COUNCIL OF EUROPE.

CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE

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CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE

Edited by

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Chapter 1. Introduction to bioethics

Monika Nowalińska, Marzena Zarzeczna-Baran, Ewa Bandurska, Piotr Popowski, Lubomira Wengler, Marzena Olszewska-Karaban

1.1 Initial comments[1]

It is impossible to deal with problems connected with Convention on Human Rights and Bioethics, named also Oviedo Convention, without an introduction to complicated bioethics matters.

It is worth to mention that on 11-12 July 2011 at Law Faculty of the oldest Portugal's University of Coimbra the conference on meaningful title: "Convention on Human Rights and Bioethics – actual or obsolete?" took place. This event is connected with European Medical Law and Bioethics School in Toulouse, and was organized for many years by Anne-Marie Duguet, PhD in medicine and law science. Due to invitation from Andre Pereira, Director of Biomedical Law Centre in Coimbra 2 participants from Poland: Lubomira Wengler, PhD (Medical Law Department) and Piotr Popowski, PhD (Public Health and Social Medicine Department) took part in the symposium. It is a good opportunity to remind that the Convention on Human Rights and Human Dignity towards the use of biology and medicine: the Convention on Human Rights and Bioethics, more commonly known as European Bioethics Convention was passed by European Council on 4th April 1997 in Spanish town Oviedo (sometimes known as Convention from Oviedo). The main aim of European Bioethics Convention is generalization of legal standards the field of human rights protection connected with development of medical science, which will be described in the following parts of the paper. Wide range of variety of legal regulations dealing with crucial aspects of human life protection from the earliest stage of prenatal phase can create an opportunity to elude existing in many countries law restrictions by technological transfer and migration of scientists. The contest of European Bioethics Convention was the base to create the program of the symposium. The participants were welcomed by Professor J.G. Silva (the President of University of Coimbra), professor A. Santos Justo (the Dean of Law Faculty), Professor Gde

[1] This text is a translation of the article of Lubomira Wengler and Piotr Popowski, dedicated to the above mentioned conference published in Gazeta AMG No 8/9/2011, p.15.

Oliveira (the Director of Bioethical Law Center) and Professor Noguchi (the Chairman of *Medical* Law Society). They underlined the importance of scientific reflection on law and ethics which are still one step after development of biomedical technology. The papers dealing with the implementation of proclaimed rules connected with European Biomedical Convention were presented. The three fundamental rules are underlined as:

- the principals of human dignity (article 1 of the Convention protects and guaranties dignity and identity of all people without any kind of discrimination
- respect for integrity and legal rights while using biology and medicine
- the primate of human in case of conflict between individual and social interests (the interest of individual is the most important; we cannot approve scientific research when a human bears the cost of them)
- the principals of fairly access to health care system.

The next session was concerned on the consent for intervention (informed consent). The Convention requires that every medical intervention was proceeded by informed contest. The next papers dealt with the right to privacy and the information about the health status of a person. The right to information is connected with the right to privacy. Everybody has the right to know all data about his health status and he is the deponent of this information. Without the permission of the deponent information cannot be transferred. The next session were concerned on human genotype, genetic engineering, transplantation and scientific researches.

During the symposium doctors taking care of their patients asked a fundamental question: “Is the human life obligatory?” During discussion the representatives of Medical University of Gdańsk stated that every human life is the highest value and the struggle for it took a very long time, so we need to give approval answer for the question. People have to life for saving lives as the most precious value; all exceptions from this perspective may cause the change in attitude to human, which is dangerous. The example of Netherlands can be an illustration. In Netherlands, after legalization of euthanasia the family members persuade older, sick people to start euthanasia procedure. Symposium was a unique opportunity of interesting and wide exchange of opinions between medical practitioners and theoreticians, ethics and philosophers. The question from the title is still up-to-dated.

1.2. Introduction to bioethics[2]

Bioethics (Greek: bios-life, ethos-tradition, character, life style) is an interdisciplinary knowledge including judgments and opinions of specialists from ethics, philosophy and medicine[3],[4],[5]. Essential identity of bioethics is connected with four aspects: definition – describing the meaning of the term "bioethics", historical – showing genealogy, the roots and genesis, structural – dealing with the structure of bioethics, systematic – concentrated on main thoughts and detailed subjects connected with bioethics.

1.3. Definitional aspect[6]

In the literature we cannot find strict and explicit definition of bioethics. The way to understand fundamental theses is to describe bioethics as a reflection on borderline situations in human life which are connected with biomedical sciences development [7],[8],[9].

Bioethics is described in a relation with its aims as an integral part of moral philosophy. Philosophic component of bioethics is connected with "searching for conclusions through rational discussion taking into account various opinions and interests trying to achieve compromise, so conclusions are not definitive"[10], so the aim in this case has advisory

[2] This is the translation of the text of A. Janaszczyk, stated in: Nauki o zdrowiu : architektonika dziedziny. T. 3. Zagadnienia społeczne, etyczne i prawne / pod red. A. Janaszczyk, L.Wengler, L.Pawłowskiego, A.Zimmermann, E.Adamskiej-Pietrzak, P.Popowskiego, Gdańsk, 2011, p. 74.

[3] J. Hartman, Bioetyka dla lekarzy, Warszawa 2009.

[4] J. Jaroń (red.), Aktualny stan bioetyki i ekologii w Polsce i na świecie, Siedlce 2005

[5] K. Szewczyk, Bioetyka. Medycyna na granicach życia, t. 1, Warszawa 2009.

[6] This is the translation of the text of A. Janaszczyk, op. cit., p. 74-76.

[7] J. Jaroń, op.cit.

[8] J. Kwapiszewski, Bioetyka – remedium na patologie i kryzysy w społeczeństwie informacyjnym, Słupsk 2005.

[9] D. Ślęczek-Czakon, Problem wartości i jakości życia w sporach bioetycznych, Katowice 2004.

[10] J. Jaroń, op.cit.

character dealing with problems at borderline situations in human life[11]. On the other hand ethical aspect deals with the perception of bioethics as a reflection connected with detailed, normative and application ethics, which was indicated by three different aims of bioethics: methodological, fundamental and strategic. Bioethics in methodological perspective is a part of detailed ethics, use moral values and theories from general ethics for specific problems connected with life protection at borderline situations in human life[12],[13]. Bioethical reflection in normative ethics category is related with describing norms and evaluating from their perspective moral assessments which give an opportunity to decide "taking into account interests and views of people"[14], in risky situations during human life[15],[16],[17]. On the other hand bioethics described as application ethics underline the strategic goal connected with using general ethics standards and setting detailed moral norms in bioethical sciences, in therapeutic practice of health care service and medical researches.

The concept of bioethical considerations is ideology of progress, which is connected with postponed effects of achievements. Critical situations correlated with the threat of human life and the need of its prevention, which is indicated by bioethics, are generated as a spectacular effect (not totally controlled) of scientific and technological development[18],[19],[20].

The progress of biomedical sciences is strictly connected with interferences in natural life processes, and taking this into account the task of bioethics is to setting rules and standards of

[11] Ibidem.

[12] Ibidem.

[13] J. Kwapiszewski, op.cit.

[14]J.Jaroń, op.cit.

[15] J.Kwapiszewski op.cit.

[16] D. Ślęczek-Czakon op.cit.

[17] M. Adamkiewicz, Zagadnienie śmierci w bioetyce, Warszawa 2002.

[18] J.Jaroń, op.cit.

[19] K. Szewczyk, op.cit.

[20] D. Ślęczek-Czakon, op.cit.

these manipulations in new treatment methods, medical care and scientific experiments[21],[22].

Practical task of bioethics is based on medicine and legal sciences, because it is connected with concrete rules of behavior and standards for decisions and actions, which are useful for doctors and employers[23],[24],[25]. Bioethics formulates specific instructions in human life and the improvement of procedural regulations connected with high moral risk of medical interventions[26].

In the broadest sense bioethics can be defined as "ethics of human life"[27],[28] based on biomedical sciences and engaged in the sphere of values in the way that actions in bioethics need to be "estimated and valuated in moral aspect"[29]. Bioethics in specific sense creates a bridge between natural sciences and human sciences[30],[31]. Frequently in a place of the term "bioethics" we use other terms: biomedical ethics, medical ethics or philosophical medical ethics[32].

[21] J.Jaroń, op.cit.

[22] K.Szewczyk, op.cit.

[23] J.Hartman, op.cit.

[24] J.Jaroń, op.cit.

[25] M. Adamkiewicz, op.cit.

[26] J.Jaroń, op.cit.

[27] K. Szewczyk, op.cit.

[28] M. Adamkiewicz, op.cit.

[29] D. Ślęczek-Czakon, op.cit.

[30] J. Kwapiszewski, op.cit.

[31] D. Ślęczek-Czakon, op.cit.

[32] M. Adamkiewicz, op.cit.

1.4. Historical aspect[33]

Bioethics as scientific discipline was first dated in sixties/seventies of XX century. Genealogy, the roots of a field of science, bioethics started at fifties and sixties and is connected with certain changes created by technical and biological revolutions effected in significant progress in medicine. The main changes were: inventing the respiratory machine (1952), kidney transplant (1954), discovery of genetic code (1956), introduction of hemodialysis (1961), heart transplant (1967). Discoveries and inventions connected with scientific development caused that new problems in biomedicine and technological medicine appeared, such as: intensive care issues, brain death criteria (Harvard death definition), reproductive medicine problems or medical experiments. Problems dealing with clinical experiments were the subject of Helsinki Declaration passed by International Physicians Association in 1964 in Helsinki. This document was the first paper in the field of bioethics.

The beginning of the ideas of bioethics was connected with considerations of Joseph Fletcher, Paul Ramsey, Richard McCormick and Hans Jonas. Fletcher in 1954 in his book *Medicine and Morals*, and Ramsey in 1970 in his book *Patient as Person* presented bioethics issues. Fletcher stated that the aim of the modern medicine is fighting with the nature, physical limitations of humans. Thoughts of ethical considerations over changes in medicine connected with scientific and technologic progress underlie the principal value of individual human choices[34],[35],[36].

The beginning of bioethics could be found in the works of three scientists: oncologist Van Rensselaer Potter, philosopher Daniel Callahan and obstetrics Andre Hellegers. In 1970 in the article *Bioethics. The science of survival* published in "Perspectives in Biology and Medicine" Potter used the term "bioethics" for the first time and after that he used that term in his book

[33] This is the translation of the text of A. Janaszczyk, op.cit., p.76-80.

[34] K. Szewczyk op.cit.

[35] M. Adamkiewicz op.cit.

[36] A. Alichniewicz, Wzorce śmierci w bioetyce amerykańskiej, Kraków 2007.

published in 1971 under the title *Bioethics: Bridge to the Future*[37],[38],[39],[40],[41]. The idea of bioethics can be explained in three points. Bioethics is the science "looking in future", which is interdisciplinary and global way of solving problems connected with biomedicine[42],[43],[44],[45]. Treating technological progress as a chance to smooth away threats for the mankind, Potter called for the necessity of development analysis and the effects caused by scientific and technical revolution and taking into account the moral responsibility of the progress. Firstly, bioethics is a discipline which- recommend certain actions "improving the quality of life" – is "a science about surviving of the mankind"[46],[47],[48]. Secondly, Potter described the new field of science should "connect biology with the knowledge concern with human values"[49],[50],[51]. Thirdly, bioethics in principals takes into account not only humans but also other organisms and the environment, so bioethics is the field of knowledge which consider the problems of the whole ecosystem[52],[53],[54]. In 1988 Potter presented holistic conception of global bioethics, the combination of medicine (e.g. rescuing human lives and health promotion) with ecological

[37] J.Jaroń, op.cit.

[38] K. Szewczyk, op.cit.

[39] J. Kwapiszewski, op.cit.

[40] D. Ślęczek-Czakon, op.cit.

[41] M. Adamkiewicz, op.cit.

[42] J.Jaroń, op.cit.

[43] K. Szewczyk, op.cit.

[44] D. Ślęczek-Czakon, op.cit.

[45] M. Adamkiewicz, op.cit.

[46] J.Jaroń, op.cit.

[47] J. Kwapiszewski, op.cit.

[48] D. Ślęczek-Czakon, op.cit.

[49] J.Jaroń, op.cit.

[50] J. Kwapiszewski, op.cit.

[51] D. Ślęczek-Czakon, op.cit.

[52] J.Jaroń, op.cit.

[53] J. Kwapiszewski op.cit.

[54] D. Ślęczek-Czakon, op.cit.

problems (e.g. conditions of the ways of human lives surviving, quality of life, and quality of environment). Potter is the author of bioethical credo for individuals, connected with cardinal rules: "1) in the world full of crisis we need to concentrate on the broad conception for survival conditions, 2) everybody by his life style can give better conditions for future generations and should avoid actions which give the opposite effects, 3) the iniquity of each human should be accepted and in human determination to improving the social group – we need to listen the other people arguments and we should be emotionally engaged in the action, 4) suffering is a constant element of the nature, but we need to lower or to eliminate suffer from humans, 5) the death should be accepted as an unavoidable part of life, we need to promote the respect to life, brotherhood between people and responsibility for next generations"[55].

In the development of bioethics as the field of knowledge the works of Callahan was significant. Callahan with psychiatrist Willard Gaylin found in 1969 Institute of Society, Ethics and the Life Science, known as Hasting Center[56],[57],[58],[59],[60]. The Institute deals with: analysis of biomedical problems in a socio-ethical context, preparing educational programs for universities, connected with bioethical problems, sanitary politics, professional ethics, criminology etc. Since 1971 in Hasting Center the journal "Hasting Center Report", known as the main bioethics journal, was published. Callahan divided bioethics into two parts: essential bioethics issues and traditional ethics. Moreover, Callahan emphasized the fact that scientific decisions especially in the field of biomedicine should be judged by moral criteria because of their effects, values and reasons in a context of human life. Callahan stated also that bioethics on the one hand should create rules connected with individual moral choices towards revolutionary changes and, on the other hand the subject of bioethical ideas should be social-civilizational field and the interaction between biomedicine and human environment[61],[62],[63].

[55] D. Ślęczek-Czakon, op.cit.

[56] K. Szewczyk, op.cit.

[57] J. Kwapiszewski, op.cit.

[58] D. Ślęczek-Czakon, op.cit.

[59] M. Adamkiewicz, op.cit.

[60] A. Alichniewicz, op.cit.

[61] K. Szewczyk, op.cit.

Under the influence of Potter, Hellegers established The Joseph and Rose Kennedy Institute for Study of Human Reproduction and Bioethics at Georgetown University known as Kennedy Institute of Ethics[64],[65],[66],[67],[68]. The three centers were organized there, which were: bioethics center, demographic researches center and reproductive biology center. By the Institute the first *Encyclopedia of Bioethics* (vol. 4, 1978, redactor T. Reich) was edited and also annuals *Bibliography of Bioethics* including worldwide literature of bioethics are published. The aims of the Institute activity are didactic matters, researches in the field of bioethics, services for public institutions in the field of population density, reproduction, bioethics[69],[70],[71],[72],[73]. In late seventies of twentieth century at Georgetown University, philosopher and biochemist Tom Beauchamp and philosopher and theologian James F. Childress published their work *Principals of Biomedical Ethics.* They formulated principal theory, also known as "Georgetown matrix" including the main middle level bioethics matters, which are the correlation between individual issues and general ethics theories: respect for patients' autonomy, charity, harmlessness [74],[75],[76].

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[62] D. Ślęczek-Czakon, op.cit.

[63] M. Adamkiewicz, op.cit.

[64] K. Szewczyk, op.cit.

[65] J. Kwapiszewski, op.cit.

[66] D. Ślęczek-Czakon, op.cit.

[67] M. Adamkiewicz, op.cit.

[68] A. Alichniewicz, op.cit.

[69] K. Szewczyk, op.cit.

[70] J. Kwapiszewski, op.cit.

[71] D. Ślęczek-Czakon, op.cit.

[72] M. Adamkiewicz, op.cit.

[73] A. Alichniewicz, op.cit.

[74] K. Szewczyk, *Bioetyka. Medycyna na granicach życia*, t. 1, Warszawa 2009.

[75] A. Alichniewicz, op.cit.

[76] B. Gert, Ch. M. Culver, K. Danner Clouser, Bioetyka ujęcie systematyczne, Gdańsk 2010.

The concept of Beauchamp and Childress was the effect of principals published in Belmont Report from 1979, which was connected with the first collegial Bioethical Council named, National Comity for Protection Humans in Biomedical and Behavioral Researches (1975), organized by the USA Congress[77].

For the first time word "bioethics" in Europe was used in 1973 in "Revue Theologique de Louvain" by *Edouard Bone.* Bioethics centers were organized in 1975 in Barcelona University at Theologian Faculty as *Instituto Borja de Bioetica.* In Poland bioethical matters were firstly mentioned by Roman Tokarczyk in 1984, in his work *The law of birth, life and death. Nowadays bioethical problems* (Lublin). Tadeusz Ślipko published first academic textbook titled *The borders of life. Nowadays bioethical dilemma*[78].

Important historical element of developing scientific field of bioethics was connected with organizing comities, known as bioethical comities. These boards "gather regularly biologists, medical doctors and professionals from other fields"[79] to deal with legalization problems of new methods and treatment techniques, diagnostic procedures and experiments. They judge on scientific researches and threats connected with scientific development. Comities and bioethical comities take under consideration the conformity of scientific-therapeutic solutions with international declaration and conventions in the field of human rights, patients' rights and animal rights[80].

1.5. Structural aspect[81]

The division of bioethics can be done differently, by the scope of researches or by the subjects of bioethical dissertation[82],[83],[84],[85]. The wide range can be described when the field of

[77] K. Szewczyk, *Bioetyka. Medycyna na granicach życia*, t. 1, Warszawa 2009.

[78] M. Adamkiewicz, op.cit.

[79] J. Bernard, Od biologii do etyki, Warszawa 1994.

[80] Ibidem.

[81] This is the translation of the text of A. Janaszczyk, op. cit., p. 80.

[82] J.Jaroń, op.cit.

[83] K. Szewczyk, *Bioetyka. Medycyna na granicach życia*, t. 1, Warszawa 2009.

bioethical deliberation is connected with ecological issues when human's influence on the nature, and moreover contractions should be done against too hasty implementation of scientific discovers, which can effect in disturbance of the earth ecosystem balance. Ecological part of bioethical aspect concerns on global survival of life on the earth by contractions against nature and natural resources devastation and prevention of biosphere and ecosystems. The narrower sense of bioethics matters means the other field of interest connected with adding problems consists of duties and permits for professional-political therapeutic, scientific and prevention interferences in individual, social and civilizational perspective[86],[87],[88],[89].

Taking into account the matter of issues, as biogenesis – issues dealing with the beginning of human life, procreation, as biotherapy – issues dealing with lasting of human life which is concerned advanced treatment methods, especially medical experiments, as thanatology, studies concerned on the last phase of human life, issues connected with the process of dying and interdisciplinary studies on death phenomenon[90],[91],[92].

1.6. Systemic aspect[93]

The main current in bioethics can be indicated as: theoretical current, clinical current, regulation-political (normative) current, cultural current[94],[95],[96]. The first one is based on

[84] J. Kwapiszewski, op.cit.

[85] M. Adamkiewicz, op.cit.

[86] J. Hartman, op.cit.

[87] K. Szewczyk,, *Bioetyka. Medycyna na granicach życia*, t. 1, Warszawa 2009.

[88] J. Kwapiszewski, op.cit.

[89] K. Szewczyk, Bioetyka. Pacjent w systemie opieki zdrowotnej, t. 2, Warszawa 2009.

[90] K. Szewczyk, *Bioetyka. Medycyna na granicach życia*, t. 1, Warszawa 2009.

[91] J. Kwapiszewski, op.cit.

[92] M. Gałuszka, K. Szewczyk (red.), Narodziny i śmierć. Bioetyka kulturowa wobec stanów granicznych życia ludzkiego, Warszawa–Łódź 2002.

[93]This is the translation of the text of A. Janaszczyk, op.cit,.p.81.

[94] J.Jaroń op.cit.

ethical theories and deals with setting moral criteria for making decisions in the field of medical and biological sciences. The second one is used in medical practice when judgments on certain patients should be made. The third one concerns on legal and institutional context on moral effects of decisions in the field of human life. It deals with moral character, legitimacy and effectiveness of the legal regulations which concerns on "human life as biological value and medical responsibility"[97]. The fourth mental current known as cultural bioethics consists of: historical, social, cultural and civilizational context of the problems in the field of philosophical medical ethics taking into account the relations of normative systems with making decisions and social consent for certain occurrences as the side-effects of scientific development[98],[99],[100].

D. Callahan was the author of the division between regular and cultural bioethics and he published his theses in the work titled *Private choices and common sense* published in "Hasting Center Reports" in 1994, number 3. In Poland, Kazimierz Szewczyk and Mieczysław Gałuszka from Medical University of Łódź represent the same trend[101],[102],[103].

[95] K. Szewczyk, *Bioetyka. Medycyna na granicach życia*, t. 1, Warszawa 2009.

[96] M. Adamkiewicz, op.cit.

[97] Ibidem.

[98] K. Szewczyk, op.cit.

[99] M. Adamkiewicz, op.cit.

[100] M. Gałuszka, op.cit.

[101] J.Jaroń, op.cit.

[102] K. Szewczyk op.cit.

[103] M. Gałuszka, op.cit.

In the systematic aspect bioethics is connected with wide range of issues, such as fertilization (in vitro, artificial), diagnostic (pre-implantation, prenatal), abortion; genetic engineering (cloning); intensive care, reanimation; issues concerned on transplantation; death definition, euthanasia, capital punishment; medical experiments on humans and animals, environmental problems in the broadest sense[104],[105],[106].

[104] K. Szewczyk, *Bioetyka. Medycyna na granicach życia*, t. 1, Warszawa 2009.

[105] K. Szewczyk, *Bioetyka. Pacjent w systemie opieki zdrowotnej*, t. 2, Warszawa 2009.

[106] M. Gałuszka. op.cit.

Chapter 2. The Council of Europe. European Convention for the Protection of Human Rights and Fundamental Freedoms

Piotr Pietrzak, Ewa Adamska-Pietrzak

2.1. The Council of Europe

The establishment of The Council of Europe was a result of the desire to create a united Europe led by an European Assembly[107]. It is an international organization founded on 5 May 1949 by 10 countries – signatories of the Treaty of London (Belgium, Denmark, France, Ireland, Italy, Luxembourg, the Netherlands, Norway, Sweden and the United Kingdom) in order to achieve a greater unity between its members for the purpose of safeguarding and realizing the ideals and principles which are their common heritage and facilitating their economic and social progress by discussion and common action in economic, social, cultural, scientific, legal and administrative matters[108]. Its meetings are a forum for discussions on Europe's political, social and economic development[109]. It currently unites 47 member states:

- Belgium, Denmark, France, Republic of Ireland, Italy, Luxembourg, the Netherlands, Norway, Sweden, United Kingdom, Greece, Turkey (all joined in 1949),
- Iceland, Germany (both joined in 1950),
- Austria (joined in 1956),
- Cyprus (joined in 1961),
- Switzerland (joined in 1963),
- Malta (joined in 1965),
- Portugal (joined in 1976),
- Spain (joined in 1977),
- Liechtenstein (joined in 1978),
- San Marino (joined in 1988),
- Finland (joined in 1989),

[107] Winston Churchill's speech on 12 August 1949, available at: http://www.coe.int.

[108] Article 1 of the Statute of the Council of Europe.

[109] Z. Czachór, C. Mojsiewicz, "Leksykon Unii Europejskiej", Wrocław 2002, p. 134.

- Hungary (joined in 1990),
- Poland (joined in 1991),
- Bulgaria (joined in 1992),
- Estonia, Lithuania, Slovenia, Czech Republic, Slovakia, Romania (all joined in 1993),
- Andorra (joined in 1994),
- Latvia, Albania, Moldova, Republic of Macedonia, Ukraine (all joined in 1995),
- Russia, Croatia (joined in 1996),
- Georgia (joined in 1999),
- Armenia, Azerbaijan (joined in 2001),
- Bosnia and Herzegovina (joined in 2002),
- Serbia (joined in 2003),
- Monaco (joined in 2004),
- Montenegro (joined in 2007).[110]

Canada, Japan, Mexico, the U.S. and the Holy See were granted the status of observers and thus are allowed to participate in the organization's work, while Morocco and the Palestinian National Council have the status of "partners for democracy".

The rise in the Council's membership in 1990s was a result of the former Communist countries recognizing the quality of the Council's work in regard to the protection of human rights and their desire to have their citizen's rights protected by the European Convention on the Protection of Human Rights and Fundamental Freedoms[111].

The Council's seat is in Strasbourg and its official languages are English and French. The Council of Europe performs its duties through two organs the Committee of Ministers and the Consultative Assembly, which are served by the Secretariat of the Council of Europe.

The Committee of Ministers consists of one representative (the Minister of Foreign Affairs or a person nominated by him) of each member and acts on behalf of the Council of Europe by concluding conventions or agreements and issuing recommendations to the members' governments.

[110] http://www.coe.int as of 01.01.2013.

[111] J. Reiss, Protocol No. 14 ECHR and the Russian Non-ratification: the Current State of affairs, Harvard Human Rights Journal Vol. 22, p. 297.

The Consultative Assembly debates matters within the aim and scope of the Council of Europe and presents its conclusions, in the form of recommendations, to the Committee of Ministers. It consists of representatives of each member, elected by its parliament from among the members thereof, or appointed from among the members of that parliament. Members are entitled to the number of representatives determined in Article 26 of the Statute of the Council of Europe with France, Germany, Italy, Russia and the United Kingdom having the most - 18 representatives each.

Despite the fact that most European countries are already members of the Council of Europe, its role isn't diminishing. The European Convention on the Protection of Human Rights and Fundamental Freedoms sets the standard for human rights protection, while the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine is aimed at combining ethical and legal matters to protect the dignity and identity of all human beings with regard to the advancements in biology, medicine and other science.

2.2. Complete list of the Council of Europe's treaties[112]

The Council of Europe's treaties	Opening of the treaty	Entry into force	Signature	Ratification
Statute of the Council of Europe General Agreement on Privileges and Immunities of the Council of Europe	5/5/1949	3/8/1949	10	47
General Agreement on Privileges and Immunities of the Council of Europe	2/9/1949	10/9/1952	12	47
Convention for the Protection of Human Rights and Fundamental Freedoms	4/11/1950	3/9/1953	47	47
Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms	20/3/1952	18/5/1954	47	45
Protocol to the General Agreement on Privileges and Immunities of the Council of Europe	6/11/1952	11/7/1956	12	47
European Interim Agreement on Social Security	11/12/1953	1/7/1954	21	21

[112] http://www.conventions.coe.int/Treaty/Commun/ListeTraites.asp?CM=8&CL=ENG

Schemes Relating to Old Age, Invalidity and Survivors				
Protocol to the European Interim Agreement on Social Security Schemes Relating to Old Age, Invalidity and Survivors	11/12/1953	1/10/1954	21	21
European Interim Agreement on Social Security other than Schemes for Old Age, Invalidity and Survivors	11/12/1953	1/7/1954	21	21
Protocol to the European Interim Agreement on Social Security other than Schemes for Old Age, Invalidity and Survivors	11/12/1953	1/10/1954	21	21
European Convention on Social and Medical Assistance	11/12/1953	1/7/1954	18	18
Protocol to the European Convention on Social and Medical Assistance	11/12/1953	1/7/1954	18	17
European Convention on the Equivalence of Diplomas leading to Admission to Universities	11/12/1953	20/4/1954	30	37
European Convention relating to the Formalities required for Patent Applications	11/12/1953	1/6/1955	16	21
European Convention on the International Classification of Patents for Inventions	19/12/1954	1/8/1955	13	15
European Cultural Convention	19/12/1954	5/5/1955	19	50
European Convention on Establishment	13/12/1955	23/2/1965	15	12
Agreement on the Exchange of War Cripples between Member Countries of the Council of Europe with a view to Medical Treatment	13/12/1955	1/1/1956	18	17
European Convention on the Equivalence of Periods of University Study	15/12/1956	18/9/1957	28	29
Second Protocol to the General Agreement on Privileges and Immunities of the Council of Europe	15/12/1956	15/12/1956	34	33
European Convention for the Peaceful Settlement of	29/4/1957	30/4/1958	20	14

Disputes				

European Convention on Extradition	13/12/1957	18/4/1960	42	50
European Agreement on Regulations governing the Movement of Persons between Member States of the Council of Europe	13/12/1957	1/1/1958	19	17
European Agreement on the Exchange of Therapeutic Substances of Human Origin	15/12/1958	1/1/1959	22	21
European Agreement concerning Programme Exchanges by means of Television Films	15/12/1958	1/7/1961	16	16
Third Protocol to the General Agreement on Privileges and Immunities of the Council of Europe	6/3/1959	15/3/1963	8	26
European Convention on Compulsory Insurance against Civil Liability in respect of Motor Vehicles	20/4/1959	22/9/1969	12	7
European Convention on Mutual Assistance in Criminal Matters	20/4/1959	12/6/1962	43	50
European Agreement on the Abolition of Visas for Refugees	20/4/1959	4/9/1960	24	23
European Convention on the Academic Recognition of University Qualifications	14/12/1959	27/11/1961	26	28
Agreement on the Temporary Importation, free of duty, of Medical, Surgical and Laboratory Equipment for use on free loan in Hospitals and other Medical Institutions for purposes of Diagnosis or Treatment	28/4/1960	29/7/1960	23	24
European Agreement on the Protection of Television Broadcasts	22/6/1960	1/7/1961	15	7
European Social Charter	18/10/1961	26/2/1965	31	27
Fourth Protocol to the General Agreement on Privileges and Immunities of the Council of Europe	16/12/1961	16/12/1961	34	33
European Agreement on Travel by Young Persons	16/12/1961	17/1/1962	21	19

on Collective Passports between the Member Countries of the Council of Europe				
European Agreement on Mutual Assistance in the matter of Special Medical Treatments and Climatic Facilities	14/5/1962	15/6/1962	11	8
European Agreement on the Exchanges of Blood-Grouping Reagents	14/5/1962	14/10/1962	20	22
Agreement between the Member States of the Council of Europe on the issue to Military and Civilian War-Disabled of an International Book of Vouchers for the repair of Prosthetic and Orthopaedic Appliances	17/12/1962	27/12/1963	10	8
Convention on the Liability of Hotel-keepers concerning the Property of their Guests	17/12/1962	15/2/1967	16	17
Agreement relating to Application of the European Convention on International Commercial Arbitration	17/12/1962	25/1/1965	8	8
Convention on the Reduction of Cases of Multiple Nationality and on Military Obligations in Cases of Multiple Nationality	6/5/1963	28/3/1968	15	13
Protocol No. 2 to the Convention for the Protection of Human Rights and Fundamental Freedoms, conferring upon the European Court of Human Rights competence to give advisory opinions	6/5/1963	21/9/1970	47	47
Protocol No. 3 to the Convention for the Protection of Human Rights and Fundamental Freedoms, amending Articles 29, 30 and 34 of the Convention	6/5/1963	21/9/1970	47	47
Protocol No. 4 to the Convention for the Protection of Human Rights and Fundamental Freedoms, securing certain rights and freedoms other than those already included in the Convention and in the first Protocol thereto	16/9/1963	2/5/1968	45	43

Convention on the Unification of Certain Points of Substantive Law on Patents for Invention	27/11/1963	1/8/1980	13	13
European Code of Social Security	16/4/1964	17/3/1968	26	21
Protocol to the European Code of Social Security	16/4/1964	17/3/1968	13	7
Protocol to the European Convention on the Equivalence of Diplomas leading to Admission to Universities	3/6/1964	4/7/1964	23	27
Convention on the Elaboration of a European Pharmacopoeia	22/7/1964	8/5/1974	8	38
European Convention on the Supervision of Conditionally Sentenced or Conditionally Released Offenders	30/11/1964	22/8/1975	17	19
European Convention on the Punishment of Road Traffic Offences	30/11/1964	18/7/1972	15	5
European Agreement for the Prevention of Broadcasts transmitted from Stations outside National Territories	22/1/1965	19/10/1967	18	19
Protocol to the European Agreement on the Protection of Television Broadcasts	22/1/1965	24/3/1965	11	6
Protocol No. 5 to the Convention for the Protection of Human Rights and Fundamental Freedoms, amending Articles 22 and 40 of the Convention	20/1/1966	20/12/1971	47	47
European Convention providing a Uniform Law on Arbitration	20/1/1966		2	1
European Convention on Establishment of Companies	20/1/1966		4	1
European Convention on the Adoption of Children	24/4/1967	26/4/1968	20	16
European Agreement on the Instruction and Education of Nurses	25/10/1967	7/8/1969	13	11
European Convention on Foreign Money Liabilities	11/12/1967		4	1

European Convention on Consular Functions	11/12/1967	9/6/2011	9	5
Protocol to the European Convention on Consular Functions concerning the Protection of Refugees	11/12/1967		6	3
Protocol to the European Convention on Consular Functions relating to Consular Functions in respect of Civil Aircraft	11/12/1967		4	2
European Convention on Information on Foreign Law	7/6/1968	17/12/1969	31	45
European Convention on the Abolition of Legalisation of Documents executed by Diplomatic Agents or Consular Officers	7/6/1968	14/8/1970	22	22
European Agreement on the Restriction of the Use of certain Detergents in Washing and Cleaning Products	16/9/1968	16/2/1971	9	10
European Convention for the Protection of Animals during International Transport	13/12/1968	20/2/1971	21	24
European Convention on the Protection of the Archaeological Heritage	6/5/1969	20/11/1970	16	25
European Agreement relating to Persons participating in Proceedings of the European Commission and Court of Human Rights	6/5/1969	17/4/1971	27	26
European Agreement on Au Pair Placement	24/11/1969	30/5/1971	13	6
European Agreement on continued Payment of Scholarships to students studying abroad	12/12/1969	2/10/1971	14	20
European Convention on the International Validity of Criminal Judgments	28/5/1970	26/7/1974	28	22
European Convention on the Repatriation of Minors	28/5/1970		9	2
Convention relating to Stops on Bearer Securities in International Circulation	28/5/1970	11/2/1979	8	4

European Convention on the Transfer of Proceedings in Criminal Matters	15/5/1972	30/3/1978	32	25
European Convention on State Immunity	16/5/1972	11/6/1976	9	8
Additional Protocol to the European Convention on State Immunity	16/5/1972	22/5/1985	8	6
European Convention on the Place of Payment of Money Liabilities	16/5/1972		3	0
European Convention on the Calculation of Time-Limits	16/5/1972	28/4/1983	10	4
Convention on the Establishment of a Scheme of Registration of Wills	16/5/1972	20/3/1976	15	12
European Convention on Social Security	14/12/1972	1/3/1977	13	8
Supplementary Agreement for the Application of the European Convention on Social Security	14/12/1972	1/3/1977	13	8
European Convention on Civil Liability for Damage caused by Motor Vehicles	14/5/1973		3	0
Agreement on the Transfer of Corpses	26/10/1973	11/11/1975	23	23
Additional Protocol to the Protocol to the European Agreement on the Protection of Television Broadcasts	14/1/1974	31/12/1974	10	10
European Convention on the Non-Applicability of Statutory Limitation to Crimes against Humanity and War Crimes	25/1/1974	27/6/2003	8	7
European Convention on the Social Protection of Farmers	6/5/1974	17/6/1977	11	9
European Agreement on the Exchange of Tissue-Typing Reagents	17/9/1974	23/4/1977	19	17
European Convention on the Legal Status of Children born out of Wedlock	15/10/1975	11/8/1978	24	23
Additional Protocol to the European Convention on Extradition	15/10/1975	20/8/1979	35	39

European Convention for the Protection of Animals kept for Farming Purposes	10/3/1976	10/9/1978	29	33

European Convention on the International Effects of Deprivation of the Right to Drive a Motor Vehicle	3/6/1976	28/4/1983	13	12
Additional Protocol to the European Agreement on the Exchange of Tissue-Typing Reagents	24/6/1976	23/4/1977	18	16
European Convention on the Suppression of Terrorism	27/1/1977	4/8/1978	47	46
European Convention on Products Liability in regard to Personal Injury and Death	27/1/1977		4	0
European Agreement on the Transmission of Applications for Legal Aid	27/1/1977	28/2/1977	32	31
European Convention on the Legal Status of Migrant Workers	24/11/1977	1/5/1983	15	11
European Convention on the Service Abroad of Documents relating to Administrative Matters	24/11/1977	1/11/1982	12	8
Protocol amending the Convention on the Reduction of Cases of Multiple Nationality and Military Obligations in Cases of Multiple Nationality	24/11/1977	8/9/1978	11	8
Additional Protocol to the Convention on the Reduction of Cases of Multiple Nationality and Military Obligations in Cases of Multiple Nationality	24/11/1977	17/10/1983	6	4
Additional Protocol to the European Convention on Information on Foreign Law	15/3/1978	31/8/1979	37	41
Second Additional Protocol to the European Convention on Extradition	17/3/1978	5/6/1983	37	42
Additional Protocol to the European Convention on Mutual Assistance in Criminal Matters	17/3/1978	12/4/1982	39	43
European Convention on the Obtaining Abroad of	15/3/1978	1/1/1983	7	6

Information and Evidence in Administrative Matters				

European Convention on the Control of the Acquisition and Possession of Firearms by Individuals	28/6/1978	1/7/1982	22	15
European Convention for the Protection of Animals for Slaughter	10/5/1979	11/6/1982	24	25
Additional Protocol to the European Convention for the Protection of Animals during International Transport	10/5/1979	7/11/1989	21	23
Convention on the Conservation of European Wildlife and Natural Habitats	19/9/1979	1/6/1982	39	51
European Convention on Recognition and Enforcement of Decisions concerning Custody of Children and on Restoration of Custody of Children	20/5/1980	1/9/1983	35	37
European Outline Convention on Transfrontier Co-operation between Territorial Communities or Authorities	21/5/1980	22/12/1981	39	38
European Agreement on Transfer of Responsibility for Refugees	16/10/1980	1/12/1980	16	13
Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data	28/1/1981	1/10/1985	46	46
Additional Protocol to the European Agreement on the Exchange of Therapeutic Substances of Human Origin	1/1/1983	1/1/1985	0	21
Additional Protocol to the Agreement on the Temporary Importation, free of duty, of Medical, Surgical and Laboratory Equipment for Use on free loan in Hospitals and other Medical Institutions for Purposes of Diagnosis or Treatment	1/1/1983	1/1/1985	0	20

Additional Protocol to the European Agreement on the Exchanges of Blood-Grouping Reagents	1/1/1983	1/1/1985		21

Convention on the Transfer of Sentenced Persons	21/3/1983	1/7/1985	41	64
Additional Protocol to the Protocol to the European Agreement on the Protection of Television Broadcasts	21/3/1983	1/1/1985	11	10
Protocol No. 6 to the Convention for the Protection of Human Rights and Fundamental Freedoms concerning the Abolition of the Death Penalty	28/4/1983	1/3/1985	47	46
Protocol amending the European Agreement on the Restriction of the Use of certain Detergents in Washing and Cleaning Products	25/10/1983	1/11/1984	7	5
European Convention on the Compensation of Victims of Violent Crimes	24/11/1983	1/2/1988	32	25
Protocol No. 7 to the Convention for the Protection of Human Rights and Fundamental Freedoms	22/11/1984	1/11/1988	46	43
Protocol No. 8 to the Convention for the Protection of Human Rights and Fundamental Freedoms	19/3/1985	1/1/1990	47	47
European Convention on Offences relating to Cultural Property	23/6/1985		6	0
European Convention on Spectator Violence and Misbehaviour at Sports Events and in particular at Football Matches	19/8/1985	1/11/1985	37	42
Convention for the Protection of the Architectural Heritage of Europe	3/10/1985	1/12/1987	34	41
European Charter of Local Self-Government	15/10/1985	1/9/1988	47	47
European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes	18/3/1986	1/1/1991	27	22
European Convention on the Recognition of the	24/4/1986	1/1/1991	11	11

Legal Personality of International Non-Governmental Organisations				

European Convention for the Protection of Pet Animals	13/11/1987	1/5/1992	24	22
European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment	26/11/1987	1/2/1989	47	47
Convention on Mutual Administrative Assistance in Tax Matters	25/1/1988	1/4/1995	64	37
Additional Protocol to the European Social Charter	5/5/1988	4/9/1992	23	10
Arrangement for the Application of the European Agreement of 17 October 1980 concerning the Provision of Medical Care to Persons during Temporary Residence	26/5/1988		0	0
Convention on Insider Trading	20/4/1989	1/10/1991	9	8
Third Additional Protocol to the Protocol to the European Agreement on the Protection of Television Broadcasts	20/4/1989		8	7
European Convention on Transfrontier Television	5/5/1989	1/5/1993	28	34
Protocol to the Convention on Insider Trading	11/9/1989	1/10/1991	9	8
Protocol to the Convention on the Elaboration of a European Pharmacopoeia	16/11/1989	1/11/1992	19	38
Anti-Doping Convention	16/11/1989	1/3/1990	40	52
European Convention on Certain International Aspects of Bankruptcy	5/6/1990		7	1
Fifth Protocol to the General Agreement on Privileges and Immunities of the Council of Europe	18/6/1990	1/11/1991	23	23
European Convention on the General Equivalence of Periods of University Study	6/11/1990	1/1/1991	22	16
European Code of Social Security (Revised)	6/11/1990		13	1

Protocol No. 9 to the Convention for the Protection of Human Rights and Fundamental Freedoms	6/11/1990	1/10/1994	29	24

Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime	8/11/1990	1/9/1993	47	48
Protocol amending the European Social Charter	21/10/1991		26	23
European Convention on the Protection of the Archaeological Heritage (Revised)	16/1/1992	25/5/1995	44	42
Convention on the Participation of Foreigners in Public Life at Local Level	5/2/1992	1/5/1997	13	8
Protocol of Amendment to the European Convention for the Protection of Animals kept for Farming Purposes	6/2/1992		23	18
Protocol No. 10 to the Convention for the Protection of Human Rights and Fundamental Freedoms	25/3/1992		28	25
European Convention on Cinematographic Co-Production	2/10/1992	1/4/1994	43	43
European Charter for Regional or Minority Languages	5/11/1992	1/3/1998	31	25
Second Protocol amending the Convention on the Reduction of Cases of Multiple Nationality and Military Obligations in Cases of Multiple Nationality	2/2/1993	24/3/1995	3	3
Convention on Civil Liability for Damage resulting from Activities Dangerous to the Environment	21/6/1993		9	0
Protocol No. 1 to the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment	4/11/1993	1/3/2002	47	47
Protocol No. 2 to the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment	4/11/1993	1/3/2002	47	47

European Convention relating to questions on Copyright Law and Neighbouring Rights in the Framework of Transfrontier Broadcasting by Satellite	11/5/1994		10	2
Protocol to the European Convention on Social Security	11/5/1994		5	1
Protocol No. 11 to the Convention for the Protection of Human Rights and Fundamental Freedoms, restructuring the control machinery established thereby	11/5/1994	1/11/1998	47	47
Agreement on Illicit Traffic by Sea, implementing Article 17 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances	31/1/1995	1/5/2000	23	15
Framework Convention for the Protection of National Minorities	1/2/1995	1/2/1998	39	39
Additional Protocol to the European Social Charter Providing for a System of Collective Complaints	9/11/1995	1/7/1998	18	13
Additional Protocol to the European Outline Convention on Transfrontier Co-operation between Territorial Communities or Authorities	9/11/1995	1/12/1998	29	23
European Convention on the Exercise of Children's Rights	25/1/1996	1/7/2000	28	17
European Agreement relating to persons participating in proceedings of the European Court of Human Rights	5/3/1996	1/1/1999	39	37
Sixth Protocol to the General Agreement on Privileges and Immunities of the Council of Europe	5/3/1996	1/11/1998	47	44

European Social Charter (revised)	3/5/1996	1/7/1999	45	33

Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine	4/4/1997	1/12/1999	35	29
Convention on the Recognition of Qualifications concerning Higher Education in the European Region	11/4/1997	1/2/1999	50	53
European Convention on Nationality	6/11/1997	1/3/2000	29	20
Additional Protocol to the Convention on the Transfer of Sentenced Persons	18/12/1997	1/6/2000	38	36
Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings	12/1/1998	1/3/2001	32	21
Protocol No. 2 to the European Outline Convention on Transfrontier Co-operation between Territorial Communities or Authorities concerning interterritorial co-operation	5/5/1998	1/2/2001	27	22
Protocol of Amendment to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes	22/6/1998	2/12/2005	23	20
Protocol amending the European Convention on Transfrontier Television	1/10/1998	1/3/2002	0	26
Convention on the Protection of Environment through Criminal Law	4/11/1998		14	1
Criminal Law Convention on Corruption	27/1/1999	1/7/2002	47	45

Civil Law Convention on Corruption	4/11/1999	1/11/2003	42	35

European Convention on the Promotion of a Transnational Long-Term Voluntary Service for Young People	11/5/2000		9	1
European Landscape Convention	20/10/2000	1/3/2004	40	38
Protocol No. 12 to the Convention for the Protection of Human Rights and Fundamental Freedoms	4/11/2000	1/4/2005	37	18
European Convention on the Legal Protection of Services based on, or consisting of, Conditional Access	24/1/2001	1/7/2003	13	10
Additional Protocol to the European Agreement on the Transmission of Applications for Legal Aid	4/10/2001	1/9/2002	22	9
Convention on Information and Legal Co-operation concerning "Information Society Services"	4/10/2001		4	2
Additional Protocol to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, regarding supervisory authorities and transborder data flows	8/11/2001	1/7/2004	44	34
Second Additional Protocol to the European Convention on Mutual Assistance in Criminal Matters	8/11/2001	1/2/2004	41	30
European Convention for the Protection of the Audiovisual Heritage	8/11/2001	1/1/2008	18	9
Protocol to the European Convention for the Protection of the Audiovisual Heritage, on the Protection of Television Productions	8/11/2001	1/4/2014	13	5
Convention on Cybercrime	23/11/2001	1/7/2004	49	41
Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation	24/1/2002	1/5/2006	21	12

of Organs and Tissues of Human Origin				

Protocol No. 13 to the Convention for the Protection of Human Rights and Fundamental Freedoms, concerning the abolition of the death penalty in all circumstances	3/5/2002	1/7/2003	45	43
Additional Protocol to the Anti-Doping Convention	12/9/2002	1/4/2004	32	26
Additional Protocol to the Convention on Cybercrime, concerning the criminalisation of acts of a racist and xenophobic nature committed through computer systems	28/1/2003	1/3/2006	38	20
Protocol amending the European Convention on the Suppression of Terrorism	15/5/2003		46	31
Additional Protocol to the Criminal Law Convention on Corruption	15/5/2003	1/2/2005	45	33
Convention on Contact concerning Children	15/5/2003	1/9/2005	18	8
European Convention for the Protection of Animals during International Transport (Revised)	6/11/2003	14/3/2006	19	11
Protocol No. 14 to the Convention for the Protection of Human Rights and Fundamental Freedoms, amending the control system of the Convention	13/5/2004	1/6/2010	47	47
Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research	25/1/2005	1/9/2007	21	9
Council of Europe Convention on the Prevention of Terrorism	16/5/2005	1/6/2007	44	30
Council of Europe Convention on Action against Trafficking in Human Beings	16/5/2005	1/2/2008	43	41
Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds	16/5/2005	1/5/2008	36	23

from Crime and on the Financing of Terrorism				
Council of Europe Framework Convention on the Value of Cultural Heritage for Society	27/10/2005	1/6/2011	21	15
Council of Europe Convention on the avoidance of statelessness in relation to State succession	19/5/2006	1/5/2009	8	6
Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse	25/10/2007	1/7/2010	46	29
European Convention on the Adoption of Children (Revised)	27/11/2008	1/9/2011	16	7
Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes	27/11/2008		7	3
Protocol No. 14bis to the Convention for the Protection of Human Rights and Fundamental Freedoms	27/5/2009	1/10/2009	22	12
Council of Europe Convention on Access to Official Documents	18/6/2009		14	6
Protocol No. 3 to the European Outline Convention on Transfrontier Co-operation between Territorial Communities or Authorities concerning Euroregional Co-operation Groupings (ECGs)	16/11/2009	1/3/2013	13	5
Additional Protocol to the European Charter of Local Self-Government on the right to participate in the affairs of a local authority	16/11/2009	1/6/2012	18	11
Protocol amending the Convention on Mutual Administrative Assistance in Tax Matters	27/5/2010	1/6/2011	61	33
Third Additional Protocol to the European Convention on Extradition	10/11/2010	1/5/2012	26	6
Council of Europe Convention on preventing and combating violence against women and domestic	11/5/2011		32	8

violence				

Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health	28/10/2011		23	2
Fourth Additional Protocol to the European Convention on Extradition	20/9/2012		13	1
Protocol No. 15 amending the Convention for the Protection of Human Rights and Fundamental Freedoms	24/6/2013		34	5
Protocol No. 16 to the Convention for the Protection of Human Rights and Fundamental Freedoms	2/10/2013		9	0

2.3. Chosen treaties

2.3.1. European interim agreement on social security schemes relating to old age, invalidity and survivors and protocol thereto European Treaty Series - No. 12 Paris, 19.XII.1953

[…]

Article 1

1 This Agreement shall apply to all social security laws and regulations which are in force at the date of signature or may subsequently come into force in any part of the territory of the Contracting Parties and which relate to:

a benefits in respect of old age;

b benefits in respect of invalidity, other than those awarded under an employment injury scheme;

c benefits payable to survivors, other than death grants or benefits awarded under an employment injury scheme.

2 This Agreement shall apply to schemes of contributory and non contributory benefits. It shall not apply to public assistance, special schemes for civil servants or benefits paid in respect of war injuries or injuries due to foreign occupation.

3 For the purpose of this Agreement the word “benefit” shall include any increase in or supplement to the benefit.

4 The terms “nationals” and “territory” of a Contracting Party shall have the meaning assigned to them by such a Party in a declaration addressed to the Secretary General of the Council of Europe for communication to all other Contracting Parties.

Article 2

1 Subject to the provisions of Article 9, a national of any one of the Contracting Parties shall be entitled to receive the benefits of the laws and regulations of any other of the Contracting Parties under the same conditions as if he were a national of the latter, provided that:

a in the case of invalidity benefit under either a contributory or non contributory scheme he had become ordinarily resident in the territory of the latter Contracting Party before the first medical certification of the sickness responsible for such invalidity;

b in the case of benefit payable under a non contributory scheme, he has been resident in that territory for a period in the aggregate of not less than fifteen years after the age of twenty, has been ordinarily resident without interruption in that territory for at least five years immediately preceding the claim for benefit and continues to be ordinarily resident in that territory;

c in the case of benefit payable under a contributory scheme, he is resident in the territory of any one of the Contracting Parties.

2 In any case where the laws and regulations of any one of the Contracting Parties impose a restriction on the rights of a national of that Party who was not born in its territory, a national of any other of the Contracting Parties born in the territory of the latter shall be treated as if he were a national of the former Contracting Party born in its territory.

Article 3

1 Any agreement relating to the laws and regulations referred to in Article 1 which has been or may be concluded by any two or more of the Contracting Parties shall, subject to the provisions of Article 9, apply to a national of any other of the Contracting Parties as if he were a national of one of the former Parties insofar as it provides, in relation to those laws and regulations:

a for determining under which laws and regulations a person should be insured;

b for maintaining acquired rights and rights in course of acquisition and, in particular, for adding together insurance periods and equivalent periods for the purpose of establishing the right to receive benefit and calculating the amount of benefit due;

c for paying benefit to persons residing in the territory of any one of the Parties to such agreement;

d for supplementing and administering the provisions of such agreement referred to in this paragraph.

2 The provisions of paragraph 1 of this article shall not apply to any provision of the said agreement which concerns benefits provided under a non contributory scheme, unless the national concerned has been resident in the territory of the Contracting Party under whose laws and regulations he claims benefit for a period in the aggregate of not less than fifteen years after the age of twenty and has been ordinarily resident without interruption in that territory for a period of at least five years immediately preceding the claim for benefit.

Article 4

Subject to the provisions of any relevant bilateral and multilateral agreements, benefits which in the absence of this Agreement have not been awarded, or have been suspended, shall be awarded or reinstated from the date of the entry into force of this Agreement for all the Contracting Parties concerned with the claim in question, provided that the claim thereto is presented within one year after such date or within such longer period as may be determined by the Contracting Party under whose laws and regulations the benefit is claimed. If the claim is not presented within such period, the benefit shall be awarded or reinstated from the date of the claim or such earlier date as may be determined by the latter Contracting Party.

Article 5

The provisions of this Agreement shall not limit the provisions of any national laws or regulations, international conventions, or bilateral or multilateral agreements which are more favourable for the beneficiary.

Article 6

This Agreement shall not affect those provisions of national laws or regulations which relate to the participation of insured persons, and of other categories of persons concerned, in the management of social security.

Article 7

1 Annex I to this Agreement sets out in relation to each Contracting Party the social security schemes to which Article 1 applies which are in force in any part of its territory at the date of signature of this Agreement.

2 Each Contracting Party shall notify the Secretary General of the Council of Europe of every new law or regulation of a type not included in Annex I in relation to that Party. Such notifications shall be made by each Contracting Party within three months of the date of publication of the new law or regulation, or if such law or regulation is published before the date of ratification of this Agreement by the Contracting Party concerned, at that date of ratification.

Article 8

1 Annex II to this Agreement sets out in relation to each Contracting Party the agreements concluded by it to which Article 3 applies which are in force at the date of signature of this Agreement.

2 Each Contracting Party shall notify the Secretary General of the Council of Europe of every new agreement concluded by it to which Article 3 applies. Such notification shall be made by each Contracting Party within three months of the date of coming into force of the agreement, or if such new agreement has come into force before the date of ratification of this Agreement, at that date of ratification.

Article 9

1 Annex III to this Agreement sets out the reservations hereto made at the date of signature.

2 Any Contracting Party may, at the time of making a notification in accordance with Article 7 or Article 8, make a reservation in respect of the application of the present Agreement to any law, regulation or agreement which is referred to in such notification. A statement of any such reservation shall accompany the notification concerned; it will take effect from the date of entry into force of the new law, regulation or agreement.

3 Any Contracting Party may withdraw either in whole or in part any reservation made by it by a notification to that effect addressed to the Secretary General of the Council of Europe. Such notification shall take effect on the first day of the month following the month in which it is received and this Agreement shall apply accordingly

Article 10

The annexes to this Agreement shall constitute an integral part of this Agreement.

Article 11

1 Arrangements, where necessary, between the competent authorities of the Contracting Parties shall determine the methods of implementation of this Agreement.

2 The competent authorities of the Contracting Parties concerned shall endeavour to resolve by negotiation any dispute relating to the interpretation or application of this Agreement.

3 If any such dispute has not been resolved by negotiation within a period of three months, the dispute shall be submitted to arbitration by an arbitral body whose composition and procedure shall be agreed upon by the Contracting Parties concerned, or, in default of such agreement, within a further period of three months, by an arbitrator chosen at the request of any of the Contracting Parties concerned by the President of the International Court of Justice. Should the latter be a national of one of the Parties to the dispute, this task shall be entrusted to the Vice President of the Court or to the next judge in order of seniority not a national of one of the Parties to the dispute.

4 The decision of the arbitral body, or arbitrator, as the case may be, shall be made in accordance with the principles and spirit of this Agreement and shall be final and binding.

Article 12

In the event of the denunciation of this Agreement by any of the Contracting Parties,

a any right acquired by a person in accordance with its provisions shall be maintained and, in particular, if he has, in accordance with its provisions, acquired the right to receive any benefit under the laws and regulations of one of the Contracting Parties while he is resident in the territory of another, he shall continue to enjoy that right;

b subject to any conditions which may be laid down by supplementary agreements concluded by the Contracting Parties concerned for the settlement of any rights then in course of acquisition, the provisions of this Agreement shall continue to apply to insurance periods and equivalent periods completed before the date when the denunciation becomes effective.

Article 13

1 This Agreement shall be open to the signature of the members of the Council of Europe. It shall be ratified. Instruments of ratification shall be deposited with the Secretary General of the Council of Europe.

2 This Agreement shall come into force on the first day of the month following the date of deposit of the second instrument of ratification.

3 As regards any signatory ratifying subsequently, the Agreement shall come into force on the first day of the month following the date of the deposit of its instrument of ratification.
Article 14

1 The Committee of Ministers of the Council of Europe may invite any State not a member of the Council of Europe to accede to this Agreement.

2 Accession shall be effected by the deposit of an instrument of accession with the Secretary General of the Council of Europe, which shall take effect on the first day of the month following the date of deposit.

3 Any instrument of accession deposited in accordance with this article shall be accompanied by a notification of such information as would be contained in the Annexes I and II to this Agreement if the government of the State concerned were, on the date of accession, a signatory hereto.

4 For the purposes of this Agreement any information notified in accordance with paragraph 3 of this article shall be deemed to be part of the annex in which it would have been recorded if the government of the State concerned were a signatory hereto.

Article 15

The Secretary General of the Council of Europe shall notify:

a the members of the Council and the Director General of the International Labour Office:

i of the date of entry into force of this Agreement and the names of any members who ratify it,

ii of the deposit of any instrument of accession in accordance with Article 14 and of such notifications as are received with it,

iii of any notification received in accordance with Article 16 and its effective date;

b the Contracting Parties and the Director General of the International Labour Office:

i of any notifications received in accordance with Articles 7 and 8,

ii of any reservation made in accordance with paragraph 2 of Article 9,

iii of the withdrawal of any reservation in accordance with paragraph 3 of Article 9.

Article 16

This Agreement shall remain in force for a period of two years from the date of its entry into force in accordance with paragraph 2 of Article 13. Thereafter it shall remain in force from year to year for such Contracting Parties as have not denounced it by a notification to that effect addressed to the Secretary General of the Council of Europe at least six months before the expiry either of the preliminary two year period, or of any subsequent yearly period. Such notification shall take effect at the end of the period to which it relates.

In witness whereof the undersigned, being duly authorised thereto, have signed this Agreement.

Done at Paris, this 11th day of December 1953, in the English and French languages, both texts being equally authoritative, in a single copy which shall remain in the archives of the Council of

Europe and of which the Secretary General shall send certified copies to each of the signatories and to the Director General of the International Labour Office.

2.3.2. European interim agreement on social security other than schemes for old age, invalidity and survivors and protocol thereto *European Treaty Series - No. 13* Paris, 11.XII.1953

[…]

Article 1

1 This Agreement shall apply to all social security laws and regulations which are in force at the date of signature or may subsequently come into force in any part of the territory of the Contracting Parties and which relate to:

a sickness, maternity and death (death grants), including medical benefits insofar as they are not subject to a needs test;

b employment injury;

c unemployment;

d family allowances.

2 This Agreement shall apply to schemes of contributory and non-contributory benefits, including employers' obligations to compensate for employment injuries. It shall not apply to public assistance, special schemes for civil servants, or benefits paid in respect of war injuries or injuries due to foreign occupation.

3 For the purposes of this Agreement, the word “benefit” includes any increase in or supplement to the benefit.

4 The terms “nationals” and “territory” of a Contracting Party shall have the meaning assigned to them by such a Party in a declaration addressed to the Secretary General of the Council of Europe for communication to all other Contracting Parties.

Article 2

1 Subject to the provisions of Article 9, a national of any one of the Contracting Parties shall be entitled to receive the benefits of the laws and regulations of any other Contracting Parties under the same conditions as if he were a national of the latter:

a in the case of benefit in respect of employment injury, provided that he resides in the territory of one of the Contracting Parties;

b in the case of any benefit other than benefit in respect of employment injury, provided that he is ordinarily resident in the territory of the latter Contracting Party;

c in the case of benefit claimed in respect of sickness, maternity or unemployment, provided that he had become ordinarily resident in the territory of the latter Contracting Party before the first medical certification of the sickness, the presumed date of conception or the beginning of the unemployment, as the case may be;

d in the case of a benefit provided under a non-contributory scheme, other than a benefit in respect of employment injury, provided that he has been resident for six months in the territory of the latter Contracting Party.

2 In any case where the laws and regulations of any one of the Contracting Parties impose a restriction on the rights of a national of that Party who was not born in its territory, a national of any other of the Contracting Parties born in the territory of the latter shall be treated as if he were a national of the former Contracting Party born in its territory.

3 In any case where in determining a right to benefit the laws and regulations of any one of the Contracting Parties make any distinction which depends on the nationality of a child, a child who is a national of any other of the Contracting Parties shall be treated as if he were a national of the former Contracting Party.

Article 3

1 Any agreement relating to the laws and regulations referred to in Article 1 which has been or may be concluded by any two or more of the Contracting Parties shall, subject to the provisions of Article 9, apply to a national of any other of the Contracting Parties as if he were a national of one of the former Parties insofar as it provides, in relation to those laws and regulations:

a for determining under which laws and regulations a person should be insured;

b for maintaining acquired rights and rights in course of acquisition and, in particular, for adding together insurance periods and equivalent periods for the purpose of establishing the right to receive benefit and calculating the amount of benefit due;

c for paying benefit to persons residing in the territory of any one of the Parties to such agreement;

d for supplementing and administering the provisions of such agreement referred to in this paragraph.

2 The provisions of paragraph 1 of this article shall not apply to any provision of the said agreement which concerns benefits provided under a non-contributory scheme unless the national concerned has resided for six months in the territory of the Contracting Party under whose laws and regulations he claims benefit.

Article 4

Subject to the provisions of any relevant bilateral and multilateral agreements, benefits which in the absence of this Agreement have not been awarded or have been suspended shall be awarded or reinstated from the date of the entry into force of this Agreement for all the Contracting Parties concerned with the claim in question, provided that the claim thereto is presented within one year after such date or within such longer period as may be determined by the Contracting Party under whose laws and regulations the benefit is claimed. If the claim is not presented within such period, the benefit shall be awarded or reinstated from the date of the claim or such earlier date as may be determined by the latter Contracting Party.

Article 5

The provisions of this Agreement shall not limit the provisions of any national laws or regulations, international conventions, or bilateral or multilateral agreements which are more favourable for the beneficiary.

Article 6

This Agreement shall not affect those provisions of national laws or regulations which relate to the participation of insured persons, and of other categories of persons, concerned in the management of social security.

Article 7

1 Annex I to this Agreement sets out in relation to each Contracting Party the social security schemes to which Article 1 applies which are in force in any part of its territory at the date of signature of this Agreement.

2 Each Contracting Party shall notify the Secretary General of the Council of Europe of every new law or regulation of a type not included in Annex I in relation to that Party. Such notifications shall be made by each Contracting Party within three months of the date of publication of the new law or regulation, or if such law or regulation is published before the date of ratification of this Agreement by the Contracting Party concerned, at that date of ratification.

Article 8

1 Annex II to this Agreement sets out in relation to each Contracting Party the agreements concluded by it to which Article 3 applies which are in force at the date of signature of this Agreement.

2 Each Contracting Party shall notify the Secretary General of the Council of Europe of every new agreement concluded by it to which Article 3 applies. Such notification shall be made by each Contracting Party within three months of the date of coming into force of the agreement, or if such new agreement has come into force before the date of ratification of this Agreement, at that date of ratification.

Article 9

1 Annex III to this Agreement sets out the reservations hereto made at the date of signature.

2 Any Contracting Party may, at the time of making a notification in accordance with Article 7 or Article 8, make a reservation in respect of the application of this Agreement to any law, regulation or agreement which is referred to in such notification. A statement of any such reservation shall accompany the notification concerned; it will take effect from the date of entry into force of the new law, regulation or agreement.

3 Any Contracting Party may withdraw either in whole or in part any reservation made by it by a notification to that effect addressed to the Secretary General of the Council of Europe. Such notification shall take effect on the first day of the month following the month in which it is received and this Agreement shall apply accordingly.

Article 10

The annexes to this Agreement shall constitute an integral part of this Agreement.

Article 11

1 Arrangements where necessary between the competent authorities of the Contracting Parties shall determine the methods of implementation of this Agreement.

2 The competent authorities of the Contracting Parties concerned shall endeavour to resolve by negotiation any dispute relating to the interpretation or application of this Agreement.

3 If any dispute has not been resolved by negotiation within a period of three months, the dispute shall be submitted to arbitration by an arbitral body whose composition and procedure shall be agreed upon by the Contracting Parties concerned, or, in default of such agreement, within a further period of three months, by an arbitrator chosen at the request of any of the Contracting Parties concerned by the President of the International Court of Justice. Should the latter be a national of one of the Parties to the dispute, this task shall be entrusted to the Vice-President of the Court or to the next judge in order of seniority not a national of one of the Parties to the dispute.

4 The decision of the arbitral body, or arbitrator, as the case may be, shall be made in accordance with the principles and spirit of this Agreement and shall be final and binding.

Article 12

In the event of the denunciation of this Agreement by any of the Contracting Parties,

a any right acquired by a person in accordance with its provisions shall be maintained and, in particular, if he has, in accordance with its provisions, acquired the right to receive any benefit under the laws and regulations of one of the Contracting Parties while he is resident in the territory of another, he shall continue to enjoy that right;

b subject to any conditions which may be laid down by supplementary agreements concluded by the Contracting Parties concerned for the settlement of any rights then in course of acquisition, the provisions of this Agreement shall continue to apply to insurance periods and equivalent periods completed before the date when the denunciation becomes effective.

Article 13

1 This Agreement shall be open to the signature of the members of the Council of Europe. It shall be ratified. Instruments of ratification shall be deposited with the Secretary General of the Council of Europe.

2 This Agreement shall come into force on the first day of the month following the date of deposit of the second instrument of ratification.

3 As regards any signatory ratifying subsequently, the Agreement shall come into force on the first day of the month following the date of the deposit of its instrument of ratification.

Article 14

1 The Committee of Ministers of the Council of Europe may invite any State not a member of the Council of Europe to accede to this Agreement.

2 Accession shall be effected by the deposit of an instrument of accession with the Secretary General of the Council of Europe, which shall take effect on the first day of the month following the date of deposit.

3 Any instrument of accession deposited in accordance with this article shall be accompanied by a notification of such information as would be contained in the Annexes I and II to this Agreement if the government of the State concerned were, on the date of accession, a signatory hereto.

4 For the purposes of this Agreement any information notified in accordance with paragraph 3 of this article shall be deemed to be part of the annex in which it would have been recorded if the government of the State concerned were a signatory hereto.

Article 15

The Secretary General of the Council of Europe shall notify:

a the members of the Council and the Director General of the International Labour Office:

i of the date of entry into force of this Agreement and the names of any members who ratify;

ii of the deposit of any instrument of accession in accordance with Article 14 and of such notifications as are received with it;

iii of any notification received in accordance with Article 16 and its effective date;

b the Contracting Parties and the Director General of the International Labour Office:

i of any notifications received in accordance with Articles 7 and 8;

ii of any reservation made in accordance with paragraph 2 of Article 9;

iii of the withdrawal of any reservation in accordance with paragraph 3 of Article 9.

Article 16

This Agreement shall remain in force for a period of two years from the date of its entry into force in accordance with paragraph 2 of Article 13. Thereafter it shall remain in force from year to year for such Contracting Parties as have not denounced it by a notification to that effect addressed to the Secretary General of the Council of Europe at least six months before the expiry either of the preliminary two-year period, or of any subsequent yearly period. Such notification shall take effect at the end of the period to which it relates.

In witness whereof, the undesigned, being duly authorised thereto, have signed this Agreement.

Done at Paris, this 11th day of December 1953, in the English and French languages, both texts being equally authoritative, in a single copy which shall remain in the archives of the Council of Europe and of which the Secretary General shall send certified copies to each of the signatories and to the Director General of the International Labour Office.

PROTOCOL TO THE EUROPEAN INTERIM AGREEMENT ON SOCIAL SECURITY OTHER THAN SCHEMES FOR OLD AGE, INVALIDITY AND SURVIVORS

The governments signatory hereto, being members of the Council of Europe,

Having regard to the provisions of the European Interim Agreement on Social Security other than Schemes for Old Age, Invalidity and Survivors, signed at Paris on the 11th day of December 1953 (hereinafter referred to as “the principal Agreement”);

Having regard to the provisions of the Convention relating to the Status of Refugees signed at Geneva on 28 July 1951 (hereinafter referred to as “the Convention”);

Being desirous of extending the provisions of the principal Agreement so as to apply to refugees as defined in the Convention,

Have agreed as follows :

Article 1

For the purposes of this Protocol the term “refugee” shall have the meaning ascribed to it in Article 1 of the Convention, provided that each Contracting Party shall make a declaration at the time of signature or ratification hereof or accession hereto, specifying which of the meanings set out in paragraph B of Article 1 of the Convention it applies for the purpose of its obligations under this Protocol, unless such Party has already made such a declaration at the time of its signature or ratification of the Convention.

Article 2

The provisions of the principal Agreement shall apply to refugees under the same conditions as they apply to the nationals of the Contracting Parties thereto, provided that Article 3 of that Agreement shall apply to refugees only in cases where the Contracting Parties to the agreements to which that article refers have ratified this Protocol or acceded thereto.

Article 3

1 This Protocol shall be open to the signature of the members of the Council of Europe who have signed the principal Agreement. It shall be ratified.

2 Any State which has acceded to the principal Agreement may accede to this Protocol.

3 This Protocol shall come into force on the first day of the month following the date of deposit of the second instrument of ratification.

4 As regards any signatory ratifying subsequently, or any acceding State, the Protocol shall come into force on the first day of the month following the date of the deposit of its instrument of ratification or accession.

5 Instruments of ratification and accession shall be deposited with the Secretary General of the Council of Europe, who shall notify the members of the Council, acceding States and the Director General of the International Labour Office of the names of those who have ratified or acceded.

In witness whereof, the undersigned, being duly authorised thereto, have signed this Protocol.

Done at Paris, this 11th day of December 1953, in the English and French languages, both texts being equally authoritative, in a single copy which shall remain in the archives of the Council of

Europe and of which the Secretary General shall send certified copies to each of the signatories and to the Director General of the International Labour Office.

2.3.3. European convention on social and medical assistance and protocol thereto

European Treaty Series - No. 14 Paris, 11.XII.1953

[…]

Article 1

Each of the Contracting Parties undertakes to ensure that nationals of the other Contracting Parties who are lawfully present in any part of its territory to which this Convention applies, and who are without sufficient resources, shall be entitled equally with its own nationals and on the same conditions to social and medical assistance (hereinafter referred to as "assistance") provided by the legislation in force from time to time in that part of its territory.

Article 2

a For the purposes of this Convention the terms "assistance", "nationals", "territory" and "country of origin" shall have the following meanings, that is to say :

i "Assistance" means in relation to each Contracting Party all assistance granted under the laws and regulations in force in any part of its territory under which persons without sufficient resources are granted means of subsistence and the care necessitated by their condition, other than non-contributory pensions and benefits paid in respect of war injuries due to foreign occupation.

ii The terms "nationals" and "territory" of a Contracting Party shall have the meaning assigned to them by such a Party in a declaration addressed to the Secretary General of the Council of Europe for communication to all other Contracting Parties, provided that a person who has lost his nationality otherwise than by deprivation and has thereby become stateless shall, until he has acquired another nationality, continue to be treated as a national.

iii "Country of origin" means the country of which a person covered by the provisions of the present Convention is a national.

b The laws and regulations in force in the territories of the Contracting Parties and to which the present Convention applies, and the reservations formulated by Contracting Parties, are set forth in Annex I and Annex II respectively.

Article 3

Proof of the nationality of the person concerned shall be provided in accordance with the regulations governing such matters under the legislation of the country of origin.

Article 4

The cost of assistance to a national of any of the Contracting Parties shall be borne by the Contracting Party which has granted the assistance.

Article 5

The Contracting Parties undertake, so far as their laws and regulations permit, to help each other to recover the full cost of assistance as far as possible either from third parties under financial obligation to the assisted person or from persons who are liable to contribute to the cost of maintenance of the person concerned.

SECTION II – REPATRIATION

Article 6

a A Contracting Party in whose territory a national of another Contracting Party is lawfully resident shall not repatriate that national on the sole ground that he is in need of assistance.

b Nothing in this Convention shall prejudice the right to deport on any ground other than the sole ground mentioned in the previous paragraph.

Article 7

a The provisions of Article 6.a notwithstanding, a Contracting Party may repatriate a national of another Contracting Party resident in its territory on the sole ground mentioned in Article 6.a if the following conditions are fulfilled:

i the person concerned has not been continuously resident in the territory of that Contracting Party for at least five years if he entered it before attaining the age of 55 years, or for at least ten years if he entered it after attaining that age;

ii he is in a fit state of health to be transported; and

iii has no close ties in the territory in which he is resident.

b The Contracting Parties agree not to have recourse to repatriation except in the greatest moderation and then only where there is no objection on humanitarian grounds.

c In the same spirit, the Contracting Parties agree that, if they repatriate an assisted person, facilities should be offered to the spouse and children, if any, to accompany the person concerned.

Article 8

a The Contracting Party repatriating any national in accordance with the provisions of Article 7 shall bear the cost of repatriation as far as the frontier of the territory to which the national is being repatriated.

b Each Contracting Party undertakes to receive any of its nationals repatriated in accordance with the provisions of Article 7.

c Each Contracting Party undertakes to facilitate the transit across its territory of any persons repatriated in accordance with Article 7.

Article 9

If the country of which the assisted person claims to be a national does not recognise him as such, the grounds of the disclaimer must be forwarded to the country of residence within thirty days or as soon as possible thereafter.

Article 10

a When repatriation is decided upon, the diplomatic or consular authorities of the country of origin shall be advised (if possible, three weeks in advance) of the repatriation of their national.

b The authorities of the country of origin shall duly inform the authorities of any country or countries of transit.

c The places for handing over such persons shall be decided by arrangement between the competent authorities of the country of residence and the country of origin.

SECTION III – RESIDENCE

Article 11

a Residence by an alien in the territory of any of the Contracting Parties shall be considered lawful within the meaning of this Convention so long as there is in force in his case a permit or such other permission as is required by the laws and regulations of the country concerned to reside therein. Failure to renew any such permit, if due solely to the inadvertence of the person concerned, shall not cause him to cease to be entitled to assistance.

b Lawful residence shall become unlawful from the date of any deportation order made out against the person concerned, unless a stay of execution is granted.

Article 12

The commencing date of the period of residence laid down in Article 7 shall in each country be established, in the absence of evidence to the contrary, on the basis of evidence supplied by official investigation or by the documents listed in Annex III or any documents recognised by the laws and regulations of the country as affording proof of residence.

Article 13

a Proof of continuity of residence may be shown by the production of any evidence acceptable in the country of residence, such as proof of occupational activity or the production of rent receipts.

b i Residence shall be regarded as continuous notwithstanding periods of absence of less than three months, provided that the absence is not caused by repatriation or deportation.

ii Periods of absence of six months or more shall be held to interrupt the continuity of residence.

iii In order to determine whether a period of absence of between three and six months shall interrupt the continuity of residence, regard shall be had to the intention or otherwise of the person concerned to return to the country of residence and to the extent to which he has preserved his connection therewith during the period of his absence.

iv Service in ships registered in the country of residence shall not be held to interrupt the continuity of residence. Service in other ships shall be treated in accordance with the provisions of sub-paragraphs i to iii above.

Article 14

There shall be excluded in the calculation of length of residence those periods during which the person concerned has been in receipt of assistance from public monies as laid down in the legislative measures mentioned in Annex I, except in the case of medical treatment for acute illness or short-term medical treatment.

SECTION IV – MISCELLANEOUS PROVISIONS

Article 15

The administrative, diplomatic and consular authorities of the Contracting Parties shall afford to one another all possible assistance in the implementation of this Convention.

Article 16

a The Contracting Parties shall notify the Secretary General of the Council of Europe of any subsequent amendment of their laws and regulations which may affect Annexes I and III.

b Each Contracting Party shall notify to the Secretary General of the Council of Europe any new law or regulation not already included in Annex I. At the time of making such notification a Contracting Party may make a reservation in respect of the application of this new law or regulation to the nationals of other Contracting Parties.

c The Secretary General of the Council of Europe shall communicate to the other Contracting Parties any information notified to him in accordance with paragraphs a and b.

Article 17

The Contracting Parties may, by bilateral arrangement, take interim measures to deal with cases in which assistance was granted prior to the entry into force of this Convention.

Article 18

The provisions of this Convention shall not limit the provisions of any national laws or regulations, international conventions or bilateral or multilateral agreements which are more favourable for the beneficiary.

Article 19

Annexes I, II and III shall constitute an integral part of this Convention.

Article 20

a The competent authorities of the Contracting Parties shall endeavour to resolve by negotiation any dispute relating to the interpretation or application of this Convention.

b If any such dispute has not been resolved by negotiation within a period of three months, the dispute shall be submitted to arbitration by an arbitral body whose composition and procedure shall be agreed upon by the Contracting Parties concerned or, in default of such agreement within a further period of three months, by an arbitrator chosen at the request of any of the Contracting Parties concerned by the President of the International Court of Justice. Should the latter be a national of one of the Parties to the dispute, this task shall be entrusted to the Vice-President of the Court or to the next judge in order of seniority not a national of one of the Parties to the dispute.

c The decision of the arbitral body or arbitrator, as the case may be, shall be made in accordance with the principles and spirit of this Convention and shall be final and binding.

Article 21

a This Convention shall be open to the signature of the members of the Council of Europe. It shall be ratified. Instruments of ratification shall be deposited with the Secretary General of the Council of Europe.

b This Convention shall come into force on the first day of the month following the date of deposit of the second instrument of ratification.

c As regards any signatory ratifying subsequently, the Convention shall come into force on the first day of the month following the date of the deposit of its instrument of ratification.

Article 22

a The Committee of Ministers of the Council of Europe may invite any State not a member of the Council to accede to this Convention.

b Accession shall be effected by the deposit of an instrument of accession with the Secretary General of the Council of Europe, which shall take effect on the first day of the month following the date of deposit.

c Any instrument of accession deposited in accordance with this article shall be accompanied by a notification of such information as would be contained in the Annexes I and III to this Convention if the government of the State concerned were, on the date of accession, a signatory hereto.

d For the purposes of this Convention any information notified in accordance with paragraph c of this article shall be deemed to be part of the annex in which it would have been recorded if the government of the State concerned were a signatory hereto.

Article 23

The Secretary General of the Council of Europe shall notify the members of the Council:

a of the date of entry into force of this Convention and the names of any members who ratify it;

b of the deposit of any instrument of accession in accordance with Article 22 and of such notifications as are received with it;

c of any notification received in accordance with Article 24 and its effective date.

Article 24

This Convention shall remain in force for a period of two years from the date of its entry into force in accordance with paragraph b of Article 21. Thereafter it shall remain in force from year to year for such Contracting Parties as have not denounced it by a notification to that effect addressed to the Secretary General of the Council of Europe at least six months before the expiry either of the preliminary two-year period or of any subsequent yearly period. Such notification shall take effect at the end of the period to which it relates.

In witness whereof the undersigned, being duly authorised thereto, have signed the present Convention.

Done at Paris, this 11th day of December 1953, in English and French, both texts being equally authoritative, in a single copy, which shall remain deposited in the archives of the Council of Europe. The Secretary General shall transmit certified copies to each of the signatories.

2.3.4. Protocol to the european convention on social and medical assistance.

[…]

Article 1

For the purposes of this Protocol the term “refugee” shall have the meaning ascribed to it in Article 1 of the Geneva Convention, provided that each Contracting Party shall make a declaration at the time of signature or ratification hereof or accession hereto, specifying which of the meanings set out in paragraph B of Article 1 of that Convention it applies for the purpose of its obligations under this Protocol, unless such Party has already made such a declaration at the time of its signature or ratification of that Convention.

Article 2

The provisions of Section I of the Assistance Convention shall apply to refugees under the same conditions as they apply to the nationals of the Contracting Parties thereto.

Article 3

1 The provisions of Section II of the Assistance Convention shall not apply to refugees.

2 In the case of a person who has ceased to qualify for the benefits of the Geneva Convention in accordance with the provisions of paragraph C of Article 1 thereof, the period for repatriation laid down in Article 7.a.i of the Assistance Convention shall begin from the date when he has thus ceased to qualify.

Article 4

As between the Contracting Parties, the provisions of Articles 1, 2 and 3 of this Protocol shall be regarded as additional articles to the Assistance Convention, and the remaining provisions of that Convention shall apply accordingly.

Article 5

1 This Protocol shall be open to the signature of the members of the Council of Europe who have signed the Assistance Convention. It shall be ratified.

2 Any State which has acceded to the Assistance Convention may accede to this Protocol.

3 This Protocol shall come into force on the first day of the month following the date of deposit of the second instrument of ratification.

4 As regards any signatory ratifying subsequently, or any acceding State, the Protocol shall come into force on the first day of the month following the date of the deposit of its instrument of ratification or accession.

5 Instruments of ratification and accession shall be deposited with the Secretary General of the Council of Europe, who shall notify the members of the Council and acceding States of the names of those who have ratified or acceded.

In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol.

Done at Paris, this 11th day of December 1953, in English and French, both texts being equally authoritative, in a single copy, which shall remain deposited in the archives of the Council of Europe. The Secretary General shall transmit certified copies to each of the signatories.

2.3.5. European agreement on the exchange of therapeutic substances of human origin

European Treaty Series - No. 26 Paris, 15.XII.1958

Preamble

The governments signatory hereto, being members of the Council of Europe,

Considering that therapeutic substances of human origin are by their very nature the result of an act of the human donor and therefore not available in unlimited quantities;

Considering that it is most desirable that member countries, in a spirit of European solidarity, should assist one another in the supply of these therapeutic substances, should the need arise;

Considering that such mutual assistance is only possible if the character and use of such therapeutic substances are subject to rules laid down jointly by the member countries and if the necessary import facilities and exemptions are granted,

Have agreed as follows:

Article 1

For the purposes of this Agreement, the expression “therapeutic substances of human origin” refers to human blood and its derivatives.

The provisions of this Agreement may be extended to cover other therapeutic substances of human origin by exchange of letters between two or more of the Contracting Parties.

Article 2

The Contracting Parties undertake, provided that they have sufficient stocks for their own needs, to make therapeutic substances of human origin available to other Parties who are in urgent need of them and to charge only those costs involved in the collection, processing and carriage of such substances.

Article 3

Therapeutic substances of human origin shall be made available to the other Contracting Parties subject to the express condition that no profit is made on them, that they shall be used solely for medical purposes and shall be delivered only to bodies designated by the governments concerned.

Article 4[113]

The Contracting Parties shall certify that the minimum requirements with regard to the properties of the therapeutic substances, and the regulations on labelling, packing and dispatch, as laid down in the Protocol to this Agreement, have been observed.

[113] The publication of the Protocol and its annexes was omitted.

They shall also comply with any rules to which they have subscribed with regard to international standardisation in this field.

All consignments of therapeutic substances of human origin shall be accompanied by a certificate to the effect that they were prepared in accordance with the specifications in the Protocol. This certificate shall be based on the model to be found in Annex 1 to the Protocol.

The Protocol and its annexes may be amended or supplemented by the governments of the Parties to this Agreement.

Article 5

The Contracting Parties shall take all necessary measures to exempt from all import duties the therapeutic substances of human origin placed at their disposal by the other Parties.

They shall also take all necessary measures to provide for the speedy delivery of these substances, by the most direct route, to the consignees referred to in Article 3 of this Agreement.

Article 6

The Contracting Parties shall forward to one another, through the Secretary General of the Council of Europe, a list of the bodies empowered to issue certificates as provided in Article 4 of this Agreement.

They shall also forward a list of bodies empowered to distribute imported therapeutic substances of human origin.

Article 7[114]

The present Agreement shall be open to the signature of members of the Council of Europe, who may become Parties to it either by:

a signature without reservation in respect of ratification, or

b signature with reservation in respect of ratification followed by ratification.

[114] By virtue of Article 1 of the Additional Protocol to the European Agreement on the Exchange of Therapeutic Substances of Human origin (ETS No. 109) which entered into force on 1 January 1985: "The European Economic Community may become a Contracting Party to the Agreement by signing it. In respect of the Community, the Agreement shall enter into force on the first day of the month following such signature."

Instruments of ratification shall be deposited with the Secretary General of the Council of Europe.

Article 8

The present Agreement shall enter into force on the first day of the month following the date on which three members of the Council shall, in accordance with Article 7, have signed the Agreement without reservation in respect of ratification or shall have ratified it.

In the case of any member of the Council who shall subsequently sign the Agreement without reservation in respect of ratification, or who shall ratify it, the Agreement shall enter into force on the first day of the month following such signature or deposit of the instrument of ratification.

Article 9

The Committee of Ministers of the Council of Europe may invite any non-member State to accede to the present Agreement. Such accession shall take effect on the first day of the month following the deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 10

The Secretary General of the Council of Europe shall notify members of the Council and acceding States:

a of the date of entry into force of this Agreement and of the names of any members who have signed without reservation in respect of ratification or who have ratified it;

b of the deposit of any instrument of accession in accordance with Article 9;

c of any notification received in accordance with Article 11 and its effective date;

d of any amendment to the Protocol or its annexes under Article 4, paragraph 4.

Article 11

The present Agreement shall remain in force indefinitely.

Any Contracting Party may terminate its own application of the Agreement by giving one year's notice to that effect to the Secretary General of the Council of Europe.

In witness whereof the undersigned, duly authorised thereto by their respective governments, have signed the present Agreement.

Done at Paris, this 15th day of December 1958, in the English and French languages, both texts being equally authoritative, in a single copy which shall remain deposited in the archives of the Council of Europe. The Secretary General shall transmit certified copies to each of the signatory and acceding governments.

PROTOCOL TO THE AGREEMENT

PART I

General provisions

A. *Labelling*

A label printed in two languages, based on the appropriate model to be found in Annexes 2 to 6 to the Protocol, shall be affixed to each container or giving-set.

B. *Packing and dispatch*

Whole human blood shall be dispatched in containers in which a temperature of 4° to 6° C. is maintained throughout the period of transport.

This condition is not required for the derivatives mentioned in the Protocol.

C. *Products and apparatus*

The products and apparatus referred to in Part II of this Protocol shall be sterile, non-pyrogenic and non-toxic.

It is recommended that the giving-set, as well as the solvents required for the dried products, be sent with each consignment.

PART II

Specific provisions

I. Whole human blood

Whole human blood is blood which has been mixed with a suitable anti- coagulant, after collection from a human subject in normal health.

The blood shall not be obtained from a human subject :

(a) who is known to be suffering from or to have suffered from syphilis,

(b) whose blood bas not been tested with negative results for evidence of syphilitic infection, or

(c) who is not, as far as can be ascertained after medical inspection or simple examination and consideration of his medical history, free from disease transmissible by blood transfusion.

The blood shall be withdrawn aseptically through a closed system of sterile tubing into a sterile container in which the anticoagulant solution has been placed before the container is sterilised. The equipment used must be pyrogen-free. When withdrawal is complete the container shall be immediately sealed and cooled to 4° to 6° C. and not opened thereafter before dispatch to one of the Member States.

The blood will be collected into a citrate solution of acid reaction containing dextrose. No antiseptic or bacteriostatic substance shall be added. The volume of the anticoagulant solution must not exceed 22 % of the whole human blood, and the haemoglobin content must not be less than 9.7 gr/100 ml.

Blood group – The blood group under the ABO system shall have been determined by examination of both corpuscles and serum and that under the Rh system by examination of the corpuscles, using a separate sample of the donor's blood. When there is a national standard, or nationally recommended technique of blood grouping, that shall be used.

Storage – Whole human blood shall be kept in a sterile container scaled so as to exclude micro-organisms and stored at a temperature of 4° to 6° C. until required for use, except during any period necessary for examination and transport at higher temperatures, any such period not to exceed thirty minutes after which the blood must immediately be cooled again to 4° to 6° C.

Labelling – The label on the container shall state :

1. the ABO group;
2. the Rh group, either Rh positive or Rh negative. The term Rh negative is only to be used when specific tests have shown the absence of the antigens C, D and E. All other bloods must be labelled Rh positive;
3. the total volume of blood, the volume and the composition of the anticoagulant solution;
4. the dates of collection and expiry;
5. the conditions under which it should be stored;
6. that the contents should not be used if there is any visible evidence of deterioriation.

2. Dried Human Plasma

Dried human plasma is prepared by drying the supernatant fluids which are separated by centrifuging or by standing from quantities of whole human blood. The litre of anti-A and anti-B, both naturally occurring and immune, should not exceed 32. To avoid untoward effect due to the products of bacterial growth in the plasma, no individual contribution shall be used if there is any evidence of bacterial contamination, and the bacterial sterility of each pool shall be tested by culturing not less than 10 ml.

During preparation no antiseptic or bacteriostatic substance shall be added. To minimise the risk of transmitting homologous serum jaundice, plasma should be prepared from pools not containing more than twelve separate donations or by any other method that has been shown to diminish this risk in a comparable manner.

The plasma shall be dried by freeze-drying or by any other method which will avoid denaturation of the proteins and will yield a product readily soluble in a quantity of water equal to the volume of the liquid from which the substance was prepared. When dissolved in a quantity of water equal to the volume of the liquid from which the substance was prepared, the solution must not contain less than 4.5 per cent w/v of protein and must show no visible evidence of the products of haemolysis.

Solubility in water – Add a quantity of water equal to the volume of the liquid from which the sample was prepared; the substance dissolves completely within ten minutes at 15° to 20° C.

Identification – Dissolve a quantity in a volume of water equal to the volume of the liquid from which it was prepared; the solution answers to the following tests :

1. by precipitation tests with specific antisera, it must be shown to contain only human serum proteins;
2. to 1 ml. add a suitable amount of thrombin or calcium chloride, and coagulation occurs, which can be accelerated by incubation at 37° C.

Loss of weight on drying – When dried over phosphorus pentoxide at a pressure not exceeding 0,02 mm. of mercury for 24 hours, it must not lose more than 0.5 percent of its weight.

Sterility – The final product, after reconstitution, should be sterile when examined by a suitable bacteriological method.

Storage – Dried human plasma must be kept in atmosphere of nitrogen or in a vacuum in a sterile container sealed so as to exclude micro-organisms and, as far as possible, moisture, protected from light and stored at a temperature below 20° C.

Labelling – The label on the container shall state :

1. the nature and percentage of anticoagulant and of any other material introduced;
2. the quantity of solvent necessary to reconstitute the original volume of liquid human plasma;
3. the minimum protein content of the reconstituted liquid human plasma;
4. the dates of preparation and expiry;
5. the conditions under which it should be stored;
6. that the reconstituted liquid human plasma must be used immediately after reconstitution.

3. Human Albumin

Human albumin is a preparation of that protein component which forms about 60 % of the total protein content of the plasma of whole human blood. The processing method used shall be one which produces a material meeting the requirements herein prescribed. Regardless of whether the final product is liquid or dried, the albumin, after the addition of a suitable stabilising agent or agents, must be heated in the liquid state during processing at 60° C ± 0.5° C. for 10 hours, in order to inactivate the agent causing homologous serum jaundice. During preparation no antiseptic or bacteriostatic substance shall be added. When the final product is freeze-dried it must contain not less than 95 0,@' of protein. When the final product is prepared as a solution, the solution shall contain not less than 20 0/ of protein and must not show any visible turbidity during the period for which the solution is approved for use. *Solubility of the dried Product* – Add water to gave a 20 % solution; the albumin must be completely soluble.

Stability – The viscosity relative to water, determined at 37° C. of a 6.25 % solution of human albumin must not increase by more than 5 % during the heating process at 60° C. for 10 hours.

Identification

1. By precipitation tests with specific antisera, it must be shown to contain only human plasma proteins.
2. By electrophoresis, using the moving boundary technique under acceptable and appropriate conditions, it must be shown to contain not less than 95 %, of the protein having the mobility of the albumin component of normal human plasma.

Sterility – The final product should be sterile when examined by a suitable bacteriological method.

Sodium content – The sodium content must not exceed 750 mg. per 100 ml. 25 % albumin solution. In the case of salt-poor albumin the sodium content must not exceed 325 mg. per 100 ml. 25 % solution.

Acidity – After dilution of the albumin solution to a protein concentration of 1 % the pH should be 6.9 ± 0.4.

Loss of weight on drying - When dried over phosphorus pentoxide at a pressure no exceeding 0.02 mm. of mercury for 24 hours it must not lose more than 0.5 per cent of its weight.

Storage – Dried human albumin must be kept in an atmosphere of nitrogen or in a vacuum in a sterile container sealed so as to exclude micro-organisms and, as far as possible, moisture, protected from light and stored at a temperature below 20° C.

Liquid human albumin must be kept in a sterile container sealed so as to exclude micro-organisms, protected from light and stored at a temperature of 4° to 6° C.

Labelling – The label on the container must state

1. the amount of human albumin contained in it and the nature and percentage of any other material introduced;
2. the amount of sodium;
3. the dates of preparation and expiry;
4. the conditions under which it should be stored;
5. in the case of the liquid product, that it should not be used unless it is clear and free from deposits;
6. in the case of the dried product, that it should be used immediately after reconstitution.

4. Human Gamma Globulin (This schedule does not apply to gamma globulin, derived from human placentae).

Human gamma globulin is a preparation of the plasma proteins, prepared from whole human blood containing the antibodies of normal adults. It is obtained from pooled liquid human plasma from not less than 1,000 donors.

The processing method used should be one which produces a material meeting the requirements herein prescribed. It should be such as to prevent the transmission of homologous serum jaundice by the final product. During preparation no antiseptic or bacteriostatic substance shall be added.

When the final product is issued in the freeze-dried form. it shall not contain less than 95 % of protein. When the final product is issued as a solution, it shall not contain less than 10 % of protein.

Solubility of the dried Product – Add water to give a 10 % solution; the gamma globulin must be completely soluble.

Identification

1. By precipitation tests with specific antisera, it must be shown to contain only human plasma proteins;
2. by electrophoresis, using the moving boundary technique under acceptable and appropriate conditions, it must be shown to contain not less than 90 % of the proteins having the mobility of the gamma components of the globulins of normal human plasma.

Sterility – The final product should be sterile when examined by a suitable bacteriological method.

Stability test – Both before and after heating the final liquid product or reconstituted dried product at 37° C. for 7 days there should be no visible evidence of precipitation or turbidity. Moreover, after heating at 57° C. for 4 hours there should be no visible evidence of gelation.

Loss of weight on drying – When dried over phosphorus pentoxide at a pressure not exceeding 0.02 mm. of mercury for 24 hours it must not lose more than 0.5 per cent of its weight.

Storage – The dried human gamma globulin must be kept in an atmosphere of nitrogen or in a vacuum in a sterile container sealed so as to exclude micro-organisms and, as far as possible, moisture, protected from light and stored at a temperature below 20° C.

Liquid human gamma globulin must be kept in a sterile container, sealed so as to exclude micro-organisms, protected from light and stored at a temperature of 4° to 6° C.

Labelling – The label on the container shall state

1. the amount of human gamma globulin contained in it and the nature and percentage of any other material introduced;
2. in the case of the dried product, the volume and composition of the solvent;
3. the dates of preparation and expiry;
4. the conditