woman;

E. there is a substantial risk that if a child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped

or, in emergency, certified by the operating practitioner as immediately necessary

F. to save the life of the pregnant woman; or

G. to prevent grave permanent injury to the physical or mental health of the pregnant woman.

No time-limit attaches to grounds A, B and E, but there is a time-limit of 24 weeks for abortions under grounds C and D.

13. The Abortion Act 1967 Act does not apply in Northern Ireland whose courts have applied the Bourne principles to interpret section 58 and 59 of the 1861 Act so as to find lawful abortions performed on minors or mentally disabled adults (Re. F, unreported judgment of the High Court (Sheil J.) of 14 October 1993, Re. A.M.N.H, unreported judgment of the High Court (Mac Dermott L.J.) of 21 January 1994, Re S.J.B. unreported judgment of the High Court (Pringle J.) of 28 September 1995 and Re C.H. unreported judgment of the High Court (Sheil J.) of 19 October 1995).

14. No Irish court had relied on the above-cited Bourne judgment. In the case of the Society for the Protection of the Unborn Child v. Grogan and Others (Unreported judgment of 6 March 1997) Keane J. maintained that “the preponderance of judicial opinion in this country would suggest that the Bourne approach could not have been adopted ... consistently with the Constitution prior to the Eighth Amendment”.

2. The Eighth Amendment of the Constitution

15. Since the early 1980s some concern was expressed about the adequacy of existing provisions concerning abortion and the possibility of abortion being deemed lawful by judicial interpretation. There was some debate as to whether the Supreme Court would follow the course adopted in *Roe v. Wade* 410 US 113 (1973) of in the above-cited *R v. Bourne* case.

16. A referendum was held in 1983 resulting in the adoption of a provision which became Article 40.3.3 of the Irish Constitution, the Eighth Amendment (53.67% of the electorate voted with 841,233 votes in favour and 416,136 against). This Article reads as follows:

“The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.”

This is a self-executing provision of the Constitution not requiring legislation to give it effect.

3. Relevant case-law thereafter and the Thirteenth and Fourteenth Amendments

17. A number of cases then came before the courts concerning the interpretation of the Eighth Amendment and the provision of information on or referral to abortion services available in other countries.

18. In 1986 the Society for the Protection of the Unborn Child (“SPUC”) obtained an injunction restraining two organisations (Open Door Counselling and the Dublin Well Woman Centre) from furnishing women with information which encouraged or facilitated an abortion. The Supreme Court held (*Attorney General (S.P.U.C.) v. Open Door Counselling* [1988] I.R. 593) that it was unlawful to disseminate information, including the address and telephone number of foreign abortion services, which had the effect of facilitating the commission of an abortion (see also, *S.P.U.C. (Ireland) v. Grogan and Others* [1989] I.R. 753). These two organisations complained to this Court about restraints on their freedom to impart and receive information. A violation of Article 10 of the Convention was established (*Open Door and Dublin Well Woman v. Ireland*, judgment of 29 October 1992, Series A no. 246 A) which led (see Committee Of Ministers resolution DH(96) 368) to the entry into force of The Regulation of Information (Services outside the State for Termination of Pregnancies) Act 1995 (“the 1995 Act” – paragraphs 24-31 below).

19. The interpretation of the Eighth Amendment was further considered in the landmark case of *Attorney General v. X* ([1992] 1 IR 1). X was a fourteen-year-old girl who became pregnant as a result of rape. Her parents took her to the UK for an abortion and then raised with the Irish police the question of having scientific tests carried out on retrieved foetal tissue with a view to determining paternity. The Director of Public Prosecutions was consulted who, in turn, informed the Attorney General. On 7 February 1992 an interim injunction was applied for by the Attorney General. It was obtained on an ex parte basis to restrain X from leaving the jurisdiction or from arranging or carrying out a termination of the pregnancy. X and her parents returned from the UK to contest the injunctions. The State undertook to pay the costs of the defendant minor, irrespective of the result. On 17 February 1992 the High Court granted an interlocutory injunction in essentially the same terms. On 26 February 1992, on appeal, a majority (4 to 1) of the Supreme Court discharged the injunctions.

The Supreme Court held that, if it were established as a matter of probability, that there was a real and substantial risk to the life, as distinct from the health, of the mother and that this real and substantial risk could only be averted by the termination of her pregnancy, such a termination was lawful. The Supreme Court accepted the evidence that had been adduced in the High Court that the girl had threatened to commit suicide if compelled to carry her child to full term and deemed this threat of suicide to constitute a real and substantial risk to the life of the mother.

20. Prior to interpreting the Eighth Amendment, the Chief Justice noted that no interpretation of the Constitution was intended to be final for all time (citing *McGee v. the Attorney General* [1974] IR 284), which statement was “peculiarly appropriate and illuminating in the interpretation of [the Eighth Amendment] which deals with the intimate human problem of the right of the unborn to life and its relationship to the right of the mother of an unborn child to her life.” He went on:

“36. Such a harmonious interpretation of the Constitution carried out in accordance with concepts of prudence, justice and charity, ... leads me to the conclusion that in vindicating and defending as far as practicable the right of the unborn to life but at the same time giving due regard to the right of the mother to life, the Court must, amongst the matters to be so regarded, concern itself with the position of the mother within a family group, with persons on whom she is dependent, with, in other instances, persons who are dependent upon her and her interaction with other citizens and members of society in the areas in which her activities occur. Having regard to that conclusion, I am satisfied that the test proposed on behalf of the Attorney General that the life of the unborn could only be terminated if it were established that an inevitable or immediate risk to the life of the mother existed, for the avoidance of which a termination of the pregnancy was necessary, insufficiently vindicates the mother’s right to life.

37. I, therefore, conclude that the proper test to be applied is that if it is established as a matter of probability that there is a real and substantial risk to the life, as distinct from the health, of the mother, which can only be avoided by the termination of her pregnancy, such termination is permissible, having regard to the true interpretation of Article [40.3.3] of the Constitution.

Considering that a suicide risk had to be taken into account in reconciling the right to life of the mother and the unborn, the Chief Justice continued:

“44. I am, therefore, satisfied that on the evidence before the learned trial judge, which was in no way contested, and on the findings which he has made, that the defendants have satisfied the test which I have laid down as being appropriate and have established, as a matter of probability, that there is a real and substantial risk to the life of the mother by self-destruction which can only be avoided by termination of her pregnancy.

45. It is for this reason that, in my view, the defendants were entitled to succeed in this appeal, and the orders made in the High Court have been set aside.”

Similar judgments on the substantive issue were delivered by three other judges. McCarthy J noted that “the right of the girl here is a right to a life in being; the right of the unborn is to a life contingent; contingent on survival in the womb until successful delivery”. He went on:

141. In my judgment, ... It is not a question of balancing the life of the unborn against the life of the mother; if it were, the life of the unborn would virtually always have to be preserved, since the termination of pregnancy means the death of the unborn; there is no certainty, however high the probability, that the mother will die if there is not a termination of pregnancy. In my view, the true construction of the Amendment, bearing in mind the other provisions of Article 40 and the fundamental rights of the family guaranteed by Article 41, is that, paying due regard to the equal right to life of the mother, when there is a real and substantial risk attached to her survival not merely at the time of application but in contemplation at least throughout the pregnancy, then it may not be practicable to vindicate the right to life of the unborn. It is not a question of a risk of a different order of magnitude; it can never be otherwise than a risk of a different order of magnitude.

142. On the facts of the case, which are not in contest, I am wholly satisfied that a real and substantial risk that the girl might take her own life was established; it follows that she should not be prevented from having a medical termination of pregnancy.”

21. Some of the obiter dicta of the majority in the Supreme Court also indicated that the constitutional right to travel could be restrained so as to prevent an abortion taking place in circumstances where there was no threat to the life of the mother: the right to travel simpliciter did not take precedence over the right to life.

22. The decision in the X case gave rise to a number of different questions: the Supreme Court had found that abortion could be lawful under Article 40.3.3 where it was necessary to avert a real and substantial risk to the life of the mother; the possible abuse of a suicide risk as a ground for obtaining an abortion; and the apparent willingness of the Supreme Court to grant injunctions to restrain persons from travelling abroad to abort.

23. A further referendum was therefore called in November 1992. 68.18% of the electorate voted. Three proposals were put forward.

The first proposal related to what was described as the “substantive” issue of the circumstances in which an abortion would be permissible within the State. The following

wording, an addition to Article 40.3.3, was proposed as the Twelfth Amendment of the Constitution but it was rejected (1,079, 297 votes to 572,177):

“It shall be unlawful to terminate the life of an unborn unless such termination is necessary to save the life, as distinct from the health, of the mother where there is an illness or disorder of the mother giving rise to a real and substantial risk to her life, not being a risk of self-destruction”.

The second proposal, an addition to Article 40.3.3, concerned the issue of travelling abroad to obtain an abortion. It was accepted (1,035,308 votes to 624,059) and this Thirteenth Amendment reads as follows:

“This subsection shall not limit freedom to travel between the State and another state”

The third proposal (the Fourteenth Amendment) was also accepted (992,833 votes to 665,106) and it concerns the provision of information and read as follows:

“This subsection shall not limit freedom to obtain or make available, in the State, subject to such conditions as may be laid down by law, information relating to services lawfully available in another State.”

4. The Regulation of Information (Services outside the State for Termination of Pregnancies) Act 1995 (“the 1995 Act”)

24. The 1995 Act defines the conditions under which information relating to abortion services lawfully available in another State might be made available in Ireland.

25. Section 2 defines “Act information” as information that (a) is likely to be required by a woman for the purpose of availing herself of services provided outside the State for the termination of pregnancies; and (b) relates to such services or to persons who provide them. Section 1 confirms that a “person to whom section 5 applies” means a person who engages in, or holds himself, herself or itself out as engaging in, the activity of giving information, advice or counselling to individual members of the public in relation to pregnancy.

26. Section 5 of the Act provides as follows:

“Where a person to whom section 5 applies is requested, by or on behalf of an individual woman who indicates or on whose behalf it is indicated that she is or may be pregnant, to give

information, advice or counselling in relation to her particular circumstances having regard to the fact that it is indicated by her or on her behalf that she is or may be pregnant-

(a) it shall not be lawful for the person or the employer or principal of the person to advocate or promote the termination of pregnancy to the woman or to any person on her behalf,

(b) it shall not be lawful for the person or the employer or principal of the person to give Act information to the woman or to any person on her behalf unless—

(i) the information and the method and manner of its publication are in compliance with subparagraphs (I) and (II) of section 3 (1) (a) and the information is given in a form and manner which do not advocate or promote the termination of pregnancy,

(ii) at the same time, information (other than Act information), counselling and advice are given directly to the woman in relation to all the courses of action that are open to her in relation to her particular circumstances aforesaid, and

(iii) the information, counselling and advice referred to in subparagraph (ii) are truthful and objective, fully inform the woman of all the courses of action that are open to her in relation to her particular circumstances aforesaid and do not advocate or promote, and are not accompanied by any advocacy or promotion of, the termination of pregnancy.”

27. Section 8 of the 1995 Act reads as follows:

“(1) It shall not be lawful for a person to whom section 5 applies or the employer or principal of the person to make an appointment or any other arrangement for or on behalf of a woman with a person who provides services outside the State for the termination of pregnancies.

(2) Nothing in subsection (1) shall be construed as prohibiting the giving to a woman by a person to whom section 5 applies or the employer or principal of the person of any medical, surgical, clinical, social or other like records or notes relating to the woman in the possession of the person or the employer or principal of the person or a copy or copies thereof in written form.”

28. A person breaching sections 5 or 8 is guilty of an offence and is liable, on summary conviction, to a fine not exceeding £1,500. A prosecution may be brought by or with the consent of the Director of Public Prosecutions.

29. Before its enactment, the 1995 Act was referred by the President to the Supreme Court for a review of its constitutionality. The Supreme Court found it to be constitutional (Information (Termination of Pregnancies) Bill [1995] 1 I.R. 1) so that the 1995 Act thereby became immune from future constitutional challenge (Article 34.3.3 of the Constitution).

30. In so concluding, the Supreme Court examined, inter alia, whether the provisions of Articles 5 and 8 were repugnant to the Constitution namely, whether, from an objective point of view, those provisions represented “a fair and reasonable balancing by [Parliament] of the various conflicting rights and was not so contrary to reason and fairness as to constitute an unjust attack on the constitutional rights of the unborn or on the constitutional rights of the mother or any other person or persons.” In this respect, the Supreme Court noted that:

“The [1995 Act] merely deals with information relating to services lawfully available outside the State for the termination of pregnancies and the persons who provide such services.

The condition subject to which such information may be provided to a woman who indicates or on whose behalf it is indicated that she is or may be pregnant is that the person giving such information is

(i) not permitted to advocate or promote the termination of pregnancy to the woman or any person on her behalf;

(ii) not permitted to give the information unless it is given in a form and manner which do not advocate or promote the termination of pregnancy

and is only permitted to give information relating to services which are lawfully available in the other State and to persons, who in providing them are acting lawfully in that place if

(a) the information and the method and manner of its publication are in compliance with the law of that place, and

(b) the information is truthful and objective and does not advocate or promote, and is not accompanied by any advocacy or promotion of the termination of pregnancy.

At the same time information, counselling and advice must be given directly to the woman in relation to all the courses of action that are open to her in relation to her particular circumstances and such information, counselling and advice must not advocate or promote and must not be accompanied by any advocacy or promotion of, the termination of pregnancy.

Subject to such restrictions, all information relating to services lawfully available outside the State and the persons who provide them is available to her.”

31. The Supreme Court went on to point out that:

“It was further submitted that in certain circumstances a woman’s life and/or health may be placed at serious risk in the event that a doctor is unable to send a letter referring her to another doctor for the purposes of having her pregnancy terminated.

This submission is based on a misinterpretation of the provisions of the [1995 Act] and in particular that of Section 8(1).

This section prohibits a doctor or any person to whom Section 5 of the [1995 Act] relates from making an appointment or any other arrangement for or on behalf of a woman with a person who provides services outside the State for the termination of pregnancies.

It does not preclude him, once such appointment is made, from communicating in the normal way with such other doctor with regard to the condition of his patient provided that such communication does not in any way advocate or promote and is not accompanied by any advocacy of the termination of pregnancy.

While a doctor is precluded by the terms of the [1995 Act] from advocating or promoting the termination of pregnancy, he is not in any way precluded from giving full information to a woman with regard to her state of health, the effect of the pregnancy thereon and the consequences to her health and life if the pregnancy continues and leaving to the mother the decision whether in all the circumstances the pregnancy should be terminated. The doctor is not in any way prohibited from giving to his pregnant patient all the information necessary to enable her to make an informed decision provided that he does not advocate or promote the termination of pregnancy.

In addition Section 8(2) does not prohibit or in any way prevent the giving to a woman of any medical, surgical, clinical, social or other like records relating to her.

...

Having regard to the obligation on [parliament] to respect, and so far as practicable, to defend and vindicate the right to life of the unborn having regard to the equal right to life of the mother, the prohibition against the advocacy or promotion of the termination of pregnancy

and the prohibition against any person to whom Section 5 of the Bill applies making an appointment or any other arrangement for and on behalf of a woman with a person who provides services outside the State for the termination of pregnancies does not constitute an unjust attack on the rights of the pregnant woman. These conditions represent a fair and reasonable balancing of the rights involved and consequently Sections 5 and 8 of the Bill are not repugnant to the Constitution on these grounds.”

5. The Constitution Review Group Report 1996

32. Established in April 1995, the Group’s terms of reference were to review the Constitution and to establish those areas where constitutional change might be necessary with a view to assisting the governmental committees in their constitutional review work. In its 1996 report, the Group considered the “substantive” law on abortion in Ireland following the X case and the rejection of the Twelfth Amendment to be unclear (for example, the scope of the admissibility of the suicidal disposition as a ground for abortion and the absence of any statutory time-limit on terminations allowed following the decision in the X case). Although no specific reference to the specific case of lethal foetal abnormality was made, the Group did consider the option of amending Article 40.3.3 so as to legalise abortion in constitutionally defined circumstances, finding in this respect that:

“Although thousands of women go abroad annually for abortions without breach of domestic law, there appears to be strong opposition to any extensive legalisation of abortion in the State. There might be some disposition to concede limited permissibility in extreme cases, such, perhaps, as those of rape, incest or other grave circumstances. On the other hand, particularly difficult problems would be posed for those committed in principle to the preservation of life from its earliest stage.”

33. The Group concluded that, while in principle the major issues discussed should ideally be tackled by constitutional amendment, there was no consensus as to what that amendment should be and no certainty of success for any referendum proposal for substantive constitutional change in relation to Article 40.3.3. The Group therefore considered that the only practical possibility at that time was the introduction of legislation to regulate the application of Article 40.3.3. That legislation would, inter alia, afford express protection for appropriate medical intervention necessary to protect the life of the mother, require written certification by appropriate medical specialists of “real and substantial risk to the life of the

mother” and impose a time-limit to prevent a viable foetus being aborted in circumstances permitted by the X case.

6. A & B v. Eastern Health Board, Mary Fahy, C and the Attorney General (notice party) [1998] 4 I.R. 464 (the “C case”).

34. This case concerned a thirteen-year-old girl (“C”) who became pregnant following a rape. The Eastern Health Board, which had subsequently taken the girl into its care, became aware that she was pregnant and, in accordance with her wishes, obtained a District Court order (21 November 1997) allowing the Health Board to bring her abroad for an abortion and to make all necessary arrangements. C’s parents sought to challenge those orders by judicial review. On 28 November 1997 the High Court accepted that, where evidence had been given to the effect that the pregnant young woman might commit suicide unless allowed to terminate her pregnancy, there was a real and substantial risk to her life and such termination was therefore a permissible medical treatment of her condition where abortion was the only means of avoiding such a risk. An abortion was therefore lawful in Ireland in C’s case and the travel issue became unnecessary to resolve.

However, the High Court indicated that it would have granted the relief sought by the parents to annul the District Court order. The Thirteenth Amendment was framed in negative terms so that one could not be prevented from travelling abroad to have an abortion but the amendment was never intended to give a new substantial right to travel abroad to have an abortion. While the High Court had advised the parties to approach the Supreme Court to facilitate an early appeal and while the Supreme Court cleared its schedule to hear any appeal within days, no appeal was lodged.

7. The Interdepartmental Working Group Green Paper on Abortion, September 1999 (“Green Paper on Abortion”)

35. The introduction noted that:

“The current situation ... is that, constitutionally, termination of pregnancy is not legal in this country unless it meets the conditions laid down by the Supreme Court in the X case; information on abortion services abroad can be provided within the terms of the Regulation of Information (Services outside the State for Termination of Pregnancies) Act, 1995; and, in general, women can travel abroad for an abortion.

There are strong bodies of opinion which express dissatisfaction with the current situation, whether in relation to the permissibility of abortion in the State or to the numbers of women travelling abroad for abortion.

Various options have been proposed to resolve what is termed the “substantive issue” of abortion but there is a wide diversity of views on how to proceed. The Taoiseach indicated shortly after the Government took office in 1997 that it was intended to issue a Green Paper on the subject. The implications of the X case were again brought sharply into focus in November 1997 as a result of the C Case, and a Cabinet Committee was established to oversee the drafting of this Green Paper, the preparatory work on which was carried out by an interdepartmental group of officials.

While the issues surrounding abortion are extremely complex, the objective of this Green Paper is to set out the issues, to provide a brief analysis of them and to consider possible options for the resolution of the problem. The Paper does not attempt to address every single issue in relation to abortion, nor to give an exhaustive analysis of each. Every effort has been made to concentrate on the main issues and to discuss them in a clear, concise and objective way.

Submissions were invited from interested members of the public, professional and voluntary organisations and any other parties who wished to contribute. ...”

36. Chapter 4 of the paper examined those circumstances, other than the suicide risk of the X and C cases, in which other jurisdictions allowed abortion. One of the grounds of abortion examined was a termination following a diagnosis of congenital malformation. The paper noted:

“4.20 A number of submissions seek that abortion be permissible on grounds of foetal impairment in cases of extreme abnormality or where the condition of the foetus is incompatible with life. Many others, however, express strong opposition to any such provision.

4.21 Many countries permit abortion on grounds of foetal impairment. Foetal impairment is sometimes referred to specifically, for example in England and Wales “where there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped”. In other countries there is no specific provision

in this regard. However, in some of these an abortion may be obtained on the grounds of adverse effect on the mother's mental health.

4.22 Congenital malformations/anomalies are a major cause of stillbirth, neonatal death and of physical and mental defects and metabolic disorders. Approximately 2% of new-born infants have a major malformation. The incidence may be as high as 5% if malformations detected later in childhood, including abnormalities of the heart, kidneys, lungs and spine, are included. Malformations are also common among spontaneous abortions.

4.23 There are many causes of congenital malformations. Approximately half are due to genetic abnormalities. In about 40% the cause is unknown and the remaining cases are due to chromosomal abnormalities, teratogens (anything capable of disrupting foetal growth and producing malformation) and other factors. Major malformations are structural abnormalities that have serious medical, surgical or cosmetic consequences. Minor anomalies which have no serious consequences however are common and affect approximately 4% of children. Abnormalities may be inherited (a chromosome defect or a gene flaw) or acquired which means that the embryo was initially normal but was damaged during its development by an injurious agent e.g. drugs, infection, irradiation or maternal metabolic disorder.

4.24 Examples of genetic abnormalities include achondroplasia (a condition causing dwarfism and hydrocephalus), cystic fibrosis and haemophilia. Other malformations include neural tube defects. These are among the more common birth defects. In Western Europe the incidence is approximately 5 per 1,000 births. There is a spectrum of neural tube defects ranging from minor defects to anencephaly. In anencephaly the brain fails to develop and the death rate is 100%, with most infants dying during delivery. Chromosomal defects account for a small percentage of abnormalities (approximately 1%). Down's syndrome is the most common chromosomal abnormality and is responsible for 30% of all cases of severe mental handicap. Its frequency is approximately 1 in every 700 births.

4.25 The identification of pregnancies that are of greater risk is a fundamental concept of antenatal care. This is achieved through a process of history taking, physical examination and screening. The purpose is to detect and treat any condition that puts the mother and baby at risk. Prenatal screening is also used to detect and assess possible congenital malformation. There are a number of prenatal diagnostic tests available. Common indications for prenatal diagnosis are advanced maternal age and a previous child with either Down's Syndrome or neural tube defect. Amniocentesis is frequently used in the detection of these conditions.

Other prenatal diagnostic tests include ultrasound and the use of cellular and biochemical markers to detect potential foetal abnormalities.

4.26 Estimates of the incidence of congenital abnormalities in Europe, which include statistics on induced abortions, suggest that induced abortions as a result of foetal malformations represented 14.8% of all reported congenital abnormalities in 1994. Induced abortions among pre-natally diagnosed cases of malformation were the most frequent in anomalies of the nervous system (anencephaly) and in chromosomal anomalies (Down's syndrome).

4.27 In 1996 in England and Wales a total of 1,929 abortions were carried out under ground E, i.e. where there is substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped. Of these, 882 were terminated because of congenital malformations, 561 were due to chromosomal abnormalities and 486 were due to other conditions. In total they account for slightly more than 1% of all abortions carried out in England and Wales.

4.28 Terminations where a congenital abnormality is suspected are usually performed before 20 weeks gestation with a number of exceptions (usually 24 weeks). Authorisation of abortions on these grounds is usually given by one, two or a panel of doctors. In Belgium and France after the first trimester two doctors must agree that the foetus is believed to be seriously impaired. In Denmark authorisation is made by a committee comprising a social worker and two doctors. In Finland an abortion on grounds of foetal impairment must be authorised by the State Medical Board. In England and Wales, in common with the other statutory grounds under which abortion is available, the abortion must be certified as justifiable by two registered medical practitioners, while in Spain authorisation involves two specialists of an approved public or private health centre neither of whom is the doctor performing the abortion or under whose direction the abortion is to be performed.”

37. Chapter 7 of the paper comprised a discussion of seven possible constitutional and legislative solutions:

- an absolute constitutional ban on abortion;
- an amendment of the Constitution so as to restrict the application of the X case;
- the retention of the current position;

- the retention of the constitutional status quo with a legislative restatement of the prohibition of abortion;
- legislation to regulate abortion as defined in the X case;
- a reversion to the pre-1983 position; and
- permitting abortion beyond the grounds specified in the X case.

38. In this latter respect, and as to the option of permitting abortion in the case of congenital abnormalities, the paper pointed out:

“7.80 This option would permit abortion where a congenital malformation of the foetus had been diagnosed ante-natally.

7.81 The relevant provisions in other countries do not seem to include detailed specification of the conditions covered by such arrangements. Diagnosis that the foetus is impaired and the question of an abortion are matters between the woman and the medical personnel treating her.

7.82 This option is one of the most complex, were it to be considered. It could be expected that the question would arise as to what types of condition would be covered and how it could be ensured that the provisions would not be open to abuse, particularly if a tightly circumscribed arrangement were considered desirable.

7.83 It would not be practical to include in the Constitution a detailed specification of the types of conditions for which abortion would be permissible. It would be difficult even to do so in legislation, given the very lengthy list of conditions which might be involved. The desired parameters of any provision would also need to be considered, for example, would only conditions incompatible with survival after birth be at issue, or would a category such as "severe handicap" be admitted? The discussion in Chapter 4 has already described the difficulty of neatly defining conditions incompatible with life and has shown that there is a wide spectrum of congenital malformations which cause greatly differing degrees of incapacitation or handicap. While pre-natal testing may indicate the likely presence of a handicapping condition, with many conditions the severity of a child's handicap is often apparent only after birth or during the child's developmental period. This could present a difficulty for any arrangement the intention of which was to permit abortion only in circumstances where a severe malformation of the foetus was diagnosed. Indeed, the

difficulty of accurately diagnosing abnormalities in utero could result in the abortion of a foetus which was in fact healthy.

7.84 The chances of a child with some of the conditions considered surviving after birth vary according to the condition involved and the circumstances of each individual case. Therefore it would probably not be practical to have a category of “incompatibility with life”, as the period of survival after birth can vary from nil to some hours, several days, weeks or even months. For example, with anencephaly, where the brain fails to develop, most infants die during delivery but some may survive for a matter of hours. With some of the conditions involving chromosomal defects many children die in the early months of life, but some may live for considerably longer, even into adulthood.

7.85 Where gene defects are concerned, the hereditary nature of the conditions involved means that that chance of the condition being inherited by a carrier’s children may be relatively high and there is a body of opinion which considers that termination should be available where pre-natal testing indicates the presence of the condition in the foetus. A contrary view is that abortion should not be permissible, even in such circumstances.

7.86 The issues identified above would require detailed examination if abortion on grounds of foetal impairment were to be considered. While other countries have legislation permitting abortion in these circumstances, it would appear that they specify in general rather than specific terms what types of condition are covered.”

8. The Oireachtas Committee on the Constitution

39. The Green Paper was then referred by the Government to the Oireachtas Committee on the Constitution for consideration. The Committee embarked on a detailed process of consultation, first seeking submissions on the options discussed in the Green Paper. Over 100,000 submissions were received from individuals and organisations. Subsequently, hearings were held at which the issues were explored in detail with many of those who had made submissions.

40. The Oireachtas Committee met representatives of the medical profession including from the “Masters” of the three major obstetric hospitals in Dublin (where 40% of Irish births take place). All three spoke in favour of permitting in Ireland termination of pregnancy in cases of foetal abnormality (including neural tube defects - Ireland having the second highest rate in the world - and anencephaly) where the foetus would not survive to term or live outside the

womb. Certain of the Masters noted that going abroad deprived a mother of a post-mortem on an aborted foetus and of full and proper advice and counselling on the source of the abnormality and the risk of recurrence in a future pregnancy and criticised the lack of ability to make any referral to a hospital providing the termination service or to make any arrangement for this to take place and for follow-up.

41. In its Fifth Progress Report published on 15 November 2000, the Committee agreed that a specific agency should be put in place to implement a strategy to reduce the number of crisis pregnancies by the provision of preventative services, to reduce the number of women with crisis pregnancies who opt for abortion by offering services which make other options more attractive and to provide post-abortion services consisting of counselling and medical check-ups. There was agreement on other matters including on the need for the Government to prepare a public memorandum outlining the State's precise responsibilities under all relevant international and European Union instruments.

42. The Committee agreed that clarity in legal provisions was essential for the guidance of the medical profession so that any legal framework should ensure that doctors could carry out best medical practice necessary to save the life of the mother. However, the Committee found that none of the seven options canvassed in the Green Paper commanded unanimous support. Three approaches were found to command substantial but not majority support in the Committee: the first approach was to concentrate on the plan to reduce the number of crisis pregnancies and the rate of abortion and to leave the legal position unchanged; the second was to support the plan to reduce the number of crisis pregnancies, accompanied by legislation which would protect medical intervention to safeguard the life of the mother, within the existing constitutional framework; and the third was to support the plan to reduce the number of crisis pregnancies, to legislate to protect best medical practice while providing for a prohibition on abortion, and consequently to accommodate such legislation by referendum to amend the Constitution. However, the Committee did not reach agreement on a single course of reform action.

9. The proposed Twenty-fifth Amendment to the Constitution

43. In 2002 a third referendum on abortion was called. The objective of the proposed Twenty-fifth Amendment of the Constitution (Protection of Human Life in Pregnancy) Bill was to resolve the legal uncertainty since the X case, by putting this draft legislation to the electorate: it proposed to permit abortions to be lawfully provided in Ireland at specific

institutions but only when, in the opinion of the doctor, it was necessary to prevent a real risk of loss of the woman's life, other than self-destruction. The Bill intended therefore to restrict the rulings in the X and C cases by excluding the risk of suicide as a ground for the lawful termination of a pregnancy.

44. On 27 February 2002 the three Masters referred to above called a press conference urging a vote in favour of the Government's proposal and also stating that the State should sanction abortion in certain cases including when a foetus would not survive outside of the womb.

45. The referendum of March 2002 resulted in the lowest turnout in all three abortion referenda (at 42.89% of the electorate) and the proposal was defeated (50.42% against and 49.58% in favour).

10. Public nature of proceedings: relevant case-law and legal provisions

(a) The Irish Constitution

46. Article 34(1) reads as follows:

“Justice shall be administered in courts established by law by judges appointed in the manner provided by this Constitution, and, save in such special and limited cases as may be prescribed by law, shall be administered in public.”

(b) The Superior Court Rules

47. Order 19, Rules 10 and 11 of the 1962 Rules provided:

“10. Every pleading shall be delivered between parties, and shall, be marked on the face with the date of the day on which it is delivered, the reference to the record number of the action, the Court (if any) to which the action is assigned, the title of the action and the description of the pleading, and shall be endorsed with the name and the registered place of business of the solicitor delivering the same, or the name and address for service of the party delivering the same if he does not act by a solicitor.

11. Copies of all pleadings shall, within two days after the same shall have been so delivered, be left with and filed by the proper officer of the Central Office, and an entry of each pleading shall, upon the same being filed, be entered in the Cause Book.”

48. Order 19, Rules 10 and 11 was replaced in 1986 by Order 19 Rule 11: the provision requiring filing of pleadings in the Central Office was omitted:

“Every pleading shall be delivered between parties, and shall, in addition to the matters specified in Order 121, rule 4, contain reference to the record number of the action, the Court (if any) to which the action is assigned, the title of the action and the description of the pleading.”

(c) Letter of 17 May 2006 from the Courts Service

49. In answer to the Government’s query concerning the confidentiality of court files, the Courts Service described the position as follows:

“- Officials in the Central Office only make files available for inspection to a party or his solicitor. The person requesting the file is required to sign for it in a book retained in the Office for that purpose.

- Files are available to the solicitors on record for each of the parties.

- Files may only be viewed by the parties upon their producing satisfactory evidence of their identity.

- Persons other than the solicitor on record are only allowed to inspect a file upon production of the written consent of one of the solicitors on record or the party if self-represented.

- Files may be viewed by members of the Law Library (barristers) as a precedent for their work, but no photocopying is permitted.

- No person viewing a file has permission to bring it outside the Central Office other than for official purposes e.g. to another Court office or to a Judge in Court.

- Where the President of the High Court or any Judge of the High Court so directs, certain files are retained by the Central Office Registrar in a safe and are not available for inspection.”

50. The letter also approved the brief reference to the Central Office procedures in the case of *Rogers v. Information Commissioner and Others* (2000 96 MCA - see paragraph 55 below).

51. As to the relevant duties of barristers who might ask to consult court files and apart from the requirement to sign for the file any court file requested, section 1(2) of the Code of Conduct for the Bar in Ireland provides as follows:

“It is the duty of a barrister:

(a) to comply with the provisions of the Code;

(b) not to engage in conduct (whether in pursuit of his profession or otherwise) which is dishonest or which may bring the barristers’ profession into disrepute or which is prejudicial to the administration of justice;

(c) to observe the ethics and etiquette of his profession; ...”

52. Section 3(3)(a) of the Code provides:

“It is the essence of a barrister’s function that he should be told by his client things which the client would not tell to others, and that he should be the recipient of other information on a basis of confidence. Confidentiality is therefore a primary and fundamental right and duty of the barrister. The barrister’s obligation of confidentiality serves the interest of the administration of justice as well as the interest of the client. Accordingly subject to the provisions of (d), (e) and (f) herein a barrister is under a duty not to communicate to any third party, information entrusted to him by or on behalf of his client and not to use such information to his client’s detriment or to his own or another client’s advantage. This duty continues at all times after the relation of barrister and client has ceased and after the death of his client and subsists unless he has the consent of his client to make such a communication or it is necessary to make such a communication when answering accusations against him by his client.”

(d) *In Re a Ward of Court* [1996] 2 IR 73

This concerned the “right to die” of persons in a vegetative state. The High Court heard the case in camera and, while the Supreme Court did not, it directed that the parties would not be identified and reserved the right to direct that part of the hearing be held in camera.

(e) *Irish Times Limited and Others v. Murphy*, [1998] 1IR 359

53. The applicants were given leave to apply for an order of certiorari by way of judicial review in respect of a circuit court order restricting press coverage of the prosecution until

after its conclusion. The High Court and the Supreme Court granted the order of certiorari (thereby lifting the reporting restrictions) but a number of comments were made by the Supreme Court as to the meaning of Article 34.1 of the Constitution. In particular, the Chief Justice noted that Article 34.1 had to be “construed in the light of the other provisions of the Constitution and in particular Article 38.1”. The latter Article provides: “No person shall be tried on any criminal charge save in due course of law”.

(f) *Roe v. the Blood Transfusion Service Board* ([1996] 3 IR 67)

54. The plaintiff had contracted hepatitis C from a blood transfusion and attempted to issue proceedings using the name Roe and the address of her solicitors (her real name and address were on the court file). She was not allowed to proceed in this manner as the “Constitution removed any judicial discretion to have proceedings held other than in public”, such proceedings to include pleadings and oral testimony.

(g) *Rogers v. the Information Commissioner and Others*, 2000 96 MCA

55. The applicant had applied to the Department of Justice, Equality and Law Reform under the Freedom of Information Act 1997 for access to the transcript and associated materials relating to proceedings in a criminal case involving the applicant, custody of which records was with the Court Service. The High Court noted that there was a general prohibition, express or implied, in the Rules of the Superior Courts with specified exceptions and a discretion with the court where appropriate to relieve from that prohibition. The applicant was not therefore entitled to access to the transcripts as their disclosure to the general public was prohibited by the court. It went on:

“While not relevant here, I would hold that, as the courts are entitled to regulate the conduct of court business, a practice not having its origin in the Rules of the Superior Courts would likewise amount to a prohibition eg. the practice of confining access to Central Office files to the parties and their representatives.”

(h) *In Re Ansbacher (Cayman) Ltd* ([2002] 2IR 517),

56. The High Court tried, as a preliminary issue, the question of whether it had any power to order an in camera hearing or a hearing which in some way limited the publication of the applicants’ names. It did so without hearing evidence and using the name of the applicants’ solicitors in order to ensure anonymity pending the result of the preliminary hearing. Having

reviewed the jurisprudence (including the above-cited Roe case), Mr Justice McCracken in the High Court noted:

“... In my view what the judgments of the Supreme Court do establish is that the phrase “as may be prescribed by law” is extended beyond statute law to special and limited cases which may expressly or by inference be prescribed in the constitution itself. ...

The judgments in [another] case would seem to confirm that the Supreme Court judgments in The Irish Times Limited case were intended to be restricted to criminal cases and to exceptions which arose under Article 38 of the Constitution. In particular, it was made quite clear that a desire for confidentiality could not under any circumstances be considered one of the special and limited cases prescribed by law.

... The applicants here claim that they have a constitutional right to privacy as one of the unenumerated personal rights guaranteed by Article 40 and also a right to their good name pursuant to Article 40.3.2. This is undoubtedly so and I think the essential question before me is whether the existence of either of these rights could be said to be a constitutional provision which could be said under any circumstances to be a special and limited case prescribed by law as referred to in Article 34.1.

... Article 40.3 is a guarantee by the State to use its laws to protect the personal rights of citizens. However, what we have in this case is not a conflict between a personal right of the citizen and the law of the State, but a possible conflict between a personal right of the citizen under Article 40.3 and the constitutional provisions under Article 34.1, which latter are not part of the laws enacted by the State, but are part of the law enacted by the people. Furthermore, Article 40.3 only applies “as far as practicable”, and only protects citizens from “unjust attack”. It is not an absolute guarantee of the personal rights of the citizen.

No case has been cited to me in which a right to a good name or a right to privacy can justify anonymity in Court proceedings. A request for such anonymity was expressly refused [in the Roe case]. ...

It has been said in a number of cases that, while there may be a hierarchy of rights under the Constitution, initially the Court should attempt to reach a judgment which harmonises the possible conflicting rights, and it is only if this is not possible that the Court continues and considers the strength or rankings of respective rights. I entirely agree with this approach, and it seems to me that to extend the right to privacy or the right to a good name to anonymity in a

Court case could not possibly be said to be a practicable way for the State to defend and vindicate these rights in the light of Article 34.1. As I have said, the personal rights are not absolute, and in considering the extent of such personal rights, one must do so in the light of other constitutional provisions including Article 34.1. The only harmonious construction of the personal rights must be that their exercise does not interfere with other constitutional requirements which are inserted for the public good. Were that not so, it would make nonsense of parts of the Constitution. In one sense it may violate a person's privacy and a person's good name to have them charged with a serious offence before the Courts, but it could not possibly be said to be a violation of their constitutional rights if they are named, or that they have a constitutional right to be charged under an assumed name. Similarly, and I think it is analogous to the present case, if a person wishes to seek an injunction to restrain the publication of a libel, such person must make such application in their own name. There are of course cases envisaged by Article 34.1 where parties' names will not be disclosed, such as the names of defendants in criminal proceedings who are minors, or the names of parties to matrimonial proceedings. These are matters regulated by statute. ...”

57. Having gone on to examine the particular circumstances of the applicants cases as regards their right to privacy and good name (including the facts that the applicants were allowed make submissions to the inspectors, that they made no complaint about the inspectors' enquiry and that procedural possibilities existed to protect their good name and defend any subsequent criminal proceedings), the High Court concluded:

“In my view, therefore, there is no possible harmonious construction of the Constitution whereby the applicants' personal rights could be considered to give rise to any special or limited case prescribed by law as an exception to Article 34.1.

Finally, I would emphasise the views expressed in the passage I have already quoted from the judgment of Denham J. in [De Gortari v. His Honour Judge Peter Smithwick [1999] 4 IR 223], at p. 233 where she said that in seeking the exercise of the jurisdiction of the Court the factors put forward by the applicant were related to the French law of procedure and the applicants wished to keep the matter confidential. She commented:-

‘Neither factor meets the requirements of Irish law: Irish Times Limited -v- Ireland. Neither matter is sufficiently weighty when balanced against the constitutional requirement of the administration of justice should be in public to warrant a decision in favour of the applicant.’

... The fact that Article 34.1 requires Courts to administer justice in public by its very nature requires the attendant publicity, including the identification of parties seeking justice. It is a small price to be paid to ensure the integrity and openness of one of the three organs of the State namely the judicial process, in which openness is a vital element. It is often said that justice must not only be done, but must also be seen to be done, and if this involves innocent parties being brought before the Courts in either civil or criminal proceedings, and wrongly accused, that is unfortunate, but is essential for the protection of the entire judicial system. I do not believe I am called upon to consider any hierarchy of rights in the present case, but if I had to do so, I have no hesitation whatever in saying that the right to have justice administered in public far exceeds any right to privacy, confidentiality or a good name.”

COMPLAINTS

58. The applicant complained about the need to travel abroad to have an abortion in the case of a lethal foetal abnormality and about the restrictions for which the 1995 Act provided. She expressly confined her complaint to the situation of a fatal foetal diagnosis, considering that her tragic situation was exacerbated by the above-noted limitations. She invoked Articles 3, 8 and 10 of the Convention.

She submitted that she was obliged to research abortion options in the United Kingdom and to travel abroad to be treated by unknown medical personnel in an unknown hospital. She did not have the involvement of her treating doctor or even a proper discussion with, or referral from, her specialist (as a result of the 1995 Act). Irish law on abortion contributed to the taboo surrounding the subject: she felt obliged to maintain the secrecy of her termination in Ireland even vis-à-vis a hospital treating her and her family doctor. Certain follow-up matters (formal genetic counselling, autopsies, counselling for bereavement, medical follow-up) are not available in Ireland following an abortion abroad and, with two children in Ireland, she could not remain in the UK for counselling there.

59. As to Article 3 specifically, the applicant complained that this situation amounted to a failure to fulfil a positive obligation to ensure that she was not subjected to “inhuman and degrading” treatment (*Pretty v. the United Kingdom*, no. 2346/02, §§ 50, 52 and 55, ECHR 2002 III).

As to Article 8, she argued that there was a disproportionate interference with an intimate and personal aspect of her private and family life and/or a failure to fulfil a positive obligation to

protect those Article 8 rights. In these respects, she pointed out that she was the person primarily concerned with the pregnancy; that the State might have had a certain margin of appreciation but not an unfettered discretion in this area; that particularly serious reasons were required to justify an interference with “a most intimate part of an individual’s private life”; that she would have preferred to have had a full and open discussion with her specialist; and that she did all she could to respect the foetus (an induced labour, a coffin and a religious burial in Ireland). The foetus was condemned in any event and, in addition, she had her own physical and mental health together with her existing family responsibilities and interests to consider. By denying the few women in her situation an abortion in Ireland through the overall ban on abortion, the State put an unduly harsh burden on such women: it was arbitrary and draconian, made worse by the information restrictions set down by the 1995 Act. Ireland was, the applicant maintained, in a minority of European countries in these respects.

As to Article 10, she submitted that her right to receive information had been violated in that sections 5 and 8 of the 1995 Act imposed unnecessary restraints on what a doctor could tell her and prohibited that doctor making proper arrangements, or a full referral, for an abortion abroad.

60. She further complained under Article 14 that she was discriminated against as a pregnant woman or as a pregnant woman with a lethal foetal abnormality: a person with a serious medical problem would never have encountered such difficulties in obtaining medical care and advice.

61. Finally, invoking Articles 1 and 13 in conjunction with Articles 3, 8 and 10, she argued that that she did not have an effective domestic remedy.

4.3.2. The Law

62. The applicant complained under Articles 3⁴⁵, 8⁴² and 10⁴⁶ about the impact on her of the constitutional (Article 40.3.3) and legislative (the 1995 Act) provisions which meant that she had to travel abroad for an abortion and which reduced her access to information, despite the accepted fatal foetal abnormality. She also made associated complaints under Articles 13⁴³ and 14. The Government disputed that the laws on abortion in Ireland or the 1995 Act (whether its provisions or impact) constituted a violation of the Convention. Although the

applicant also invoked Article 1, the Court did not consider that the application gave rise to an issue under that Article of the Convention.

63. Four non-governmental organisations were accorded leave by the President under Rule 44 of the Rules of Court to make submissions in the case. All made submissions on the merits of the complaints. The Irish Family Planning Association argued that the laws on abortion in Ireland violated Articles 3, 8 and 14⁴⁴ and the Center for Reproductive Rights also considered that the abortion laws together with the restrictions of the 1995 Act violated, inter alia, those Articles. The Pro-Life Campaign and the Society for the Protection of Unborn Children were both of the view, inter alia, that Irish law on abortion did not violate Articles 3, 8 or 14 and that the 1995 Act did not breach Article 10 of the Convention.

Exhaustion of domestic remedies: Article 35 § 1⁴⁷ of the Convention

64. However, in the first instance the parties disagreed as to whether the applicant had complied with the requirement to exhaust domestic remedies laid down in Article 35 § 1 of the Convention. The Government maintained that, as soon as the diagnosis of Trisomy 18 was confirmed, the applicant should have initiated an action in the High Court, pursued if unsuccessful to the Supreme Court, to obtain a declaration that Article 40.3.3 of the Constitution allowed an abortion in Ireland in the case of a fatal foetal abnormality together with the necessary ancillary mandatory order. The applicant maintained that any such remedy would have been inadequate in the circumstances.

1. Submissions of the Government.

65. The Government emphasised the underlying rationale of the doctrine of exhaustion and its importance in defining the subsidiary role of the Court. The exhaustion requirement assisted the Court's assessment of cases through an analysis of the individual circumstances. It was disrespectful of the domestic legal order for this Court to assume what would be a domestic court's response to a novel question.

This was particularly the case for a common-law constitutional system which had a distinguished record in the protection of human rights. Where there were key factual, legal and interpretative issues, it was vital to submit them to domestic courts and in Ireland via declaratory relief to assert constitutional rights, thereby testing the extent of the protection and allowing the domestic courts to develop such protection by interpretation. In such cases, the Court should be slow to proceed on the assumption that it would be futile to ventilate

questions such as the appropriate interpretation of a constitutional provision on abortion and of the 1995 Act. The X case demonstrated the fundamental and exclusive role of the domestic courts in interpreting the Constitution: the issue of abortion in Ireland involved a delicate mingling of social attitudes, values and legal provisions and the decisions of the Supreme Court in that respect demonstrated both the difficulty of the issues and the care with which the Irish courts have considered them.

66. Any doubts about the chances of success of a constitutional action would not exempt an applicant from the requirement to so exhaust. Indeed, and while the applicant admitted she never contemplated even taking advice, an unfavourable counsel's opinion had been found insufficient to justify a failure to exhaust domestic remedies (K., F. and P. v. the United Kingdom, no. 10789/84 Commission decision of 11.10.1984, Decisions and Reports (DR) 40, p. 298).

67. The Government considered that the failure by the applicant to bring certain factual and legal questions before the High and Supreme Courts left a vacuum precluding this Court's proper examination of the case.

68. They argued that the applicant had failed to clarify many factual issues before this Court: the prognosis of her foetus or indeed of Trisomy 18; the precise contacts with and the advice and assistance received from, Irish and UK medical consultants before the termination and thereafter; any direct contact between her Irish and UK treating doctors; as well as her psychological state before and after the abortion. Genetic counselling was available from the National Centre for Medical Genetics.

69. As to the legal issues, the Government noted that a number of impugned matters did not result, at all or at least exclusively, from the challenged legal provisions but rather from the diagnosis itself and its tragic consequences.

More centrally, it was an open question as to whether Article 40.3.3 could have allowed a lawful abortion in Ireland in the applicant's circumstances. The X case demonstrated the potential for judicial development in this area and, further, the X case did not exclude possible evolution in cases such as the applicant's: the foetus was viable in the X case whereas in the present case there might be an issue as to the extent to which the State was required to guarantee the right to life of a foetus which suffered from a lethal genetic abnormality. The meaning of "unborn" in Article 40.3.3 had attracted some public and academic comment

(notably, the Green Paper on Abortion at paragraphs 35-38 above and a leading textbook on Irish constitutional law “The Irish Constitution”, Kelly, at § 7.3.28). However, there had been little judicial examination of the meaning of “unborn” and certainly no case comparable to the present. Accordingly, although it was true that Article 40.3.3 had to be understood as excluding a liberal abortion regime, the courts were nonetheless unlikely to interpret the provision with remorseless logic particularly when the facts were exceptional. If therefore it had been established that there was no realistic prospect of the foetus being born alive, then there was “at least a tenable” argument which would be seriously considered by the domestic courts to the effect that the foetus was not an “unborn” for the purposes of Article 40.3.3 or that, even if it was an “unborn”, its right to life was not actually engaged as it had no prospect of life outside the womb. In the absence of a domestic decision, it was impossible to foresee that Article 40.3.3 clearly excluded an abortion in the applicant’s situation in Ireland.

The Government also maintained that the applicant’s interpretation of the 1995 Act was erroneous and would have benefited from examination in domestic declaratory proceedings. The 1995 Act only prohibited a doctor doing two things: (a) giving “act information” in a manner which advocated or promoted abortion; and (b) making the initial appointment or having a formal arrangement with an abortion provider. In short, the 1995 Act allowed non-directive advice, assistance and counselling by doctors. In any event, she stated that she had already made up her own mind before she spoke to the doctors so the non-directive limitation in the 1995 Act was irrelevant. The Act did not preclude communication between Irish and UK doctors or interrupt the continuity of care as she alleged: Article 8(2) of the 1995 Act specifically envisaged the giving to a woman of her medical notes and, importantly the Supreme Court found that it did not prohibit referral information and referral communication in the normal way between Irish and UK practitioners; and the Act did not therefore prevent a formal referral from an Irish Consultant to another hospital, provided the Irish doctor did not make the actual appointment. Any inability to be reimbursed for treatment abroad resulted from her insurance policy and not from the 1995 Act: the Supreme Court found that there was no ground for suggesting that section 7 would create problems for women with medical insurance with regard to medical fees concerning abortion. Nothing in the Act prevented her from discussing with a doctor the necessary post-abortion medical follow-up (indeed this was recommended by the Primary Care Guidelines 2004 and by the guidelines published by the Irish College of General Practitioners in 1995): it was the applicant who chose not to consult on her return. There had been no prosecutions to date under the 1995 Act.

70. The Government responded to three specific procedural points raised by the applicant as impeding her access to the constitutional remedy as regards Article 40.3.3. They maintained that she should have attempted the proceedings in order to clear up any doubts about those issues.

71. In the first place, they agreed with the applicant that the Irish courts would not examine a case it considered “moot” but disagreed that the above-proposed litigation would have been so defined. They referred to the speed with which the courts examined the above-cited X (initiated by the State) and C cases (the latter brought by private individuals). They also referred to a case of a national of Ukraine in October 1999 who required an exit visa to stay in her asylum process in Ireland to allow her to travel abroad briefly for an abortion. The Irish authorities would only allow travel for an abortion if she met the X case criteria (risk to life including suicide). The applicant briefed Counsel on Friday night, papers were ready on Saturday afternoon and a High Court judge heard the matter at his home on Saturday evening, granting the relief sought and suggesting that the interim substantive hearing take place within days. The sitting High Court, the following Monday morning, quashed the refusal of the travel visa, the application not being opposed by the State. The judicial response to the home birth cases upon which the applicant relied (see paragraph 78 below) was explained by the plaintiffs’ delay in issuing the proceedings in the first place.

72. Secondly, the Government also submitted at the oral hearing before this Court that it was “improbable in the highest degree” that the proposed domestic remedies would have resulted in the forced disclosure of her identity.

They argued that the “prescribed by law” exceptions to the publicity rule in Article 34(1) meant a restriction imposed by legislation (and they argued that section 45 of the Courts Supplemental Provisions Act 1961 concerning minors had some application to the present case) as well as under the courts’ inherent jurisdiction to make an exception to the publicity rule when necessary to vindicate constitutional rights, such as, those of the accused in criminal cases (the above cited Irish Times Ltd and Ansbacher cases). Beyond this, there remained the power exercised by Irish Courts to request that parties should not be identified, and so far those requests had been honoured. The Courts always treated sensitive cases with care: see the above-cited X and C cases together with *Re a Ward of Court*. Even if (since the above-cited Roe case) proceedings could not have been commenced under a pseudonym, the change to the Superior Court Rules in 1986 meant that pleadings (apart from the initiating

summons) did not have to be filed in the plenary proceedings the Government proposed. Relying on the letter from the Courts Service in Ireland (paragraphs 49-50 above) and the above-cited case of *Rogers v. Information Commissioner and Others*), the Government maintained that pleadings were available to third parties only with the consent of the relevant party. A plenary summons would therefore be served on the other party and filed in the Central Office, the name of the litigant and case number would be on that document and published, but otherwise the subject matter and any other detail about the case would not be known. While it was “most likely” that the applicant’s case would have been heard in open court, “in all likelihood” neither the full name or identity of the applicant would have been disclosed: “in practice” the courts did “not insist” on the reading out of the personal details of litigants save to the extent necessary for the case; it was “not uncommon” for the courts to “request” journalists not to reveal the identity of the litigant, although the courts would make it clear that they had no power to impose such a restriction; and, consistently, a judgment of the court “would frequently” only use initials and not disclose either the identity or address of the applicant or other parties.

73. Thirdly, the general rule that costs followed the event was not inflexible and the courts retained some discretion: in several recent important constitutional cases cited by the Government, the courts had awarded costs to the losing party. Given the applicant’s tragic personal circumstances and the major constitutional issues raised, it was “most unlikely” that there would be an award of costs against her and, “quite likely” that there would be an award of costs in her favour. Indeed, “it was by no means clear” that the State would have applied for costs and they referred also to the State’s costs’ undertaking in the above-cited X case. In the most unlikely event of an award of costs, the Government disagreed with the applicant’s estimations based on the security for costs payment in the *Superwood Holdings* case (*Superwood Holdings plc v Sun Alliance et al* [2004] 1 ILRM 124): that was a long-running commercial case which had taken up some 281 days in the High Court.

2. The applicant’s submissions

74. She underlined, in the first place, a number of general matters.

75. She emphasised how important the continuity of medical care was for someone in her position and that it had been ruptured: if she did not have to travel abroad she could have been cared for in a local hospital with her own doctor’s pre- and post-abortion care. The report from the National Centre for Medical Genetics confirmed the diagnosis of Trisomy 18 but did

not offer genetic counselling: in any event, her consultant told her that he could give her the necessary counselling. The 2004 Primary Care Guidelines post-dated the relevant events and they were, in any event, of little relevance to her. The 1995 General Practitioners Guidelines were also not relevant since foetal abnormalities were diagnosed in hospitals, the guidelines made no mention of abortion for women so diagnosed nor did they address the special post-abortion needs of women in her situation.

She reiterated that her profound distress was exacerbated by the draconian regime in Ireland requiring her to travel abroad and to leave behind the comfort of the familiar, by the associated lack of information or support and by the lack of post-abortion services and facilities. She maintained that the legal position contributed to the stigma attaching to abortion in Ireland and, consequently, added to the already heavy psychological weight of an abortion. She considered that she had given sufficient substantiation of her submission that she was distressed and depressed, which situation was augmented by the regulation of abortion in Ireland.

As to the 1995 Act, she essentially argued that the Act's restrictions were so broadly drafted and its sanctions of such severity that Irish doctors were intimidated, guarded and cautious and were put off communicating with their patients about abortion in a free and frank manner. It was unlawful for her doctors to "make an appointment" for her or to make "any other arrangement" with a foreign abortion service provider including, she argued, making a referral. She was unable to obtain a referral and Hospital B advised that it could not provide her medical notes. In any event, the therapeutic relationship is such that the doctor should be allowed to take the lead in making appointments and arrangements with other health professionals. It was no answer for the Government to seek to shift the responsibility for the harm, inflicted by the underlying legislative and constitutional limitations, to her efforts to alleviate its impact. There may have been no criminal prosecutions under the 1995 Act as yet, but that was simply because doctors erred on the side of caution.

76. As to whether she had complied with the requirement to exhaust domestic remedies generally, she confirmed that the idea of legal action had never entered her mind at the time of the diagnosis. However, a number of obstacles stood in the way of her exhausting the constitutional remedy proposed by the Government.

77. In the first place, she argued that such a case had no prospects of success. She would be seeking a declaration that an abortion in Ireland in the case of a fatal foetal abnormality was

not unconstitutional and, to ensure the enforcement of any such declaration, a mandatory order. There was no “real and substantial risk” to her life (she was not suicidal) and that was the only accepted termination possibility in Ireland: abortion in the case of a strong negative impact on her physical or mental health was insufficient given the “equal rights” of the foetus under the Constitution. No ruling allowing a termination in Ireland for fatal foetal abnormality had ever been obtained. She had simply no plea to make: indeed, the Eighth Amendment itself was designed to be restrictive and self-executing. There was no legal agreement on when the foetus became an “unborn” for the purposes of Article 40.3.3: even the Government was rather non-committal on the point. Without any prospect of success, she would have obtained no interlocutory ruling. Certain official publications (notably the Green Paper on Abortion) and academic comment at the time confirmed that legal position. In any event, the Government had not demonstrated how any declaration could have ensured that she would have actually obtained an abortion in Ireland in the time left to her.

78. Secondly, and as to the timing of any proceedings, the results of an amniocentesis are not reliable until the 14th week of pregnancy so that her situation was not definitive until after that test and, reasonably, its confirmation. She could not then (at her 17th/18th week) put her pregnancy on hold so she was in a different position to the ordinary litigant: she had a small window of opportunity. Any constitutional challenge would have taken time to prepare, the High Court would have had to hear the case immediately and it would have been incumbent on the State to appeal to obtain the Supreme Court’s view in the unlikely event there was a High Court finding in her favour. The X and C cases were treated quickly because those actions essentially concerned the obligations of the public administration in dispute with individuals, and the courts were more amenable to ensuring that those obligations were clarified for the State.

Moreover, the Irish courts would not examine an issue that it considered moot and such an action was likely to be so classified given her advancing pregnancy. She cited a number of cases concerning women who wished to have home births and alleged that the State purposefully delayed those cases until after the birth when the issue became, and was found to be, moot (including, *Nevin Maguire v. South Eastern Health Board* [2001] 3 IR 26 and subsequently in at least five other home birth cases). Indeed the courts had even refused to continue with a case where it was foreseen that the issue would become moot by the time it was finally heard. In *Julie Walsh v. Mid Western Health Board* case (unreported, JR 250/2003) the plaintiff was planning a home birth for late June 2003 and instituted

proceedings on 7 April 2003 to secure a home birth service. On 28 April 2003 the High Court held that, notwithstanding that she had an arguable case for her action to be heard, it would not be permitted to proceed because the date of birth was too close. Similarly, any proceedings launched or continued after an abortion in UK would even more surely have fallen at the same “moot” hurdle.

79. Thirdly, she argued that her identity would have been disclosed in any such litigation and, given the abortion debate raging at the time in Ireland, she would have attracted immense national and international media attention. She had two minor children at the time.

None of the statutory exceptions to the publicity rule in Article 34(1)³² was relevant to her case: it was simply untenable to suggest that section 45 of the 1961 Act had any application. While preliminary applications for an in camera hearing protected the identity of the relevant persons (the above-cited Roe and Ansbacher cases), she considered it unlikely that the courts would have accepted that she had a constitutional right to privacy which was superior to the publicity rule, given the findings in, especially, the above-cited Ansbacher case. In any event, to issue proceedings she would have had to disclose her identity on the Court pleadings as she could not use a pseudonym.

The question of access to the court files in the Central Office had not been “conclusively resolved”. If Order 19 of the Superior Court Rules as amended in 1986 omitted the requirement to file pleadings, Orders 5, 12, 36 and 39 of the Superior Court Rules continued to require the filing of summonses, appearances, books of pleadings to set a case down for trial, evidence presented in open court, affidavits, judgments and transcripts. Any documents relied upon in open court, as a matter of principle also entered the public domain. Although the applicant referred in her oral submissions to the Court to a direction by the President of the High Court of 1986, she did not provide any further detail, noting simply that Order 126, Rule 5 provided that “any file or record may be kept in such form as may be approved from time to time by the President of the High Court”. The courts and not the Courts Service controlled the court records (section 65 of the Courts Officers Act 1926 and section 46 of the Freedom of Information Act 1997) and the matters referred to in the letter of the Courts Service (paragraphs 49-50 above) were simply practices, never challenged in proceedings. It was difficult to see, despite the reference in the above-cited Rogers case, how this practice was consistent with the publicity requirement of Article 34(1)³². The Ansbacher line of authority was not considered in the Rogers case. The applicant was not persuaded that the

Irish Bar's Code of Conduct was a sufficient guarantee of the confidentiality of pleadings inspected by barristers. She pointed out that, when a hearing began, the parties' names and addresses were read out: a request to avoid that could be made but it was "by no means clear" that a judge would agree and, even if the judge did, it would not be binding so that any accidental revelation of the name during the hearing could be lawfully reported upon.

80. Fourthly, the applicant considered it "highly likely" that the High and Supreme Court costs would have been awarded against her if she lost (as they were in the above-cited case of *Julie Walsh v. Mid Western Health Board* in the sum of 31,000 euros (EUR)). The costs in her case would have been substantial and she referred to a recent security for costs ruling by the Supreme Court (in the sum of EUR1.6 million, in the above-cited *Superwood Holdings* case). Even if an award was not made against her, her own costs would have been substantial.

81. Accordingly, had she sought legal advice at the time, it would have confirmed that she had no effective remedy and the doctrine of exhaustion did not require a litigant to embark on exceptionally hazardous and uncertain litigation.

82. The applicant concluded that the burden of exhausting domestic remedies in the circumstances was excessive having regard, in addition, to the following: she was 17-18 weeks pregnant with twins and had just received confirmation that one foetus was dead and that the other was effectively dying; she would be forced into adversarial proceedings with the latter foetus, which would be represented by State appointed lawyers; she might have been required to give oral evidence and be cross-examined; and the State would have been entitled to her medical records.

3. The Court's assessment

(a) General principles

83. The Court recalls the requirements of the rule of exhaustion of domestic remedies summarised in its judgment in the case of *Selmouni v. France* ([GC], no. 25803/94, §§ 74-77, ECHR 1999 V):

"74. The Court points out that the purpose of Article 35 is to afford the Contracting States the opportunity of preventing or putting right the violations alleged against them before those allegations are submitted to the Convention institutions Consequently, States are dispensed from answering for their acts before an international body before they have had an

opportunity to put matters right through their own legal system. That rule is based on the assumption, reflected in Article 13 of the Convention – with which it has close affinity – that there is an effective remedy available in respect of the alleged breach in the domestic system. In this way, it is an important aspect of the principle that the machinery of protection established by the Convention is subsidiary to the national systems safeguarding human rights Thus the complaint intended to be made subsequently to the Court must first have been made – at least in substance – to the appropriate domestic body, and in compliance with the formal requirements and time-limits laid down in domestic law

75. However, the only remedies which Article 35⁴⁷ of the Convention requires to be exhausted are those that relate to the breaches alleged and at the same time are available and sufficient. The existence of such remedies must be sufficiently certain not only in theory but also in practice, failing which they will lack the requisite accessibility and effectiveness; it falls to the respondent State to establish that these various conditions are satisfied In addition, according to the “generally recognised principles of international law”, there may be special circumstances which absolve the applicant from the obligation to exhaust the domestic remedies at his disposal

76. Article 35 provides for a distribution of the burden of proof. It is incumbent on the Government claiming non-exhaustion to satisfy the Court that the remedy was an effective one available in theory and in practice at the relevant time, that is to say, that it was accessible, was one which was capable of providing redress in respect of the applicant’s complaints and offered reasonable prospects of success. However, once this burden of proof has been satisfied it falls to the applicant to establish that the remedy advanced by the Government was in fact exhausted or was for some reason inadequate and ineffective in the particular circumstances of the case or that there existed special circumstances absolving him or her from the requirement One such reason may be constituted by the national authorities’ remaining totally passive in the face of serious allegations of misconduct or infliction of harm by State agents, for example where they have failed to undertake investigations or offer assistance. In such circumstances it can be said that the burden of proof shifts once again, so that it becomes incumbent on the respondent Government to show what they have done in response to the scale and seriousness of the matters complained of (ibid.).

77. The Court would emphasise that the application of this rule must make due allowance for the [Convention] context. Accordingly, it has recognised that Article 35 must be applied with

some degree of flexibility and without excessive formalism It has further recognised that the rule of exhaustion of domestic remedies is neither absolute nor capable of being applied automatically; in reviewing whether the rule has been observed, it is essential to have regard to the particular circumstances of the individual case This means, amongst other things, that the Court must take realistic account not only of the existence of formal remedies in the legal system of the Contracting Party concerned but also of the general legal and political context in which they operate as well as the personal circumstances of the applicants”

84. It must then decide whether, in all the circumstances of the case, the applicant did everything that could reasonably be expected of her to exhaust domestic remedies (*Aksoy v. Turkey*, judgment of 18 December 1996, Reports of Judgments and Decisions 1996-VI, § 54 and, more recently, *Merit v. Ukraine*, no. 66561/01, § 58, 30 March 2004 and *Isayeva and Others v. Russia*, nos. 57947/00, 57948/00 and 57949/00, §145, 24 February 2005).

85. The Court would also emphasise that it is an established principle, that in a legal system providing constitutional protection for fundamental rights, it is incumbent on the aggrieved individual to test the extent of that protection and, in a common law system, to allow the domestic courts to develop those rights by way of interpretation. In this respect, it is recalled that a declaratory action before the High Court, with a possibility of an appeal to the Supreme Court, constitutes the most appropriate method under Irish law of seeking to assert and vindicate constitutional rights (*Patrick Holland v. Ireland*, no. 24827/94, Commission decision of 14.4.1998, DR 93, p. 15 and *Independent News and Media and Independent Newspapers Ireland Limited v. Ireland*, no. 55120/00, (dec.) 19 June 2003).

(b) Application to the present case

86. The Court has first considered whether the Government have discharged the burden on them to show that the proposed constitutional remedy as regards abortion was “accessible”, “capable of providing redress” and “offered reasonable prospects of success”.

87. As to the accessibility of the remedy, there is no Convention basis for arguing that legal representation is, as a general rule, required for High Court proceedings to be considered accessible (indeed in *Airey v. Ireland*, judgment of 9 October 1979, Series A no. 32, § 26, the Court made it clear that it was not suggesting this). Even if it could be assumed that the present applicant’s case gave rise to the same special needs as Ms Airey’s, the applicant did

not argue that she would have been unable to obtain legal representation in what would have been a landmark case. The Court has examined below the question of her costs exposure.

88. The Court also considers that a declaration by the Supreme Court that a self-executing provision of the Constitution allowed an abortion in Ireland in the applicant's case, accompanied by a mandatory order, would have been capable of providing redress. Since abortions (in the case of a "real and substantial risk" to the mother's life) were already available in Ireland and since the Masters of the main obstetric hospitals were not against terminations in the case of a fatal foetal abnormality (see paragraph 44 above), the Court finds unsubstantiated the suggestion that the relevant declaratory and mandatory orders would not have been implemented in good time. The Court would clarify at this point that the applicant's central complaint concerns the necessity to travel abroad for an abortion so that it is not considered, and indeed the Government did not suggest, that a post-abortion remedy would have been capable of providing the applicant with redress.

89. The parties had differing views on the chances of success of the proposed constitutional action. The applicant maintained that there was no constitutional argument to be made since her life was not in danger and the Government disagreed given the fatal foetal abnormality of the surviving foetus. It is recalled that, while mere doubts on the part of the applicant will not absolve her from attempting a particular remedy (*Pellegrini v. Italy*, No. 77363/01, (dec.) 26 May 2005 and *MPP Golub v. Ukraine*, No. 6778/05, (dec.) 18 October 2005), if a remedy does not offer reasonable prospects of success her failure to use it would not bar admissibility (for example, *Radio France v. France*, No. 53984/00, decision of 23 September 2003, § 33).

90. The Court considers it important to begin this assessment by recalling the comments of the Chief Justice in the *X* case when he indicated, prior to interpreting the Eighth Amendment, that no interpretation of the Constitution was intended to be final for all time a statement he considered to be "peculiarly appropriate and illuminating in the interpretation of [the Eighth Amendment] which deals with the intimate human problem of the right of the unborn to life and its relationship to the right of the mother of an unborn child to her life".

The recognition in the *X* case, of an exception to the protection of the unborn when the mother's life was at risk from self harm, was not a judicial interpretation of Article 40.3.3 which had been foreseeable with any certainty. Indeed, as argued by the Government, the *X* case illustrated the potential of the constitutional courts to develop the protection of individual rights by way of interpretation and the consequent importance of providing those courts with

the opportunity to do so: this is particularly the case when the central issue is a novel one, requiring a complex and sensitive balancing of equal rights to life and demanding a delicate analysis of country-specific values and morals. Moreover, it is precisely the interplay between the equal right to life of the mother and the “unborn”, so central to Article 40.3.3, that renders it arguable that the X case does not exclude a further exception to the prohibition of abortion in Ireland. The presumption in the X case was that the foetus had a normal life expectancy and there is, in the Court’s view, a feasible argument to be made that the constitutionally enshrined balance between the right to life of the mother and of the foetus could have shifted in favour of the mother when the “unborn” suffered from a abnormality incompatible with life. The Court also notes the subsequent rejection (in 1992 and 2002) of the proposed amendments to the Constitution to restrict the effect of the judgment in the X case.

91. The applicant considers that legal opinion at the time suggested that she would have had no chance of success and it true that an applicant would not, in principle, be obliged to make use of a remedy which, “according to settled legal opinion existing at the relevant time” (including counsel’s opinion), did not provide redress for her complaint (*De Wilde, Ooms and Versyp v. Belgium*, judgment of 18 June 1971, Series A no. 12, § 62; *K., F. and P. v. the United Kingdom*, cited above; *H v. the United Kingdom*, no. 10000/82, Commission decision of 4.7.1983, DR 33, p. 247; and *Selvanayagam v. the United Kingdom*, No. 57981/00 (dec.), 12 December 2002). However, and while one of the seven solutions proposed by the Green Paper on Abortion went beyond the X case, the Oireachtas Committee examining the Paper did not reach any agreement on a single course of reform. The Constitution Review Group concluded that there was no consensus as to what constitutional amendment was required and no certainty as to which one would be accepted by referendum. The academic comment referred to by the parties contained little discussion on the meaning of “unborn” in relation to a foetus with a fatal condition or on the likely position of the courts on whether Article 40.3.3 would permit an abortion in such a situation. Finally, and importantly, the Court considers the applicant’s argument as to the legal opinion at the time to be substantially undermined by her failure to obtain counsel’s opinion at that point.

92. The Court finds that, if the question of whether Article 40.3.3 excluded an abortion in the case of a fatal foetal abnormality was novel, it was, nevertheless, an arguable one with sufficient chances of success to allow the initial burden on the Government to be considered satisfied. Accordingly, on 25 January 2002 a legal constitutional remedy was in principle

available to the applicant to obtain declaratory and mandatory orders with a view to obtaining a lawful abortion in Ireland.

93. The Court has therefore examined whether the proposed remedy could be considered adequate and effective in the circumstances of the applicant's case, whether there were special circumstances absolving the applicant from so exhausting and, more generally, whether it can be concluded that she did everything that could be reasonably expected of her in the circumstances to satisfy the exhaustion requirements of Article 35 § 1 of the Convention (paragraph 84 above). The applicant considered that she could not have been reasonably expected to undertake the proposed constitutional remedy for a number of reasons.

94. In the first place, she pointed to the delay any such proceedings would involve. The parties, relying on different domestic case-law, disputed whether the High and Supreme Courts could and/or would have examined her case within an appropriate period of time.

95. The Court notes that it was not disputed that it was necessary to await the 14th week of pregnancy before the results of an amniocentesis test could be considered reliable and it finds reasonable that the applicant awaited a confirmatory result given the seriousness of the diagnosis. She was then 17-18 weeks pregnant which left her approximately 6 weeks before the maximum 24-week period for a "normal" abortion in the UK (Section 37(1)(a) of the Human Fertilisation and Embryology Act 1990). While she may have been able to extend that time-limit further given the serious abnormality in question (section 37(1)(d) of the 1990 Act), each day of pregnancy that passed after the confirmed diagnosis took the applicant further away from her initial aim of not carrying a dead and a condemned foetus closer to term. The time available for completing the proposed constitutional action before the High and Supreme Courts must therefore be accepted to have been extremely limited.

96. The applicant cited the "home birth" cases, arguing that she risked her case being found to be "moot" and the Government cited three "abortion" cases (the X and C cases together with an unreported case concerning a Ukrainian asylum seeker), decided in less than a month (the X case) and in a matter of days (the other two cases). The Court notes that, in those abortion cases, the courts had before them the vital question whether those plaintiffs could have an abortion at all, so that it was imperative that a decision be rendered in time, whereas the present case is arguably closer to the home birth cases which concerned a choice of location as opposed to the basic entitlement itself. However, it was equally feasible that the courts could have considered the novel point to be of such constitutional importance as to

merit an interpretative judgment and, as the X and C cases, for example, demonstrate, it was possible for the High and Supreme Court to render judgments within days on complex constitutional matters. The Court finds unsubstantiated the applicant's suggestion that the domestic courts treated the cases cited by the Government quickly because the courts were amenable to clarifying for the State its obligations when those were disputed by an individual and her claim that the State had deliberately delayed the home birth cases until their outcome became moot.

97. Secondly, the applicant also maintained that such proceedings could lead to her identification and that she would be unable to cope with the inevitable publicity her case would attract. The Government did not dispute that any revelation of her identity would have attracted a significant amount of publicity and the Court is satisfied that the burden of publicity would have been such, in the particular circumstances of the case, as to have rendered the confidentiality of the applicant's identity essential to the effectiveness of the proposed constitutional action. In this latter respect, the Court notes that the applicant had no objection to any pleading, proceeding or judgment which revealed the nature of the issue in the case and confined her objection to any revelation of her identity. The Court also notes the intimate nature of the choice to abort, the fact that one of the most significant abortion debates of recent years in Ireland was taking place at the relevant time in early 2002, the sensitive, heated and often polarised nature of the debate in Ireland and the fact that the applicant had two other minor children at the time. She was granted confidentiality before this Court (Rules 33(3) and 47(3) of the Rules of Court).

98. The Court considers the following to emerge from the parties' detailed and conflicting submissions as to the public nature of proceedings.

The general rule is that proceedings must take place in public (Article 34(1) of the Constitution). The Court finds unpersuasive the Government's suggestion that section 45 of the Courts Supplemental Provisions Act 1961 (a statutory exception to the publicity rule as regards minors) had any application to the applicant's surviving foetus. More pertinent to the present case is the courts' inherent power to recognise that a competing constitutional right of a particular person may be sufficiently strong as to override the constitutional publicity rule: non-statutory exceptions to the publicity rule have therefore been recognised to ensure a fair criminal trial (the above-cited cases of *The Irish Times Limited and Others v. Ireland* and *Ansbacher*). The Court notes the above-cited comments of Mr Justice McCracken in the

Ansbacher case in refusing to make an exception in favour of the right to privacy of two applicants who were to be named in a report of inspectors appointed under the Companies Act 1990. However, it does not appear that that judgment excluded, as a matter of principle, such an exception from the publicity rule since Mr Justice McCracken went on to assess the particular position of those applicants before refusing them the in camera order they had requested. The present applicant had, in the Court's view, a stronger case for an exception, given the intimate and personal nature of the subject matter of the proceedings and since the attention from the media and other quarters would have been exceptionally intrusive. In addition, as in the Ansbacher and Roe cases, the applicant could have requested that any preliminary application for such an exception to the publicity rule did not itself disclose her identity.

If an in camera hearing was eventually refused, it is true that there remained certain practices which the applicant could have requested should be adopted to keep her identity secret. However, the Government could not be more definite than indicating that "in practice" the courts would "not insist" on reading out the names of the parties to the action and accepted that a request by a judge to those in attendance not to publish identities did not amount to a legal obligation of discretion. Using her initials in judgments would not have assisted the applicant if the prior proceedings had not kept her identity confidential.

99. Turning to the written pleadings in any constitutional action, the parties agreed that the applicant would have been obliged to file a Plenary Summons in the central office in her own name. The name of the proceedings (her name) and the case number would have been publicly listed. However, while the applicant questioned its compliance with Article 34(1) and even assuming in her favour that all pleadings (and not just the Plenary Summons as argued by the Government) generally had to be filed in the Central Office as well as served, the evidence from the Courts Service is that the practice was that any pleadings or other documents filed could only be made available to third parties with the consent of the parties (paragraphs 49-50 above), which practice is reflected in a comment by the High Court in the above-described Rogers case. While barristers could consult files for precedent purposes, the Court considers, contrary to the applicant's views, that their professional obligations (see the Code of Conduct at paragraphs 51-52 above) would have required them to accord the necessary discretion to information found on the court file. Indeed, from the moment that the applicant accepts that the courts had an inherent jurisdiction to order non-public proceedings to protect identity (Article 34(1) of the Constitution) and, further, that the courts controlled

court files (Section 65 of the Court Officers Act 1926, Section 46 of the Freedom of Information Act 1997 and Order 126, Rule 5 of the Rules of the Superior Courts), it is not persuasive to suggest that those courts did not at the same time possess the means to prevent filed documents being disclosed to third parties.

100. Thirdly, she maintained that her costs exposure was too high. It was not disputed that the costs of such an action would be substantial (although the Superwood Holdings case was not a useful example of the likely level for reasons outlined by the Government). However, and as to her own legal costs, the Court recalls that a lack of financial means does not absolve an applicant from making some attempt to take legal proceedings (*Cyprus v. Turkey* [GC], no. 25781/94, § 352, ECHR 2001 IV). As to the other costs in the proceedings including those of the Government, it was not disputed that ‘costs following the event’ was the general position. However, the costs’ risk does not, as a matter of principle, constitute a reason to classify a constitutional remedy as generally ineffective and, indeed, a costs’ order against an unsuccessful litigant is not, of itself, considered contrary to the Convention (for example, *Dawson v. Ireland* (dec.), no. 21826/02, 8 July 2004). In any event, the constitutional novelty and importance increased the chances of the courts making an exception to the general position, a possibility which, in turn, might have facilitated a request to the State not to apply for its own costs.

101. Finally, the applicant also referred to various other matters which would have absolved her from exhausting the proposed remedy. It is undoubtedly the case that the applicant was deeply distressed by, *inter alia*, the diagnosis and its consequences. However, such distress cannot, of itself, exempt an applicant from the obligation to exhaust domestic remedies (see *B v. Belgium*, no. 16301/90, Commission decision of 12.1.1990, DR 68, p. 290, at p.297). It may be that the surviving foetus might have been separately represented in any constitutional proceedings but this simply means that any rights attaching to the foetus would be fully aired. The Court does not consider that the need to provide medical notes or to give evidence could, of itself, constitute a reason not to exhaust domestic remedies: the core concern in that respect is the publicity of the proceedings examined above.

102. In sum, the Court finds that there was a constitutional remedy in principle available to the applicant but that some uncertainty attached to three relevant matters arising from the novelty of the substantive issue and the procedural imperatives of the applicant’s position -

the chances of success, the timing of the proceedings and the guarantees of the confidentiality of the applicant's identity.

The Court is of the view that, having regard to the potential and importance of the constitutional remedy in a common law system especially as regards the matter at issue (detailed at paragraph 90 above), the applicant could reasonably have been expected (see paragraphs 84 and 93 above) to have taken certain preliminary steps towards resolving the above-noted

uncertainties. In the Court's view, she should have obtained legal advice on those substantive and procedural uncertainties and issued a Plenary Summons allowing her to apply for an urgent, preliminary and in camera hearing to obtain the High Court's response to her timing and publicity concerns. It is true that it is assumed by the above that the applicant would continue during those steps an already advanced pregnancy. However, the Court is satisfied on the evidence that such preliminary steps could have been completed without disclosing the applicant's identity and in a matter of days and, further, that the evolution of those initial steps would have elucidated some of the uncertainties and allowed her to assess the effectiveness of the remedy in her situation as the days went by.

In her oral submissions, the applicant alluded to the fact that she had "sought advice, informally, from a friend who was a lawyer" who had "told her that if she wrote to the authorities to protest, the State might try and prevent her travelling abroad for a termination" and that she was "not prepared to take this risk". The Court does not consider that informally consulting a friend amounts to instructing a solicitor or barrister and obtaining a formal opinion. In any event, and as made clear in the C case, the purpose of the Thirteenth Amendment was to ensure that a person could not be prevented from travelling abroad for an abortion (paragraph 23 above).

Accordingly, in the absence of those preliminary steps, the Court is unable to dismiss as ineffective the constitutional remedy available in principle to the applicant.

103. Having regard to all of the above, the Court considers that the applicant did not comply with the requirement to exhaust domestic remedies as regards the availability of abortion in Ireland in the case of fatal foetal abnormality.

104. Moreover, the Court notes that the limitations of the 1995 Act, about which the applicant complained also under Articles 3, 8 and 10, concerned abortion services abroad and had no application to a lawful abortion in Ireland. Consequently, the applicant's failure to pursue domestic remedies as regards obtaining a lawful abortion in Ireland means that her complaints about the 1995 Act, together with her associated complaints under Article 13 and 14, must also be rejected under Article 35 §§ 1 and 4⁴⁷ of the Convention on the grounds of a failure to exhaust domestic remedies.

4.3.3. The Court's decision

Declares the application inadmissible.

4.4. Case Of Open Door And Dublin Well Woman v. Ireland²¹

4.4.1. The procedure

1. The case was referred to the Court by the European Commission of Human Rights ("the Commission") on 24 April 1991, and on 3 July 1991 by the Government of Ireland ("the Government"), within the three-month period laid down in Article 32 para. 1⁴⁸ and Article 47⁴⁹ (art. 32-1, art. 47) of the Convention for the Protection of Human Rights and Fundamental Freedoms ("the Convention"). It originated in two applications against Ireland lodged with the Commission under Article 25 (art. 25) on 10 August and 15 September 1988. The first (no. 14234/88) was brought by Open Door Counselling Ltd, a company incorporated

²¹ Judgment Strasbourg 29 October 1992 (Application no. 14234/88; 14235/88) Case Of Open Door And Dublin Well Woman v. Ireland

in Ireland; the second (no. 14235/88) by another Irish company, Dublin Well Woman Centre Ltd, and one citizen of the United States of America, Ms Bonnie Maher, and three Irish citizens, Ms Ann Downes, Mrs X and Ms Maeve Geraghty.

The Commission's request referred to Articles 44 and 48 (art. 44, art. 48) and the declaration whereby Ireland recognised the compulsory jurisdiction of the Court (Article 46) (art. 46) and the Government's application referred to Article 48 (art. 48). The object of the request and the application was to obtain a decision as to whether or not the facts of the case disclosed a breach by Ireland of its obligations under Articles 8, 10 and 14 (art. 8, art. 10, art. 14) and also, in the case of the application, to examine these issues in the context of Articles 2, 17 and 60 (art. 2, art. 17, art. 60).

2. In response to the enquiry made in accordance with Rule 33 para. 3 (d) of the Rules of Court, the applicants stated that they wished to take part in the proceedings and designated the lawyers who would represent them (Rule 30). On 23 January 1992 the President granted leave, pursuant to Rule 30 of the Rules of Court, to the first applicant company to be represented at the oral proceedings by a lawyer from the United States of America.

3. The Chamber to be constituted included ex officio Mr B. Walsh, the elected judge of Irish nationality (Article 43 of the Convention) (art. 43), and Mr R. Ryssdal, the President of the Court (Rule 21 para. 3 (b)). In a letter to the President of 8 May 1991, Mr Walsh stated that he wished to withdraw pursuant to Rule 24 para. 2, as the case arose out of a decision of the Irish Supreme Court in which he had participated. On 19 June the Agent of the Government informed the Registrar that the Hon. Mr Justice Blayney had been appointed as ad hoc judge (Article 43 of the Convention and Rule 23) (art. 43).

On 26 April the President of the Court had drawn by lot the names of the other seven members of the Chamber, namely Mr J. Cremona, Mr L.-E. Pettiti, Mr J. De Meyer, Mrs E. Palm, Mr R. Pekkanen, Mr A.N. Loizou and Mr J.M. Morenilla (Article 43 in fine of the Convention and Rule 21 para. 4) (art. 43).

4. Mr Ryssdal assumed the office of President of the Chamber (Rule 21 para. 5) and, through the Registrar, consulted the Agent of the Government, the Delegate of the Commission and the representatives of the applicants on the organisation of the procedure (Rules 37 para. 1 and 38). In accordance with the President's orders and directions, the Registrar received, on

31 October and 4 November 1991, the memorials of the applicants and the Government and, on 6 December 1991, the observations of the Delegate of the Commission.

5. On 28 August 1991, the President had granted, under Rule 37 para. 2, leave to "Article 19" (the International Centre against Censorship) to submit written comments on specific aspects of the case. Leave had been granted on the same date to the Society for the Protection of Unborn Children (S.P.U.C.). The respective comments were received on 28 November.

6. On 27 January 1992 the President consented to the filing of a document, pursuant to Rule 37 para. 1, second sub-paragraph, submitted by Dublin Well Woman Centre Ltd.

7. As directed by the President, the hearing took place in public in the Human Rights Building, Strasbourg, on 24 March 1992. The Chamber had held a preparatory meeting beforehand during which it decided, pursuant to Rule 51, to relinquish jurisdiction forthwith in favour of the plenary Court. It also consented to the filing of various documents by the applicants and refused a request by lawyers acting on behalf of S.P.U.C. to address the Court.

There appeared before the Court:

- for the Government

Mrs E. KILCULLEN, Assistant Legal Adviser,

Department of Foreign Affairs, Agent,

Mr D. GLEESON, Senior Counsel,

Mr J. O'REILLY, Senior Counsel, Counsel,

Mr J.F. GORMLEY, Office of the Attorney General, Adviser;

- for the Commission

Mr J. FROWEIN, Delegate;

- for the applicants

Open Door Counselling Ltd

Mr F. CLARKE, Senior Counsel,

Mr D. COLE, Centre for Constitutional Rights (New York), Counsel,

Mr J. HICKEY, Solicitor,

Ms R. RIDDICK, Adviser;

Dublin Well Woman Centre Ltd and Others

Mr A. HARDIMAN, Senior Counsel,

Mr B. MURRAY, Counsel,

Ms B. HUSSEY, Solicitor,

Ms R. BURTENSHAW, Chief Executive,

Ms P. RYDER, Director,

Ms M. MCNEANEY, Counsellor, Advisers.

The Court heard addresses by Mr Gleeson and Mr O'Reilly for the Government, by Mr Frowein for the Commission and by Mr Clarke, Mr Hardiman and Mr Cole for the applicants, as well as replies to questions put by the Court.

8. The Government made further submissions concerning the applicants' claims under Article 50 (art. 50) on 10 April 1992. Comments by the applicants in reply were filed on 15 June 1992.

4.4.2. The facts

I. INTRODUCTION

A. The applicants

9. The applicants in this case are (a) Open Door Counselling Ltd (hereinafter referred to as Open Door), a company incorporated under Irish law, which was engaged, inter alia, in counselling pregnant women in Dublin and in other parts of Ireland; and (b) Dublin Well Woman Centre Ltd (hereinafter referred to as Dublin Well Woman), a company also incorporated under Irish law which provided similar services at two clinics in Dublin; (c) Bonnie Maher and Ann Downes, who worked as trained counsellors for Dublin Well Woman; (d) Mrs X, born in 1950 and Ms Maeve Geraghty, born in 1970, who join in the Dublin Well

Woman application as women of child-bearing age. The applicants complained of an injunction imposed by the Irish courts on Open Door and Dublin Well Woman to restrain them from providing certain information to pregnant women concerning abortion facilities outside the jurisdiction of Ireland by way of non-directive counselling (see paragraphs 13 and 20 below).

Open Door and Dublin Well Woman are both non-profit-making organisations. Open Door ceased to operate in 1988 (see paragraph 21 below). Dublin Well Woman was established in 1977 and provides a broad range of services relating to counselling and marriage, family planning, procreation and health matters. The services offered by Dublin Well Woman relate to every aspect of women's health, ranging from smear tests to breast examinations, infertility, artificial insemination and the counselling of pregnant women.

10. In 1983, at the time of the referendum leading to the Eighth Amendment of the Constitution (see paragraph 28 below), Dublin Well Woman issued a pamphlet stating *inter alia* that legal advice on the implications of the wording of the provision had been obtained and that "with this wording anybody could seek a court injunction to prevent us offering" the non-directive counselling service. The pamphlet also warned that "it would also be possible for an individual to seek a court injunction to prevent a woman travelling abroad if they believe she intends to have an abortion".

B. The injunction proceedings

1. Before the High Court

11. The applicant companies were the defendants in proceedings before the High Court which were commenced on 28 June 1985 as a private action brought by the Society for the Protection of Unborn Children (Ireland) Ltd (hereinafter referred to as S.P.U.C.), which was converted into a relator action brought at the suit of the Attorney General by order of the High Court of 24 September 1986 (the Attorney General at the relation of the Society for the Protection of Unborn Children (Ireland) Ltd v. Open Door Counselling Ltd and Dublin Well Woman Centre Ltd [1988] Irish Reports, pp. 593-627).

12. S.P.U.C. sought a declaration that the activities of the applicant companies in counselling pregnant women within the jurisdiction of the court to travel abroad to obtain an abortion were unlawful having regard to Article 40.3.3o of the Constitution which protects the right to

life of the unborn (see paragraph 28 below) and an order restraining the defendants from such counselling or assistance.

13. No evidence was adduced at the hearing of the action which proceeded on the basis of certain agreed facts. The facts as agreed at that time by Dublin Well Woman may be summarised as follows:

- (a) It counsels in a non-directive manner pregnant women resident in Ireland;
- (b) Abortion or termination of pregnancy may be one of the options discussed within the said counselling;
- (c) If a pregnant woman wants to consider the abortion option further, arrangements will be made by the applicant to refer her to a medical clinic in Great Britain;
- (d) In certain circumstances, the applicant may arrange for the travel of such pregnant women;
- (e) The applicant will inspect the medical clinic in Great Britain to ensure that it operates at the highest standards;
- (f) At those medical clinics abortions have been performed on pregnant women who have been previously counselled by the applicant;
- (g) Pregnant women resident in Ireland have been referred to medical clinics in Great Britain where abortions have been performed for many years including 1984.

The facts agreed by Open Door were the same as above with the exception of point (d).

14. The meaning of the concept of non-directive counselling was described in the following terms by Mr Justice Finlay CJ in the judgment of the Supreme Court in the case (judgment of 16 March 1988, [1988] Irish Reports 618 at p. 621):

"It was submitted on behalf of each of the Defendants that the meaning of non-directive counselling in these agreed sets of facts was that it was counselling which neither included advice nor was judgmental but that it was a service essentially directed to eliciting from the client her own appreciation of her problem and her own considered choice for its solution. This interpretation of the phrase 'non-directive counselling' in the context of the activities of the Defendants was not disputed on behalf of the Respondent. It follows from this, of course, that non- directive counselling to pregnant women would never involve the actual advising of

an abortion as the preferred option but neither, of course, could it permit the giving of advice for any reason to the pregnant women receiving such counselling against choosing to have an abortion."

15. On 19 December 1986 Mr Justice Hamilton, President of the High Court, found that the activities of Open Door and Dublin Well Woman in counselling pregnant women within the jurisdiction of the court to travel abroad to obtain an abortion or to obtain further advice on abortion within a foreign jurisdiction were unlawful having regard to the provisions of Article 40.3.3o of the Constitution of Ireland.

He confirmed that Irish criminal law made it an offence to procure or attempt to procure an abortion, to administer an abortion or to assist in an abortion by supplying any noxious thing or instrument (sections 58 and 59 of the Offences against the Person Act 1861 - see paragraph 29 below). Furthermore, Irish constitutional law also protected the right to life of the unborn from the moment of conception onwards.

An injunction was accordingly granted "... that the Defendants [Open Door and Dublin Well Woman] and each of them, their servants or agents, be perpetually restrained from counselling or assisting pregnant women within the jurisdiction of this Court to obtain further advice on abortion or to obtain an abortion". The High Court made no order relating to the costs of the proceedings, leaving each side to bear its own legal costs.

2. Before the Supreme Court

16. Open Door and Dublin Well Woman appealed against this decision to the Supreme Court which in a unanimous judgment delivered on 16 March 1988 by Mr Justice Finlay CJ rejected the appeal.

The Supreme Court noted that the appellants did not consider it essential to the service which they provided for pregnant women in Ireland that they should take any part in arranging the travel of women who wished to go abroad for the purpose of having an abortion or that they arranged bookings in clinics for such women. However, they did consider it essential to inform women who wished to have an abortion outside the jurisdiction of the court of the name, address, telephone number and method of communication with a specified clinic which they had examined and were satisfied was one which maintained a high standard.

17. On the question of whether the above activity should be restrained as being contrary to the Constitution, Mr Justice Finlay CJ stated:

"... the essential issues in this case do not in any way depend upon the Plaintiff establishing that the Defendants were advising or encouraging the procuring of abortions. The essential issue in this case, having regard to the nature of the guarantees contained in Article 40, s.3, sub-s.3 of the Constitution, is the issue as to whether the Defendants' admitted activities were assisting pregnant women within the jurisdiction to travel outside that jurisdiction in order to have an abortion. To put the matter in another way, the issue and the question of fact to be determined is: were they thus assisting in the destruction of the life of the unborn?"

I am satisfied beyond doubt that having regard to the admitted facts the Defendants were assisting in the ultimate destruction of the life of the unborn by abortion in that they were helping the pregnant woman who had decided upon that option to get in touch with a clinic in Great Britain which would provide the service of abortion. It seems to me an inescapable conclusion that if a woman was anxious to obtain an abortion and if she was able by availing of the counselling services of one or other of the Defendants to obtain the precise location, address and telephone number of, and method of communication with, a clinic in Great Britain which provided that service, put in plain language, that was knowingly helping her to attain her objective. I am, therefore, satisfied that the finding made by the learned trial Judge that the Defendants were assisting pregnant women to travel abroad to obtain further advice on abortion and to secure an abortion is well supported on the evidence ..."

The Court further noted that the phrase in Article 40.3.3o "with due regard to the equal right to life of the mother" did not arise for interpretation in the case since the applicants were not claiming that the service they were providing for pregnant women was "in any way confined to or especially directed towards the due regard to the equal right to life of the mother ...".

18. Open Door and Dublin Well Woman had submitted that if they did not provide this counselling service it was likely that pregnant women would succeed nevertheless in obtaining an abortion in circumstances less advantageous to their health. The Court rejected this argument in the following terms:

"Even if it could be established, however, it would not be a valid reason why the Court should not restrain the activities in which the defendants were engaged.

The function of the courts, which is not dependent on the existence of legislation, when their jurisdiction to defend and vindicate a constitutionally guaranteed right has been invoked, must be confined to the issues and to the parties before them.

If the Oireachtas enacts legislation to defend and vindicate a constitutionally guaranteed right it may well do so in wider terms than are necessary for the resolution of any individual case. The courts cannot take that wide approach. They are confined to dealing with the parties and issues before them. I am satisfied, therefore, that it is no answer to the making of an order restraining these defendants' activities that there may be other persons or the activities of other groups or bodies which will provide the same result as that assisted by these defendants' activities."

19. As to whether there was a constitutional right to information about the availability of abortion outside the State, the court stated as follows:

"The performing of an abortion on a pregnant woman terminates the unborn life which she is carrying. Within the terms of Article 40.3.3o it is a direct destruction of the constitutionally guaranteed right to life of that unborn child.

It must follow from this that there could not be an implied and unenumerated constitutional right to information about the availability of a service of abortion outside the State which, if availed of, would have the direct consequence of destroying the expressly guaranteed constitutional right to life of the unborn. As part of the submission on this issue it was further suggested that the right to receive and give information which, it was alleged, existed and was material to this case was, though not expressly granted, impliedly referred to or involved in the right of citizens to express freely their convictions and opinions provided by Article 40, s.6, sub-s.1 (i) of the Constitution, since, it was claimed, the right to express freely convictions and opinions may, under some circumstances, involve as an ancillary right the right to obtain information. I am satisfied that no right could constitutionally arise to obtain information the purpose of the obtaining of which was to defeat the constitutional right to life of the unborn child."

20. The court upheld the decision of the High Court to grant an injunction but varied the terms of the order as follows:

"... that the defendants and each of them, their servants or agents be perpetually restrained from assisting pregnant women within the jurisdiction to travel abroad to obtain abortions by

referral to a clinic, by the making for them of travel arrangements, or by informing them of the identity and location of and the method of communication with a specified clinic or clinics or otherwise."

The costs of the Supreme Court appeal were awarded against the applicant companies on 3 May 1988.

21. Following the judgment of the Supreme Court, Open Door, having no assets, ceased its activities.

C. Subsequent legal developments

22. On 25 September 1989 S.P.U.C. applied to the High Court for a declaration that the dissemination in certain student publications of information concerning the identity and location of abortion clinics outside the jurisdiction was unlawful and for an injunction restraining its distribution. Their standing to apply to the courts for measures to protect the right to life of the unborn had previously been recognised by the Supreme Court following a similar action in the case of *Society for the Protection of Unborn Children (Ireland) Ltd v. Coogan and Others* ([1989] Irish Reports, pp. 734-751).

By a judgment of 11 October 1989 the High Court decided to refer certain questions to the European Court of Justice for a preliminary ruling under Article 177 of the EEC Treaty concerning, *inter alia*, the question whether the right to information concerning abortion services outside Ireland was protected by Community law.

23. An appeal was brought against this decision and, on 19 December 1989, the Supreme Court granted an interlocutory injunction restraining the students from "publishing or distributing or assisting in the printing, publishing or distribution of any publication produced under their aegis providing information to persons (including pregnant women) of the identity and location of and the method of communication with a specified clinic or clinics where abortions are performed" (*Society for the Protection of Unborn Children (Ireland) Ltd v. Stephen Grogan and Others*, [1989] Irish Reports, pp. 753-771).

Mr Justice Finlay CJ (with whom Mr Justice Walsh, Mr Justice Griffin and Mr Justice Hederman concurred) considered that the reasoning of the court in the case brought against the applicant companies applied to the activities of the students:

"I reject as unsound the contention that the activity involved in this case of publishing in the students' manuals the name, address and telephone number, when telephoned from this State, of abortion clinics in the United Kingdom, and distributing such manuals in Ireland, can be distinguished from the activity condemned by this Court in [the Open Door Counselling case] on the grounds that the facts of that case were that the information was conveyed during periods of one to one non-directive counselling. It is clearly the fact that such information is conveyed to pregnant women, and not the method of communication which creates the unconstitutional illegality, and the judgment of this Court in the Open Door Counselling case is not open to any other interpretation."

Mr Justice McCarthy also considered that an injunction should be issued and commented as follows:

"In the light of the availability of such information from a variety of sources, such as imported magazines, etc., I am far from satisfied that the granting of an injunction to restrain these defendants from publishing the material impugned would save the life of a single unborn child, but I am more than satisfied that if the courts fail to enforce, and enforce forthwith, that guarantee as construed in *A.G. (S.P.U.C.) v. Open Door Counselling Ltd* ([1988] Irish Reports 593), then the rule of law will be set at naught."

24. In a judgment of 4 October 1991 on the questions referred under Article 177 of the EEC Treaty, following the Supreme Court's judgment, the Court of Justice of the European Communities ruled that the medical termination of pregnancy, performed in accordance with the law of the State in which it is carried out, constitutes a service within the meaning of Article 60 of the Treaty. However it found that the link between the activity of the student associations and medical terminations of pregnancy carried out in clinics in another member State was too tenuous for the prohibition on the distribution of information to be capable of being regarded as a restriction on the freedom to supply services within the meaning of Article 59 of the Treaty. The Court did not examine whether the prohibition was in breach of Article 10 (art. 10) of the Convention. In the light of its conclusions concerning the restriction on services it considered that it had no jurisdiction with regard to national legislation "lying outside the scope of Community law". Accordingly, the restrictions on the publication of information by student associations were not considered to be contrary to Community law (see paragraphs 22-23 above, *Society for the Protection of Unborn Children (Ireland) Ltd v. Stephen Grogan and Others* [1991] European Court Reports I, pp. 4733-4742).

25. The interpretation to be given to Article 40.3.3o of the Constitution also arose before the Supreme Court in the case of *The Attorney General v. X and Others* which concerned an application to the courts by the Attorney General for an injunction to prevent a 14-year-old girl who was pregnant from leaving the jurisdiction to have an abortion abroad. The girl alleged that she had been raped and had expressed the desire to commit suicide. The Supreme Court, in its judgment of 5 March 1992, found that termination of pregnancy was permissible under Article 40.3.3o where it was established as a matter of probability that there was a real and substantial risk to the life of the mother if such termination was not effected. Finding that this test was satisfied on the facts of the case the Supreme Court discharged the injunction which had been granted by the High Court at first instance.

A majority of three judges of the Supreme Court (Finlay CJ, Hederman and Egan JJ.) expressed the view that Article 40.3.3o empowered the courts in proper cases to restrain by injunction a pregnant woman from leaving the jurisdiction to have an abortion so that the right to life of the unborn might be defended and vindicated.

During the oral hearing before the European Court of Human Rights, the Government made the following statement in the light of the Supreme Court's judgment in this case:

"... persons who are deemed to be entitled under Irish law to avail themselves of termination of pregnancy in these circumstances must be regarded as being entitled to have appropriate access to information in relation to the facilities for such operations, either in Ireland or abroad."

D. Evidence presented by the applicants

26. The applicants presented evidence to the Court that there had been no significant drop in the number of Irish women having abortions in Great Britain since the granting of the injunction, that number being well over 3,500 women per year. They also submitted an opinion from an expert in public health (Dr J.R. Ashton) which concludes that there are five possible adverse implications for the health of Irish women arising from the injunction in the present case:

1. An increase in the birth of unwanted and rejected children;
2. An increase in illegal and unsafe abortions;
3. A lack of adequate preparation of Irish women obtaining abortions;

4. Increases in delay in obtaining abortions with ensuing increased complication rates;
5. Poor aftercare with a failure to deal adequately with medical complications and a failure to provide adequate contraceptive advice.

In their written comments to the Court, S.P.U.C. claimed that the number of abortions obtained by Irish women in England, which had been rising rapidly prior to the enactment of Article 40.3.3o, had increased at a much reduced pace. They further submitted that the number of births to married women had increased at a "very substantial rate".

27. The applicants claimed that the impugned information was available in British newspapers and magazines which were imported into Ireland as well as in the yellow pages of the London telephone directory which could be purchased from the Irish telephone service. It was also available in publications such as the British Medical Journal which was obtainable in Ireland.

While not challenging the accuracy of the above information the Government observed that no newspaper or magazine had been produced in evidence to the Court.

II. RELEVANT DOMESTIC LAW AND PRACTICE CONCERNING PROTECTION OF THE UNBORN

A. Constitutional protection

28. Article 40.3.3o of the Irish Constitution (the Eighth Amendment), which came into force in 1983 following a referendum, reads:

"The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right."

This provision has been interpreted by the Supreme Court in the present case, in the *Society for the Protection of Unborn Children (Ireland) Ltd v. Grogan and Others* ([1989] Irish Reports, p. 753) and in *The Attorney General v. X and Others* (see paragraphs 22-25 above).

B. Statutory protection

29. The statutory prohibition of abortion is contained in sections 58 and 59 of the *Offences Against the Person Act 1861*. Section 58 provides that:

"Every woman, being with child, who, with intent to procure her own miscarriage, shall unlawfully administer to herself any poison or other noxious thing or shall unlawfully use any instrument or other means whatsoever with the like intent, and whosoever, with intent to procure the miscarriage of any woman, whether she be or not be with child, shall unlawfully administer to her or cause to be taken by her any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, shall be guilty of a felony, and being convicted thereof shall be liable, [to imprisonment for life] ..."

Section 59 states that:

"Whoever shall unlawfully supply or procure any poison or other noxious thing, or any instrument or thing whatsoever, knowing that the same is intended to be unlawfully used or employed with intent to procure the miscarriage of any woman, whether she be or be not with child, shall be guilty of a misdemeanour, and being convicted thereof, ..."

30. Section 16 of the Censorship of Publications Act 1929 as amended by section 12 of the Health (Family Planning) Act 1979 provides that:

"It shall not be lawful for any person, otherwise than under and in accordance with a permit in writing granted to him under this section

(a) to print or publish or cause or procure to be printed or published, or

(b) to sell or expose, offer or keep for sale or

(c) to distribute, offer or keep for distribution,

any book or periodical publication (whether appearing on the register of prohibited publications or not) which advocates or which might reasonably be supposed to advocate the procurement of abortion or miscarriage or any method, treatment or appliance to be used for the purpose of such procurement."

31. Section 58 of the Civil Liability Act 1961 provides that "the law relating to wrongs shall apply to an unborn child for his protection in like manner as if the child were born, provided the child is subsequently born alive".

32. Section 10 of the Health (Family Planning) Act 1979 re-affirms the statutory prohibition of abortion and states as follows:

"Nothing in this Act shall be construed as authorising -

(a) the procuring of abortion,

(b) the doing of any other thing the doing of which is prohibited by section 58 or 59 of the Offences Against the Person Act, 1861 (which sections prohibit the administering of drugs or the use of any instruments to procure abortion) or,

(c) the sale, importation into the State, manufacture, advertising or display of abortifacients."

C. Case-law

33. Apart from the present case and subsequent developments (see paragraphs 11-25 above), reference has been made to the right to life of the unborn in various decisions of the Supreme Court (see, for example, *McGee v. Attorney General* [1974] Irish Reports, p. 264, *G. v. An Bord Uchtala* [1980] Irish Reports, p. 32, *Norris v. Attorney General* [1984] Irish Reports, p. 36).

34. In the case of *G. v. An Bord Uchtala* (*loc. cit.*) Mr Justice Walsh stated as follows:

"[A child] has the right to life itself and the right to be guarded against all threats directed to its existence, whether before or after birth ... The right to life necessarily implies the right to be born, the right to preserve and defend and to have preserved and defended that life ..."

35. The Supreme Court has also stated that the courts are the custodians of the fundamental rights set out in the Constitution and that their powers in this regard are as ample as the defence of the Constitution requires (*The State (Quinn) v. Ryan* [1965] Irish Reports 70). Moreover, an infringement of a constitutional right by an individual may be actionable in damages as a constitutional tort (*Meskill v. C.I.E.* [1973] Irish Reports, p. 121).

In his judgment in *The People v. Shaw* ([1982] Irish Reports, p. 1), Mr Justice Kenny observed:

"When the People enacted the Constitution of 1937, they provided (Article 40,s.3) that the State guaranteed in its laws to respect, and, as far as practicable, by its laws to defend and vindicate the personal rights of the citizen and that the State should, in particular, by its laws protect as best it might from unjust attack and in the case of injustice done, vindicate the life, person, good name and property rights of every citizen. I draw attention to the use of the words 'the State'. The obligation to implement this guarantee is imposed not on the

Oireachtas only, but on each branch of the State which exercises the powers of legislating, executing and giving judgment on those laws: Article 6. The word 'laws' in Article 40,s.3 is not confined to laws which have been enacted by the Oireachtas, but comprehends the laws made by judges and by ministers of State when they make statutory instruments or regulations."

PROCEEDINGS BEFORE THE COMMISSION

36. In their applications (nos. 14234 and 14235/88) lodged with the Commission on 19 August and 22 September 1988 the applicants complained that the injunction in question constituted an unjustified interference with their right to impart or receive information contrary to Article 10 (art. 10) of the Convention. Open Door, Mrs X and Ms Geraghty further claimed that the restrictions amounted to an interference with their right to respect for private life in breach of Article 8 (art. 8) and, in the case of Open Door, discrimination contrary to Article 14 in conjunction with Articles 8 and 10 (art. 14+8, art. 14+10).

37. The Commission joined the applications on 14 March 1989 and declared the case admissible on 15 May 1990. In its report of 7 March 1991 (Article 31) (art. 31), it expressed the opinion:

- (a) by eight votes to five, that there had been a violation of Article 10 (art. 10) in respect of the Supreme Court injunction as it affected the applicant companies and counsellors;
- (b) by seven votes to six, that there had been a violation of Article 10 (art. 10) in respect of the Supreme Court injunction as it affected Mrs X and Ms Geraghty;
- (c) by seven votes to two, with four abstentions, that it was not necessary to examine further the complaints of Mrs X and Ms Geraghty under Article 8 (art. 8);
- (d) unanimously, that there had been no violation of Articles 8 and 14 (art. 8, art. 14) in respect of Open Door.

The full text of the Commission's opinion and of the seven separate opinions contained in the report is reproduced as an annex to this judgment□.

FINAL SUBMISSIONS MADE TO THE COURT BY THE GOVERNMENT

38. At the public hearing on 24 March 1992 the Government maintained in substance the arguments and submissions set out in their memorial whereby they invited the Court to find that there had been no breach of the Convention.

4.4.3. The law

I. SCOPE OF THE DUBLIN WELL WOMAN CASE

39. In their original application to the Commission Dublin Well Woman and the two counsellors, Ms Maher and Ms Downes, alleged that the Supreme Court injunction constituted an unjustified interference with their right to impart information, in breach of Article 10 (art. 10) of the Convention.

In their pleadings before the Court they further complained that there had also been a breach of Article 8 (art. 8). They had not raised this complaint before the Commission.

40. The scope of the Court's jurisdiction is determined by the Commission's decision declaring the originating application admissible (see, *inter alia*, the *Brogan and Others v. the United Kingdom* judgment of 29 November 1988, Series A no. 145-B, p. 27, para. 46). The Court considers that the applicants are now seeking to raise before the Court a new and separate complaint. As such it has no jurisdiction to entertain it.

II. THE GOVERNMENT'S PRELIMINARY OBJECTIONS

A. Whether Ms Maher, Ms Downes, Mrs X and Ms Geraghty can claim to be "victims" of a violation of the Convention

41. The Government submitted, as they had done before the Commission, that only the corporate applicants could claim to be "victims" of an infringement of their Convention rights. Ms Maher, Ms Downes, Mrs X and Ms Geraghty had not been involved in the proceedings before the Irish courts. Moreover the applicants had failed to identify a single pregnant woman who could claim to be a "victim" of the matters complained of. In this respect the case was in the nature of an *actio popularis*, particularly as regards Mrs X and Ms Geraghty.

1. Ms MahDoneer and Ms Downes

42. The Delegate of the Commission pointed out that the Government's plea as regards the applicant counsellors (Ms Maher and Ms Downes) conflicted with their concession in the pleadings before the Commission that these applicants were subject to the restraint of the Supreme Court injunction and could therefore properly claim to have suffered an interference with their Article 10 (art. 10) rights.

43. The Court agrees with the Commission that Ms Maher and Ms Downes can properly claim to be "victims" of an interference with their rights since they were directly affected by the Supreme Court injunction. Moreover, it considers that the Government are precluded from making submissions as regards preliminary exceptions which are inconsistent with concessions previously made in their pleadings before the Commission (see, *mutatis mutandis*, the *Pine Valley Developments Ltd and Others v. Ireland* judgment of 29 November 1991, Series A no. 222, pp. 21-22, para. 47, and the *Kolompar v. Belgium* judgment of 24 September 1992, Series A no. 235-C, p. 54, para. 32).

2. Mrs X and Ms Geraghty

44. The Court recalls that Article 25 (art. 25) entitles individuals to contend that a law violates their rights by itself, in the absence of an individual measure of implementation, if they run the risk of being directly affected by it (see, *inter alia*, the *Johnston and Others v. Ireland* judgment of 18 December 1986, Series A no. 112, p. 21, para. 42).

In the present case the Supreme Court injunction restrained the corporate applicants and their servants and agents from providing certain information to pregnant women. Although it has not been asserted that Mrs X and Ms Geraghty are pregnant, it is not disputed that they belong to a class of women of child-bearing age which may be adversely affected by the restrictions imposed by the injunction. They are not seeking to challenge in abstracto the compatibility of Irish law with the Convention since they run a risk of being directly prejudiced by the measure complained of. They can thus claim to be "victims" within the meaning of Article 25 para. 1 (art. 25-1).

B. Whether the application complies with the six-month rule

45. At the oral hearing the Government submitted that the application should be rejected under Article 26 (art. 26) for failure to comply with the six-month rule, on the grounds that

the applicants were relying on case-law and arguments which were not raised before the domestic courts.

46. The Court observes that while this plea was made before the Commission (see Appendix II of the Commission's report) it was not re-iterated in the Government's memorial to the Court and was raised solely at the oral hearing. Rule 48 para. 1 of the Rules of Court, however, required them to file it before the expiry of the time-limit laid down for the filing of their memorial, with the result that it must therefore be rejected as being out of time (see, *inter alia*, the *Olsson v. Sweden* judgment of 24 March 1988, Series A no. 130, p. 28, para. 56).

C. Whether the applicants had exhausted domestic remedies

47. In their memorial the Government submitted - as they had also done before the Commission - that domestic remedies had not been exhausted, as required by Article 26 (art. 26), by:

1. Open Door as regards its complaints under Articles 8 and 14 (art. 8, art. 14);
2. both Open Door and Dublin Well Woman in so far as they sought to introduce in their complaint under Article 10 (art. 10) evidence and submissions concerning abortion and the impact of the Supreme Court injunction on women's health that had not been raised before the Irish courts;
3. Ms Maher, Ms Downes, Mrs X and Ms Geraghty on the grounds that they had made no attempt to exhaust domestic remedies under Irish law and that they had not been involved in any capacity in the relevant proceedings before the Irish courts.

48. As regards (1) the Court observes that Open Door would have had no prospect of success in asserting these complaints having regard to the reasoning of the Supreme Court concerning the high level of protection afforded to the right to life of the unborn child under Irish law (see paragraphs 16-25 above).

49. As regards (2) Open Door and Dublin Well Woman are not introducing a fresh complaint in respect of which they have not exhausted domestic remedies. They are merely developing their submissions in respect of complaints which have already been examined by the Irish courts. Article 26 (art. 26) imposes no impediments to applicants in this regard. It is clear from the judgment of the Supreme Court that the applicants had in fact argued that an

injunction would adversely affect women's health and that this submission was rejected (see paragraph 18 above).

50. Finally, as regards (3) it emerges from the judgments of the Supreme Court in the present case and in subsequent cases (see paragraphs 16-25 above) that any action brought by the four individual applicants would have had no prospects of success.

51. Accordingly, the Government's objection based on non-exhaustion of domestic remedies fails.

Conclusion

52. To sum up, the Court is able to take cognisance of the merits of the case as regards all of the applicants.

III. ALLEGED VIOLATION OF ARTICLE 10 (art. 10)

53. The applicants alleged that the Supreme Court injunction, restraining them from assisting pregnant women to travel abroad to obtain abortions, infringed the rights of the corporate applicants and the two counsellors to impart information, as well as the rights of Mrs X and Ms Geraghty to receive information. They confined their complaint to that part of the injunction which concerned the provision of information to pregnant women as opposed to the making of travel arrangements or referral to clinics (see paragraph 20 above). They invoked Article 10 (art. 10) which provides:

"1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers ...

2. The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary."

54. In their submissions to the Court the Government contested these claims and also contended that Article 10 (art. 10) should be interpreted against the background of Articles 2, 17 and 60 (art. 2, art. 17, art. 60) of the Convention the relevant parts of which state:

Article 2 (art. 2)

"1. Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.

..."

Article 17 (art. 17)

"Nothing in [the] Convention may be interpreted as implying for any State, group or person any right to engage in any activity or perform any act aimed at the destruction of any of the rights and freedoms set forth herein or at their limitation to a greater extent than is provided for in the Convention."

Article 60 (art. 60)

"Nothing in [the] Convention shall be construed as limiting or derogating from any of the human rights and fundamental freedoms which may be ensured under the laws of any High Contracting Party or under any other agreement to which it is a Party."

A. Was there an interference with the applicants' rights?

55. The Court notes that the Government accepted that the injunction interfered with the freedom of the corporate applicants to impart information. Having regard to the scope of the injunction which also restrains the "servants or agents" of the corporate applicants from assisting "pregnant women" (see paragraph 20 above), there can be no doubt that there was also an interference with the rights of the applicant counsellors to impart information and with the rights of Mrs X and Ms Geraghty to receive information in the event of being pregnant.

To determine whether such an interference entails a violation of Article 10 (art. 10), the Court must examine whether or not it was justified under Article 10 para. 2 (art. 10-2) by reason of being a restriction "prescribed by law" which was necessary in a democratic society on one or other of the grounds specified in Article 10 para. 2 (art. 10-2).

B. Was the restriction "prescribed by law"?

1. Arguments presented by those appearing before the Court

56. Open Door and Dublin Well Woman submitted that the law was not formulated with sufficient precision to have enabled them to foresee that the non-directive counselling in which they were involved would be restrained by the courts. It was not clear from the wording of Article 40.3.3o of the Constitution (the Eighth Amendment), which gave rise to many difficulties of interpretation and application, that those giving information to pregnant women would be in breach of this provision. In the same way, it was not clear whether it could have been used as a means of prohibiting access to foreign periodicals containing advertisements for abortion facilities abroad or of restricting other activities involving a "threat" to the life of the unborn such as travelling abroad to have an abortion.

In this respect the applicants pointed out that the provision had been criticised at the time of its enactment by both the Attorney General and the Director of Public Prosecutions on the grounds that it was ambiguous and uncertain. Furthermore, although there was an expectation that there would be legislation to clarify the meaning of the provision, none was in fact enacted.

They also maintained that on its face Article 40.3.3o is addressed only to the State and not to private persons. Thus they had no way of knowing that it would apply to non-directive counselling by private agencies. Indeed, since none of Ireland's other laws concerning abortion forbids such counselling or travelling abroad to have an abortion they had good reason to believe that this activity was lawful.

Finally, the insufficient precision of the Eighth Amendment was well reflected in the recent judgment of the Supreme Court of 5 March 1992 in *The Attorney General v. X and Others* which, as conceded by the Government, had the consequence that it would now be lawful to provide information concerning abortion services abroad in certain circumstances (see paragraph 25 above).

In sum, given the uncertain scope of this provision and the considerable doubt as to its meaning and effect, even amongst the most authoritative opinion, the applicants could not have foreseen that such non-directive counselling was unlawful.

57. The Government submitted that the legal position was reasonably foreseeable with appropriate legal advice, within the meaning of the Court's case-law. The applicants ought to have known that an injunction could be obtained against them to protect or defend rights guaranteed by the Constitution, or recognised at common law, or under the principles of the law of equity. Indeed, evidence had now come to light subsequent to the publication of the Commission's report that Dublin Well Woman had actually received legal advice concerning the implications of the wording of the Amendment which warned that a court injunction to restrain their counselling activities was possible (see paragraph 10 in fine above). It was thus not open to the applicants, against this background, to argue that the injunction was unforeseeable.

58. For the Commission, the Eighth Amendment did not provide a clear basis for the applicants to have foreseen that providing information about lawful services abroad would be unlawful. A law restricting freedom of expression across frontiers in such a vital area required particular precision to enable individuals to regulate their conduct accordingly. Since it was not against the criminal law for women to travel abroad to have an abortion, lawyers could reasonably have concluded that the provision of information did not involve a criminal offence. In addition, the Government had been unable to show, with reference to case-law, that the applicant companies could have foreseen that their counselling service was a constitutional tort (see paragraph 35 above). Moreover, the wording of the Amendment suggested that legislation was to have been enacted regulating the protection of the rights of the unborn.

2. Court's examination of the issue

59. This question must be approached by considering not merely the wording of Article 40.3.3o in isolation but also the protection given under Irish law to the rights of the unborn in statute law and in case-law (see paragraphs 28-35 above).

It is true that it is not a criminal offence to have an abortion outside Ireland and that the practice of non-directive counselling of pregnant women did not infringe the criminal law as such. Moreover, on its face the language of Article 40.3.3o appears to enjoin only the State to protect the right to life of the unborn and suggests that regulatory legislation will be introduced at some future stage.

On the other hand, it is clear from Irish case-law, even prior to 1983, that infringement of constitutional rights by private individuals as well as by the State may be actionable (see paragraph 35 above). Furthermore, the constitutional obligation that the State defend and vindicate personal rights "by its laws" has been interpreted by the courts as not being confined merely to "laws" which have been enacted by the Irish Parliament (Oireachtas) but as also comprehending judge-made "law". In this regard the Irish courts, as the custodians of fundamental rights, have emphasised that they are endowed with the necessary powers to ensure their protection (ibid.).

60. Taking into consideration the high threshold of protection of the unborn provided under Irish law generally and the manner in which the courts have interpreted their role as the guarantors of constitutional rights, the possibility that action might be taken against the corporate applicants must have been, with appropriate legal advice, reasonably foreseeable (See the *Sunday Times v. the United Kingdom* judgment of 26 April 1979, Series A no. 30, p. 31, para. 49). This conclusion is reinforced by the legal advice that was actually given to Dublin Well Woman that, in the light of Article 40.3.3o, an injunction could be sought against its counselling activities (see paragraph 10 in fine above).

The restriction was accordingly "prescribed by law".

C. Did the restriction have aims that were legitimate under Article 10 para. 2 (art. 10-2)?

61. The Government submitted that the relevant provisions of Irish law are intended for the protection of the rights of others - in this instance the unborn -, for the protection of morals and, where appropriate, for the prevention of crime.

62. The applicants disagreed, contending inter alia that, in view of the use of the term "everyone" in Article 10 para. 1 (art. 10-1) and throughout the Convention, it would be illogical to interpret the "rights of others" in Article 10 para. 2 (art. 10-2) as encompassing the unborn.

63. The Court cannot accept that the restrictions at issue pursued the aim of the prevention of crime since, as noted above (paragraph 59), neither the provision of the information in question nor the obtaining of an abortion outside the jurisdiction involved any criminal offence. However, it is evident that the protection afforded under Irish law to the right to life of the unborn is based on profound moral values concerning the nature of life which were reflected in the stance of the majority of the Irish people against abortion as expressed in the

1983 referendum (see paragraph 28 above). The restriction thus pursued the legitimate aim of the protection of morals of which the protection in Ireland of the right to life of the unborn is one aspect. It is not necessary in the light of this conclusion to decide whether the term "others" under Article 10 para. 2 (art. 10-2) extends to the unborn.

D. Was the restriction necessary in a democratic society?

64. The Government submitted that the Court's approach to the assessment of the "necessity" of the restraint should be guided by the fact that the protection of the rights of the unborn in Ireland could be derived from Articles 2, 17 and 60 (art. 2, art. 17, art. 60) of the Convention. They further contended that the "proportionality" test was inadequate where the rights of the unborn were at issue. The Court will examine these issues in turn.

1. Article 2 (art. 2)

65. The Government maintained that the injunction was necessary in a democratic society for the protection of the right to life of the unborn and that Article 10 (art. 10) should be interpreted *inter alia* against the background of Article 2 (art. 2) of the Convention which, they argued, also protected unborn life. The view that abortion was morally wrong was the deeply held view of the majority of the people in Ireland and it was not the proper function of the Court to seek to impose a different viewpoint.

66. The Court observes at the outset that in the present case it is not called upon to examine whether a right to abortion is guaranteed under the Convention or whether the foetus is encompassed by the right to life as contained in Article 2 (art. 2). The applicants have not claimed that the Convention contains a right to abortion, as such, their complaint being limited to that part of the injunction which restricts their freedom to impart and receive information concerning abortion abroad (see paragraph 20 above).

Thus the only issue to be addressed is whether the restrictions on the freedom to impart and receive information contained in the relevant part of the injunction are necessary in a democratic society for the legitimate aim of the protection of morals as explained above (see paragraph 63). It follows from this approach that the Government's argument based on Article 2 (art. 2) of the Convention does not fall to be examined in the present case. On the other hand, the arguments based on Articles 17 and 60 (art. 17, art. 60) fall to be considered below (see paragraphs 78 and 79).

2. Proportionality

67. The Government stressed the limited nature of the Supreme Court's injunction which only restrained the provision of certain information (see paragraph 20 above). There was no limitation on discussion in Ireland about abortion generally or the right of women to travel abroad to obtain one. They further contended that the Convention test as regards the proportionality of the restriction was inadequate where a question concerning the extinction of life was at stake. The right to life could not, like other rights, be measured according to a graduated scale. It was either respected or it was not. Accordingly, the traditional approach of weighing competing rights and interests in the balance was inappropriate where the destruction of unborn life was concerned. Since life was a primary value which was antecedent to and a prerequisite for the enjoyment of every other right, its protection might involve the infringement of other rights such as freedom of expression in a manner which might not be acceptable in the defence of rights of a lesser nature.

The Government also emphasised that, in granting the injunction, the Supreme Court was merely sustaining the logic of Article 40.3.3o of the Constitution. The determination by the Irish courts that the provision of information by the relevant applicants assisted in the destruction of unborn life was not open to review by the Convention institutions.

68. The Court cannot agree that the State's discretion in the field of the protection of morals is unfettered and unreviewable (see, *mutatis mutandis*, for a similar argument, the *Norris v. Ireland* judgment of 26 October 1988, Series A no. 142, p. 20, para. 45).

It acknowledges that the national authorities enjoy a wide margin of appreciation in matters of morals, particularly in an area such as the present which touches on matters of belief concerning the nature of human life. As the Court has observed before, it is not possible to find in the legal and social orders of the Contracting States a uniform European conception of morals, and the State authorities are, in principle, in a better position than the international judge to give an opinion on the exact content of the requirements of morals as well as on the "necessity" of a "restriction" or "penalty" intended to meet them (see, *inter alia*, the *Handyside v. the United Kingdom* judgment of 7 December 1976, Series A no. 24, p. 22, para. 48, and the *Müller and Others v. Switzerland* judgment of 24 May 1988, Series A no. 133, p. 22, para. 35).

However this power of appreciation is not unlimited. It is for the Court, in this field also, to supervise whether a restriction is compatible with the Convention.

69. As regards the application of the "proportionality" test, the logical consequence of the Government's argument is that measures taken by the national authorities to protect the right to life of the unborn or to uphold the constitutional guarantee on the subject would be automatically justified under the Convention where infringement of a right of a lesser stature was alleged. It is, in principle, open to the national authorities to take such action as they consider necessary to respect the rule of law or to give effect to constitutional rights. However, they must do so in a manner which is compatible with their obligations under the Convention and subject to review by the Convention institutions. To accept the Government's pleading on this point would amount to an abdication of the Court's responsibility under Article 19 (art. 19) "to ensure the observance of the engagements undertaken by the High Contracting Parties ...".

70. Accordingly, the Court must examine the question of "necessity" in the light of the principles developed in its case-law (see, *inter alia*, the *Observer and Guardian v. the United Kingdom* judgment of 26 November 1991, Series A no. 216, pp. 29-30, para. 59). It must determine whether there existed a pressing social need for the measures in question and, in particular, whether the restriction complained of was "proportionate to the legitimate aim pursued" (*ibid.*).

71. In this context, it is appropriate to recall that freedom of expression is also applicable to "information" or "ideas" that offend, shock or disturb the State or any sector of the population. Such are the demands of that pluralism, tolerance and broadmindedness without which there is no "democratic society" (see, *inter alia*, the above-mentioned *Handyside* judgment, Series A no. 24, p. 23, para. 49).

72. While the relevant restriction, as observed by the Government, is limited to the provision of information, it is recalled that it is not a criminal offence under Irish law for a pregnant woman to travel abroad in order to have an abortion. Furthermore, the injunction limited the freedom to receive and impart information with respect to services which are lawful in other Convention countries and may be crucial to a woman's health and well-being. Limitations on information concerning activities which, notwithstanding their moral implications, have been and continue to be tolerated by national authorities, call for careful scrutiny by the Convention institutions as to their conformity with the tenets of a democratic society.

73. The Court is first struck by the absolute nature of the Supreme Court injunction which imposed a "perpetual" restraint on the provision of information to pregnant women concerning abortion facilities abroad, regardless of age or state of health or their reasons for seeking counselling on the termination of pregnancy. The sweeping nature of this restriction has since been highlighted by the case of *The Attorney General v. X and Others* and by the concession made by the Government at the oral hearing that the injunction no longer applied to women who, in the circumstances as defined in the Supreme Court's judgment in that case, were now free to have an abortion in Ireland or abroad (see paragraph 25 above).

74. On that ground alone the restriction appears over broad and disproportionate. Moreover, this assessment is confirmed by other factors.

75. In the first place, it is to be noted that the corporate applicants were engaged in the counselling of pregnant women in the course of which counsellors neither advocated nor encouraged abortion, but confined themselves to an explanation of the available options (see paragraphs 13 and 14 above). The decision as to whether or not to act on the information so provided was that of the woman concerned. There can be little doubt that following such counselling there were women who decided against a termination of pregnancy. Accordingly, the link between the provision of information and the destruction of unborn life is not as definite as contended. Such counselling had in fact been tolerated by the State authorities even after the passing of the Eighth Amendment in 1983 until the Supreme Court's judgment in the present case. Furthermore, the information that was provided by the relevant applicants concerning abortion facilities abroad was not made available to the public at large.

76. It has not been seriously contested by the Government that information concerning abortion facilities abroad can be obtained from other sources in Ireland such as magazines and telephone directories (see paragraphs 23 and 27 above) or by persons with contacts in Great Britain. Accordingly, information that the injunction sought to restrict was already available elsewhere although in a manner which was not supervised by qualified personnel and thus less protective of women's health. Furthermore, the injunction appears to have been largely ineffective in protecting the right to life of the unborn since it did not prevent large numbers of Irish women from continuing to obtain abortions in Great Britain (see paragraph 26 above).

77. In addition, the available evidence, which has not been disputed by the Government, suggests that the injunction has created a risk to the health of those women who are now seeking abortions at a later stage in their pregnancy, due to lack of proper counselling, and

who are not availing themselves of customary medical supervision after the abortion has taken place (see paragraph 26 above). Moreover, the injunction may have had more adverse effects on women who were not sufficiently resourceful or had not the necessary level of education to have access to alternative sources of information (see paragraph 76 above). These are certainly legitimate factors to take into consideration in assessing the proportionality of the restriction.

3. Articles 17 and 60 (art. 17, art. 60)

78. The Government, invoking Articles 17 and 60 (art. 17, art. 60) of the Convention, have submitted that Article 10 (art. 10) should not be interpreted in such a manner as to limit, destroy or derogate from the right to life of the unborn which enjoys special protection under Irish law.

79. Without calling into question under the Convention the regime of protection of unborn life that exists under Irish law, the Court recalls that the injunction did not prevent Irish women from having abortions abroad and that the information it sought to restrain was available from other sources (see paragraph 76 above). Accordingly, it is not the interpretation of Article 10 (art. 10) but the position in Ireland as regards the implementation of the law that makes possible the continuance of the current level of abortions obtained by Irish women abroad.

4. Conclusion

80. In the light of the above, the Court concludes that the restraint imposed on the applicants from receiving or imparting information was disproportionate to the aims pursued. Accordingly there has been a breach of Article 10 (art. 10).

IV. ALLEGED VIOLATIONS OF ARTICLES 8 AND 14 (art. 8, art. 14)

81. Open Door also alleged a violation of the right to respect for private life contrary to Article 8 (art. 8) claiming that it should be open to it to complain of an interference with the privacy rights of its clients. Similarly, Mrs X and Ms Geraghty complained under this provision that the denial to them of access to information concerning abortion abroad constituted an unjustifiable interference with their right to respect for private life.

Open Door further claimed discrimination contrary to Article 14 in conjunction with Article 8 (art. 14+8) alleging that the injunction discriminated against women since men were not denied information "critical to their reproductive and health choices". It also invoked Article

14 in conjunction with Article 10 (art. 14+10) claiming discrimination on the grounds of political or other opinion since those who seek to counsel against abortion are permitted to express their views without restriction.

82. The applicants in the Dublin Well Woman case, in their memorial to the Court, similarly complained of discrimination contrary to Article 14, firstly, in conjunction with Article 8 (art. 14+8) on the same basis as Open Door, and secondly, in conjunction with Article 10 (art. 14+10) on the grounds that it followed from the decision of the Court of Justice of the European Communities in the Grogan case (see paragraph 24 above) that, had Dublin Well Woman been an "economic operator", they would have been permitted to distribute and receive such information.

83. The Court notes that the complaints of discrimination made by the applicants in Dublin Well Woman were made for the first time in the proceedings before the Court and that consequently it may be questioned whether it has jurisdiction to examine them (see paragraph 40 above). However, having regard to its finding that there had been a breach of Article 10 (art. 10) (see paragraph 80 above) the Court considers that it is not necessary to examine either these complaints or those made by Open Door, Mrs X and Ms Geraghty.

V. APPLICATION OF ARTICLE 50 (art. 50)

84. Article 50 (art. 50) provides as follows:

"If the Court finds that a decision or a measure taken by a legal authority or any other authority of a High Contracting Party is completely or partially in conflict with the obligations arising from the ... Convention, and if the internal law of the said Party allows only partial reparation to be made for the consequences of this decision or measure, the decision of the Court shall, if necessary, afford just satisfaction to the injured party."

A. Damage

85. Open Door made no claim for compensation for damage. Dublin Well Woman, on the other hand, claimed pecuniary damages amounting to IR£62,172 in respect of loss of income for the period January 1987 to June 1988 due to the discontinuance of the pregnancy counselling service.

86. The Government submitted that the claim should be rejected. In particular, they contended that it was made belatedly; that it was inconsistent with Dublin Well Woman's status as a non-profit-making company to claim pecuniary damage and was excessive.

87. The Court notes that the claim was made on 24 February 1992 and thus well in advance of the hearing of the case on 24 March 1992. Furthermore, it considers that even a non-profit-making company such as the applicant can incur losses for which it should be compensated.

The Government have submitted that it was unclear on what basis or in what manner the sum of IR£62,172 was computed and Dublin Well Woman has not indicated how these losses were calculated or sought to substantiate them. Nevertheless, the discontinuance of the counselling service must have resulted in a loss of income. Having regard to equitable considerations as required by Article 50 (art. 50), the Court awards IR£25,000 under this head.

B. Costs and expenses

1. Open Door

88. Open Door claimed the sum of IR£68,985.75 referable to both the national proceedings and to those before the Convention institutions. This sum did not take into account what had been received by way of legal aid from the Council of Europe in respect of fees. On 1 May 1992 Mr Cole, a lawyer who had appeared on behalf of Open Door, filed a supplementary claim for US\$24,300 on behalf of the Centre for Constitutional Rights.

89. The Government considered the claim made by Open Door to be reasonable.

90. The Court observes that the claim made by Open Door includes an amount for the services of Mr Cole of the Centre for Constitutional Rights. It rejects his supplementary claim on behalf of the Centre for Constitutional Rights which was not itself a party to the proceedings. However, it allows Open Door's uncontested claim less 6,900 French francs paid by way of legal aid in respect of fees.

2. Dublin Well Woman

91. Dublin Well Woman claimed a total sum of IR£63,302.84 for costs and expenses incurred in the national proceedings. They further claimed IR£21,084.95 and IR£27,116.30 in respect of proceedings before the Commission and the Court. These sums did not take into account what had been received by way of legal aid in respect of fees and expenses.

92. The Government accepted that the claims for domestic costs were reasonable. However they submitted that, in the light of the claim made by Open Door, IR£16,000 and IR£19,000 were more appropriate sums for the proceedings before the Commission and Court.

93. The Court also considers that the amount claimed in respect of the proceedings before the Commission and Court is excessive taking into account the fees claimed by Open Door and the differences between the two applications. It holds that Dublin Well Woman should be awarded IR£100,000 under this head less 52,577 French francs already paid by way of legal aid in respect of fees and expenses.

94. The amounts awarded in this judgment are to be increased by any value-added tax that may be chargeable.

4.4.4. The Court's decision

1. Dismisses by fifteen votes to eight the Government's plea that Mrs X and Ms Geraghty cannot claim to be victims of a violation of the Convention;

2. Dismisses unanimously the remainder of the Government's preliminary objections;

3. Holds by fifteen votes to eight that there has been a violation of Article 10⁵⁰ (art. 10);

4. Holds unanimously that it is not necessary to examine the remaining complaints;

5. Holds by seventeen votes to six that Ireland is to pay to Dublin Well Woman, within three months, IR£25,000 (twenty-five thousand Irish pounds) in respect of damages;

6. Holds unanimously that Ireland is to pay to Open Door and Dublin Well Woman, within three months, in respect of costs and expenses, the sums resulting from the calculation to be made in accordance with paragraphs 90, 93 and 94 of the judgment;

7. Dismisses unanimously the remainder of the claims for just satisfaction.

¹ Article 49

Within the framework of the provisions set out below, restrictions on freedom to provide services within the Community shall be prohibited in respect of nationals of Member States who are established in a State of the Community other than that of the person for whom the services are intended. The Council may, acting by a qualified majority on a proposal from the Commission, extend the provisions of the Chapter to nationals of a third country who provide services and who are established within the Community

² Article 22

Stay outside the competent State - Return to or transfer of residence to another Member State during sickness or maternity - Need to go to another Member State in order to receive appropriate treatment

1. A worker who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:

(a) whose condition necessitates immediate benefits during a stay in the territory of another Member State, or
(b) who, having become entitled to benefits chargeable to the competent institution, is authorised by that institution to return to the territory of the Member State where he resides, or to transfer his residence to the territory of another Member State, or

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition, shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed however by the legislation of the competent State;

(ii) to cash benefits provided by the competent institution in accordance with the legislation which it administers. However, by agreement between the competent institution and the institution of the place of stay or residence, such benefits may be provided by the latter institution on behalf of the former, in accordance with the legislation of the competent State.

2. The authorisation required under paragraph 1 (b) may be refused only if it is established that movement of the person concerned would be prejudicial to his state of health or the receipt of medical treatment.

The authorisation required under paragraph 1 (c) may not be refused where the treatment in question cannot be provided for the person concerned within the territory of the Member State in which he resides.

3. The provisions of paragraphs 1 and 2 shall apply to members of a worker's family in respect of benefits in kind.

4. The fact that the provisions of paragraph 1 apply to a worker shall not affect the right to benefit of members of his family.

³ Section 43

1. The right to health protection is recognised.
2. It is incumbent upon the public authorities to organize and watch over public health by means of preventive measures and the necessary benefits and services. The law shall establish the rights and duties of all in this respect.
3. The public authorities shall foster health education, physical education and sports. Likewise, they shall encourage the proper use of leisure time.

⁴ Article 34

Content of periodic safety update reports

1. The periodic safety update report shall be based on all available data and shall focus on new information which has emerged since the data lock point of the last periodic safety update report.
2. The periodic safety update report shall provide an accurate estimate of the population exposed to the medicinal product, including all data relating to the volume of sales and volume of prescriptions. This estimate of exposure shall be accompanied by a qualitative and quantitative analysis of actual use, which shall indicate, where appropriate, how actual use differs from the indicated use based on all data available to the marketing authorisation holder, including the results of observational or drug utilisation studies.
L 159/16 Official Journal of the European Union 20.6.2012 EN3. The periodic safety update report shall contain the results of assessments of the effectiveness of risk minimisation activities relevant to the risk-benefit assessment.
4. Marketing authorisation holders shall not be required to include systematically detailed listings of individual cases, including case narratives, in the periodic safety update report. However, they shall provide case narratives in the relevant risk evaluation section of the periodic safety update report where integral to the scientific analysis of a signal or safety concern in the relevant risk evaluation section.
5. Based on the evaluation of the cumulative safety data and the risk-benefit analysis, the marketing authorisation holder shall draw conclusions in the periodic safety update report as to the need for changes and/or actions, including implications for the approved summary of product characteristics for the product(s) for which the periodic safety update report is submitted.
6. Unless otherwise specified in the list of Union reference dates and frequency of submission referred to in Article 107c of Directive 2001/83/EC or agreed with the national competent authorities or the Agency, as appropriate, a single periodic safety update report shall be prepared for all medicinal products containing the same active substance and authorised for one marketing authorisation holder. The periodic safety update report shall cover all indications, routes of administration, dosage forms and dosing regimens, irrespective of whether authorised under different names and through separate procedures. Where relevant, data relating to a particular indication, dosage form, route of administration or dosing regimen shall be presented in a separate section of the periodic safety update report and any safety concerns shall be addressed accordingly.
7. Unless otherwise specified in the list of Union reference dates and frequency of submission referred to in Article 107c of Directive 2001/83/EC, if the substance that is the subject of the periodic safety update report is also authorised as a component of a fixed combination medicinal product, the marketing authorisation holder shall either submit a separate periodic safety update report for the combination of active substances authorised for the same marketing authorisation holder, with cross-references to the single-substance periodic safety update report(s), or provide the combination data within one of the single-substance periodic safety update reports.

⁵ Article 38

1. An application of the kind referred to in Article 21 of the Statute shall state:
 - (a) the name and address of the applicant;
 - (b) the designation of the party against whom the application is made;
 - (c) the subject-matter of the proceedings and a summary of the pleas in law on which the application is based;
 - (d) the form of order sought by the applicant;
 - (e) where appropriate, the nature of any evidence offered in support.

⁶ Article 226

If the Commission considers that a Member State has failed to fulfil an obligation under this Treaty, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its

observations. If the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice.

⁷ Article 69

1. A decision as to costs shall be given in the final judgment or in the order which closes the proceedings.
2. The unsuccessful party shall be ordered to pay the costs if they have been applied for in the successful party's pleadings. Where there are several unsuccessful parties the Court shall decide how the costs are to be shared.
3. Where each party succeeds on some and fails on other heads, or where the circumstances are exceptional, the Court may order that the costs be shared or that the parties bear their own costs. The Court may order a party, even if successful, to pay costs which the Court considers that party to have unreasonably or vexatiously caused the opposite party to incur.
4. The Member States and institutions which intervene in the proceedings shall bear their own costs. The States, other than the Member States, which are parties to the EEA Agreement, and also the EFTA Surveillance Authority, shall bear their own costs if they intervene in the proceedings. The Court may order an intervener other than those mentioned in the preceding subparagraphs to bear his own costs.
5. A party who discontinues or withdraws from proceedings shall be ordered to pay the costs if they have been applied for in the other party's observations on the discontinuance. However, upon application by the party who discontinues or withdraws from proceedings, the costs shall be borne by the other party if this appears justified by the conduct of that party. Where the parties have come to an agreement on costs, the decision as to costs shall be in accordance with that agreement. If costs are not claimed, the parties shall bear their own costs.
6. Where a case does not proceed to judgment the costs shall be in the discretion of the Court.

⁸ Article 234

The Court of Justice shall have jurisdiction to give preliminary rulings concerning:

- (a) the interpretation of this Treaty;
- (b) the validity and interpretation of acts of the institutions of the Community and of the ECB;
- (c) the interpretation of the statutes of bodies established by an act of the Council, where those statutes so provide. Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a decision on the question is necessary to enable it to give judgment, request the Court of Justice to give a ruling thereon. 29.12.2006 EN Official Journal of the European Union C 321 E/147 Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court of Justice.

⁹ Article 36

1. Without prejudice to the provisions of Article 32, benefits in kind provided pursuant to this Chapter by the institution of one Member State on behalf of the institution of another Member State shall be fully refunded.

2. The refunds referred to in paragraph 1 shall be determined and made in accordance with the procedure provided for by the implementing regulation referred to in Article 97, either on production of proof of actual expenditure or on the basis of lump-sum payments.

In the latter case, the lump-sum payments shall be such as to ensure that the refund is as close as possible to actual expenditure.

3. Two or more Member States, or the competent authorities of those States, may provide for other methods of reimbursement or may waive all reimbursement between institutions under their jurisdiction.

¹⁰ Article 177

1. Community policy in the sphere of development cooperation, which shall be complementary to the policies pursued by the Member States, shall foster:

— the sustainable economic and social development of the developing countries, and more particularly the most disadvantaged among them,

29.12.2006 EN Official Journal of the European Union C 321 E/125 — the smooth and gradual integration of the developing countries into the world economy,

— the campaign against poverty in the developing countries.

2. Community policy in this area shall contribute to the general objective of developing and consolidating democracy and the rule of law, and to that of respecting human rights and fundamental freedoms.

3. The Community and the Member States shall comply with the commitments and take account of the objectives they have approved in the context of the United Nations and other competent international organisations.

¹¹ Article 59

Where an appeal is brought against a decision of the Court of First Instance, the procedure before the Court of Justice shall consist of a written part and an oral part. In accordance with conditions laid down in the Rules of Procedure, the Court of Justice, having heard the Advocate-General and the parties, may dispense with the oral procedure.

¹² Article 60

Without prejudice to Articles 242 and 243 of the EC Treaty or Articles 157 and 158 of the EAEC Treaty, an appeal shall not have suspensory effect.

By way of derogation from Article 244 of the EC Treaty and Article 159 of the EAEC Treaty, decisions of the Court of First Instance declaring a regulation to be void shall take effect only as from the date of expiry of the period referred to in the first paragraph of Article 56 of this Statute or, if an appeal shall have been brought within that period, as from the date of dismissal of the appeal, without prejudice, however, to the right of a party to apply to the Court of Justice, pursuant to Articles 242 and 243 of the EC Treaty or Articles 157 and 158 of the EAEC Treaty, for the suspension of the effects of the regulation which has been declared void or for the prescription of any other interim measure.

¹³ Article 56

An appeal may be brought before the Court of Justice, within two months of the notification of the decision appealed against, against final decisions of the Court of First Instance and decisions of that Court disposing of the substantive issues in part only or disposing of a procedural issue concerning a plea of lack of competence or inadmissibility. Such an appeal may be brought by any party which has been unsuccessful, in whole or in part, in its submissions. However, interveners other than the Member States and the institutions of the Communities may bring such an appeal only where the decision of the Court of First Instance directly affects them. With the exception of cases relating to disputes between the Communities and their servants, an appeal may also be brought by Member States and institutions of the Communities which did not intervene in the proceedings before the Court of First Instance. Such Member States and institutions shall be in the same position as Member States or institutions which intervened at first instance.

¹⁴ Article 66

The Council, acting in accordance with the procedure referred to in Article 67, shall take measures to ensure cooperation between the relevant departments of the administrations of the Member States in the areas covered by this title, as well as between those departments and the Commission

¹⁵ The provisions of the Chapter relating to rules on competition shall apply to production of and trade in agricultural products only to the extent determined by the Council within the framework of Article 37(2) and (3) and in accordance with the procedure laid down therein, account being taken of the objectives set out in Article 33. The Council may, in particular, authorise the granting of aid: (a) for the protection of enterprises handicapped by structural or natural conditions; (b) within the framework of economic development programmes.

¹⁶ Article 177

1. Community policy in the sphere of development cooperation, which shall be complementary to the policies pursued by the Member States, shall foster:

- the sustainable economic and social development of the developing countries, and more particularly the most disadvantaged among them, 29.12.2006 EN Official Journal of the European Union C 321 E/125— the smooth and gradual integration of the developing countries into the world economy,
- the campaign against poverty in the developing countries.

2. Community policy in this area shall contribute to the general objective of developing and consolidating democracy and the rule of law, and to that of respecting human rights and fundamental freedoms.

3. The Community and the Member States shall comply with the commitments and take account of the objectives they have approved in the context of the United Nations and other competent international organisations.

¹⁷ Article 30

The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

¹⁸ Article 50

Services shall be considered to be 'services' within the meaning of this Treaty where they are normally provided for remuneration, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital and persons.

'Services' shall in particular include:

- (a) activities of an industrial character;
- (b) activities of a commercial character;
- (c) activities of craftsmen;
- (d) activities of the professions.

Without prejudice to the provisions of the Chapter relating to the right of establishment, the person providing a service may, in order to do so, temporarily pursue his activity in the State where the service is provided, under the same conditions as are imposed by that State on its own nationals.

¹⁹ Article 51

1. Freedom to provide services in the field of transport shall be governed by the provisions of the title relating to transport.
2. The liberalisation of banking and insurance services connected with movements of capital shall be effected in step with the liberalisation of movement of capital.

²⁰ Article 34

General provision

The provisions of Articles 27 to 33 shall not apply to a pensioner or to members of his family who are entitled to benefits in kind under the legislation of a Member State as a result of pursuing a professional or trade activity. In such a case the person concerned shall for the purposes of this Chapter, be considered as a worker or as a member of a worker's family.

²¹ Article 46

1. The provisions of this Chapter and measures taken in pursuance thereof shall not prejudice the applicability of provisions laid down by law, regulation or administrative action providing for special treatment for foreign nationals on grounds of public policy, public security or public health.
2. The Council shall, acting in accordance with the procedure referred to in Article 251, issue directives for the coordination of the abovementioned provisions.

²² Article 152

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities. Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education. The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. C 321 E/114 EN Official Journal of the European Union 29.12.2006 Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.

The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

²³ Patentable inventions

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

(3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

²⁴ Article 53

Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

²⁶ Article 22

Enlarged Board of Appeal

(1) The Enlarged Board of Appeal shall be responsible for:

(a) deciding points of law referred to it by Boards of Appeal;

(b) giving opinions on points of law referred to it by the President of the European Patent Office under the conditions laid down in Article 112.

(2) For giving decisions or opinions, the Enlarged Board of Appeal shall consist of five legally qualified members and two technically qualified members. One of the legally qualified members shall be the Chair-man.

²⁷ Article 5

The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein. In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community. Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty.

²⁸ Article 85

1. Without prejudice to Article 84, the Commission shall ensure the application of the principles laid down in Articles 81 and 82. On application by a Member State or on its own initiative, and in cooperation with the competent authorities in the Member States, which shall give it their assistance, the Commission shall investigate cases of suspected infringement of these principles. If it finds that there has been an infringement, it shall propose appropriate measures to bring it to an end.

2. If the infringement is not brought to an end, the Commission shall record such infringement of the principles in a reasoned decision. The Commission may publish its decision and authorise Member States to take the measures, the conditions and details of which it shall determine, needed to remedy the situation.

²⁹ Article 86

1. In the case of public undertakings and undertakings to which Member States grant special or exclusive rights, Member States shall neither enact nor maintain in force any measure contrary to the rules contained in this Treaty, in particular to those rules provided for in Article 12 and Articles 81 to 89.

2. Undertakings entrusted with the operation of services of general economic interest or having the character of a revenue-producing monopoly shall be subject to the rules contained in this Treaty, in particular to the rules on competition, in so far as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them. The development of trade must not be affected to such an extent as would be contrary to the interests of the Community.

3. The Commission shall ensure the application of the provisions of this Article and shall, where necessary, address appropriate directives or decisions to Member States.

³⁰ Article 249

In order to carry out their task and in accordance with the provisions of this Treaty, the European Parliament acting jointly with the Council, the Council and the Commission shall make regulations and issue directives, take decisions, make recommendations or deliver opinions. A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States. A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. A decision shall be binding in its entirety upon those to whom it is addressed.

Recommendations and opinions shall have no binding force.

³¹ Article 43

Within the framework of the provisions set out below, restrictions on the freedom of establishment of nationals of a Member State in the territory of another Member State shall be prohibited. Such prohibition shall also apply to restrictions on the setting-up of agencies, branches or subsidiaries by nationals of any Member State established in the territory of any Member State. Freedom of establishment shall include the right to take up and pursue activities as self-employed persons and to set up and manage undertakings, in particular companies or firms within the meaning of the second paragraph of Article 48, under the conditions laid down for its own nationals by the law of the country where such establishment is effected, subject to the provisions of the Chapter relating to capital.

³² ARTICLE 34

Individual applications

The Court may receive applications from any person, nongovernmental organisation or group of individuals claiming to be the victim of a violation by one of the High Contracting Parties of the rights set forth in the Convention or the Protocols thereto. The High Contracting Parties undertake not to hinder in any way the effective exercise of this right.

³³ Rule 47

Contents of an individual application

1. Any application under Article 34 of the Convention shall be made on the application form provided by the Registry, unless the President of the Section concerned decides otherwise. It shall set out

- (a) the name, date of birth, nationality, sex, occupation and address of the applicant;
- (b) the name, occupation and address of the representative, if any;

1. As amended by the Court on 17 June and 8 July 2002, 11 December 2007 and 22 September 2008. Rules of Court – 1 September 2012

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- (c) the name of the Contracting Party or Parties against which the application is made;
- (d) a succinct statement of the facts;
- (e) a succinct statement of the alleged violation(s) of the Convention and the relevant arguments;
- (f) a succinct statement on the applicant's compliance with the admissibility criteria (exhaustion of domestic remedies and the six-month rule) laid down in Article 35 § 1 of the Convention; and
- (g) the object of the application; and be accompanied by
- (h) copies of any relevant documents and in particular the decisions, whether judicial or not, relating to the object of the application.

2. Applicants shall furthermore

- (a) provide information, notably the documents and decisions referred to in paragraph 1 (h) of this Rule, enabling it to be shown that the admissibility criteria (exhaustion of domestic remedies and the six-month rule) laid down in Article 35 § 1 of the Convention have been satisfied; and
- (b) indicate whether they have submitted their complaints to any other procedure of international investigation or settlement.

3. Applicants who do not wish their identity to be disclosed to the public shall so indicate and shall submit a statement of the reasons justifying such a departure from the normal rule of public access to information in proceedings before the Court. The President of the Chamber may authorise anonymity or grant it of his or her own motion.

4. Failure to comply with the requirements set out in paragraphs 1 and 2 of this Rule may result in the application not being examined by the Court.

5. The date of introduction of the application for the purposes of Article 35 § 1 of the Convention shall as a general rule be considered to be the date of the first communication from the applicant setting out, even summarily, the subject matter of the application, provided that a duly completed application form has been submitted within the time-limits laid down by the Court. The Court may for good cause nevertheless decide that a different date shall be considered to be the date of introduction.

6. Applicants shall keep the Court informed of any change of address and of all circumstances relevant to the application.

³⁴ Rule 52

Assignment of applications to the Sections

1. Any application made under Article 34 of the Convention shall be assigned to a Section by the President of the Court, who in so doing shall endeavour to ensure a fair distribution of cases between the Sections.

2. The Chamber of seven judges provided for in Article 26 § 1 of the Convention shall be constituted by the President of the Section concerned in accordance with Rule 26 § 1.

3. Pending the constitution of a Chamber in accordance with paragraph 2 of this Rule, the President of the Section shall exercise any powers conferred on the President of the Chamber by these Rules.

³⁵ ARTICLE 36

Third party intervention

1. In all cases before a Chamber or the Grand Chamber, a High Contracting Party one of whose nationals is an applicant shall have the right to submit written comments and to take part in hearings.

2. The President of the Court may, in the interest of the proper administration of justice, invite any High Contracting Party which is not a party to the proceedings or any person concerned who is not the applicant to submit written comments or take part in hearings.

3. In all cases before a Chamber or the Grand Chamber, the Council of Europe Commissioner for Human Rights may submit written comments and take part in hearings.

³⁶ Rule 44

Third-party intervention

1. (a) When notice of an application lodged under Article 33 or 34 of the Convention is given to the respondent Contracting Party under Rules 51 § 1 or 54 § 2 (b), a copy of the application shall at the same time be transmitted by the Registrar to any other Contracting Party one of whose nationals is an applicant in the case. The Registrar shall similarly notify any such Contracting Party of a decision to hold an oral hearing in the case.

1. As amended by the Court on 17 June and 8 July 2002, 7 July 2003, 13 November 2006 and 2 April 2012.

2. As amended by the Court on 7 July 2003 and 13 November 2006. Rules of Court – 1 September 2012 23 (b) If a Contracting Party wishes to exercise its right under Article 36 § 1 of the Convention to submit written comments or to take part in a hearing, it shall so advise the Registrar in writing not later than twelve weeks after the transmission or notification referred to in the preceding sub-paragraph. Another time-limit may be fixed by the President of the Chamber for exceptional reasons.

2. If the Council of Europe Commissioner for Human Rights wishes to exercise the right under Article 36 § 3 of the Convention to submit written observations or take part in a hearing, he or she shall so advise the Registrar in writing not later than twelve weeks after transmission of the application to the respondent Contracting Party or notification to it of the decision to hold an oral hearing. Another time-limit may be fixed by the President of the Chamber for exceptional reasons. Should the Commissioner for Human Rights be unable to take part in the proceedings before the Court himself, he or she shall indicate the name of the person or persons from his or her Office whom he or she has appointed to represent him. He or she may be assisted by an advocate.

3. (a) Once notice of an application has been given to the respondent Contracting Party under Rules 51 § 1 or 54 § 2 (b), the President of the Chamber may, in the interests of the proper administration of justice, as provided in Article 36 § 2 of the Convention, invite, or grant leave to, any Contracting Party which is not a party to the proceedings, or any person concerned who is not the applicant, to submit written comments or, in exceptional cases, to take part in a hearing.

(b) Requests for leave for this purpose must be duly reasoned and submitted in writing in one of the official languages as provided in Rule 34 § 4 not later than twelve weeks after notice of the application has been given to the respondent Contracting Party. Another time-limit may be fixed by the President of the Chamber for exceptional reasons.

4. (a) In cases to be considered by the Grand Chamber, the periods of time prescribed in the preceding paragraphs shall run from the notification to the parties of the decision of the Chamber under Rule 72 § 1 to relinquish jurisdiction in favour of the Grand Chamber or of the decision of the panel of the Grand Chamber under Rule 73 § 2 to accept a request by a party for referral of the case to the Grand Chamber.

(b) The time-limits laid down in this Rule may exceptionally be extended by the President of the Chamber if sufficient cause is shown.

5. Any invitation or grant of leave referred to in paragraph 3 (a) of this Rule shall be subject to any conditions, including time-limits, set by the President of the Chamber. Where such conditions are not complied with, the President may decide not to include the comments in the case file or to limit participation in the hearing to the extent that he or she considers appropriate.

6. Written comments submitted under this Rule shall be drafted in one of the official languages as provided in Rule 34 § 4. They shall be forwarded by the Registrar to the parties to the case, who shall be entitled, subject to any conditions, including time-limits, set by the President of the Chamber, to file written observations in reply or, where appropriate, to reply at the hearing.

³⁷ ARTICLE 30

Relinquishment of jurisdiction to the Grand Chamber Where a case pending before a Chamber raises a serious question affecting the interpretation of the Convention or the Protocols thereto, or where the resolution of a question before the Chamber might have a result inconsistent with a judgment previously delivered by the Court, the Chamber may, at any time before it has rendered its judgment, relinquish jurisdiction in favour of the Grand Chamber, unless one of the parties to the case objects.

³⁸ Rule 72 – Relinquishment of jurisdiction by a Chamber in favour of the Grand Chamber

1. In accordance with Article 30 of the Convention, where a case pending before a Chamber raises a serious question affecting the interpretation of the Convention or the Protocols thereto or where the resolution of a question before it might have a result inconsistent with a judgment previously delivered by the Court, the Chamber may, at any time before it has rendered its judgment, relinquish jurisdiction in favour of the Grand Chamber, unless one of the parties to the case has objected in accordance with paragraph 2 of this Rule. Reasons need not be given for the decision to relinquish.

2. The Registrar shall notify the parties of the Chamber's intention to relinquish jurisdiction. The parties shall have one month from the date of that notification within which to file at the Registry a duly reasoned objection. An objection which does not fulfil these conditions shall be considered invalid by the Chamber.

³⁹ ARTICLE 27

Competence of single judges

1. A single judge may declare inadmissible or strike out of the Court's list of cases an application submitted under Article 34, where such a decision can be taken without further examination.

2. The decision shall be final. 18 19

3. If the single judge does not declare an application inadmissible or strike it out, that judge shall forward it to a committee or to a Chamber for further examination.

⁴⁰ Rule 24

Composition of the Grand Chamber

1. The Grand Chamber shall be composed of seventeen judges and at least three substitute judges.

2. (a) The Grand Chamber shall include the President and the Vice-Presidents of the Court and the Presidents of the Sections. Any Vice-President of the Court or President of a Section who is unable to sit as a member of the Grand Chamber shall be replaced by the Vice-President of the relevant Section.

(b) The judge elected in respect of the Contracting Party concerned or, where appropriate, the judge designated by virtue of Rule 29 or Rule 30 shall sit as an ex officio member of the Grand Chamber in accordance with Article 26 §§ 4 and 5 of the Convention.

(c) In cases referred to the Grand Chamber under Article 30 of the Convention, the Grand Chamber shall also include the members of the Chamber which relinquished jurisdiction.

(d) In cases referred to it under Article 43 of the Convention, the Grand Chamber shall not include any judge who sat in the Chamber which rendered the judgment in the case so referred, with the exception of the President of that Chamber and the judge who sat in respect of the State Party concerned, or any judge who sat in the Chamber or Chambers which ruled on the admissibility of the application.

(e) The judges and substitute judges who are to complete the Grand Chamber in each case referred to it shall be designated from among the remaining judges by a drawing of lots by the President of the Court in the presence of the Registrar. The modalities for the drawing of lots shall be laid down by the Plenary Court, having due regard to the need for a geographically balanced composition reflecting the different legal systems among the Contracting Parties.

(f) In examining a request for an advisory opinion under Article 47 of the Convention, the Grand Chamber shall be constituted in accordance with the provisions of paragraph 2

(a) and (e) of this Rule.

(g) In examining a request under Article 46 § 4 of the Convention, the Grand Chamber shall include, in addition to the judges referred to in paragraph 2 (a) and (b) of this Rule, the members of the Chamber or Committee which rendered the judgment in the case concerned. If the judgment was rendered by a Grand Chamber, the Grand Chamber shall be constituted as the original Grand Chamber. In all cases, including those where it is not possible to reconstitute the original Grand Chamber, the judges and substitute judges who are to complete the Grand Chamber shall be designated in accordance with paragraph 2 (e) of this Rule.

3. If any judges are prevented from sitting, they shall be replaced by the substitute judges in the order in which the latter were selected under paragraph 2 (e) of this Rule.

4. The judges and substitute judges designated in accordance with the above provisions shall continue to sit in the Grand Chamber for the consideration of the case until the

1. As amended by the Court on 8 December 2000, 13 December 2004, 4 July and 7 November 2005 and 29 May and 13 November 2006. Rules of Court – 1 September 2012

proceedings have been completed. Even after the end of their terms of office, they shall continue to deal with the case if they have participated in the consideration of the merits. These provisions shall also apply to proceedings relating to advisory opinions.

5. (a) The panel of five judges of the Grand Chamber called upon to consider a request submitted under Article 43 of the Convention shall be composed of

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- the President of the Court. If the President of the Court is prevented from sitting, he or she shall be replaced by the Vice-President of the Court taking precedence;
 - two Presidents of Sections designated by rotation. If the Presidents of the Sections so designated are prevented from sitting, they shall be replaced by the Vice-Presidents of their Sections;
 - two judges designated by rotation from among the judges elected by the remaining Sections to sit on the panel for a period of six months;
 - at least two substitute judges designated in rotation from among the judges elected by the Sections to serve on the panel for a period of six months.
- (b) When considering a referral request, the panel shall not include any judge who took part in the consideration of the admissibility or merits of the case in question.
- (c) No judge elected in respect of, or who is a national of, a Contracting Party concerned by a referral request may be a member of the panel when it examines that request. An elected judge appointed by the Contracting Party concerned pursuant to Rules 29 or 30 shall likewise be excluded from consideration of any such request.
- (d) Any member of the panel unable to sit, for the reasons set out in (b) or (c) shall be replaced by a substitute judge designated in rotation from among the judges elected by the Sections to serve on the panel for a period of six months.

⁴¹ ARTICLE 26

Single-judge formation, Committees, Chambers and Grand Chamber

1. To consider cases brought before it, the Court shall sit in a single-judge formation, in committees of three judges, in Chambers of seven judges and in a Grand Chamber of seventeen judges. The Court's Chambers shall set up committees for a fixed period of time.
2. At the request of the plenary Court, the Committee of Ministers may, by a unanimous decision and for a fixed period, reduce to five the number of judges of the Chambers.
3. When sitting as a single judge, a judge shall not examine any application against the High Contracting Party in respect of which that judge has been elected.
4. There shall sit as an ex-officio member of the Chamber and the Grand Chamber the judge elected in respect of the High Contracting Party concerned. If there is none or if that judge is unable to sit, a person chosen by the President of the Court from a list submitted in advance by that Party shall sit in the capacity of judge.
5. The Grand Chamber shall also include the President of the Court, the Vice-Presidents, the Presidents of the Chambers and other judges chosen in accordance with the rules of the Court. When a case is referred to the Grand Chamber under Article 43, no judge from the Chamber which rendered the judgment shall sit in the Grand Chamber, with the exception of the President of the Chamber and the judge who sat in respect of the High Contracting Party concerned.

⁴² ARTICLE 8

Right to respect for private and family life

1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

⁴³ ARTICLE 13

Right to an effective remedy Everyone whose rights and freedoms as set forth in this Convention are violated shall have an effective remedy before a national authority notwithstanding that the violation has been committed by persons acting in an official capacity.

⁴⁴ ARTICLE 14

Prohibition of discrimination

The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.

⁴⁵ ARTICLE 3

Prohibition of torture

No one shall be subjected to torture or to inhuman or degrading treatment or punishment.

⁴⁶ ARTICLE 10

Freedom of expression

1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This Article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.

2. The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary.

⁴⁷ ARTICLE 35

Admissibility criteria

1. The Court may only deal with the matter after all domestic remedies have been exhausted, according to the generally recognised rules of international law, and within a period of six months from the date on which the final decision was taken.

2. The Court shall not deal with any application submitted under Article 34 that

(a) is anonymous; or

(b) is substantially the same as a matter that has already been examined by the Court or has already been submitted to another procedure of international investigation or settlement and contains no relevant new information.

3. The Court shall declare inadmissible any individual application submitted under Article 34 if it considers that:

(a) the application is incompatible with the provisions of the Convention or the Protocols thereto, manifestly ill-founded, or an abuse of the right of individual application; or

(b) the applicant has not suffered a significant disadvantage, unless respect for human rights as defined in the Convention and the Protocols thereto requires an examination of the application on the merits and provided that no case may be rejected on this ground which has not been duly considered by a domestic tribunal.

4. The Court shall reject any application which it considers inadmissible under this Article. It may do so at any stage of the proceedings.

⁴⁸ ARTICLE 32

Jurisdiction of the Court

1. The jurisdiction of the Court shall extend to all matters concerning the interpretation and application of the Convention and the Protocols thereto which are referred to it as provided in Articles 33, 34, 46 and 47.

2. In the event of dispute as to whether the Court has jurisdiction, the Court shall decide.

⁴⁹ ARTICLE 47

Advisory opinions

1. The Court may, at the request of the Committee of Ministers, give advisory opinions on legal questions concerning the interpretation of the Convention and the Protocols thereto.

2. Such opinions shall not deal with any question relating to the content or scope of the rights or freedoms defined in Section I of the Convention and the Protocols thereto, or with any other question which the Court or the Committee of Ministers might have to consider in consequence of any such proceedings as could be instituted in accordance with the Convention.

3. Decisions of the Committee of Ministers to request an advisory opinion of the Court shall require a majority vote of the representatives entitled to sit on the committee.

⁵⁰ ARTICLE 10

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1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This Article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.

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preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary.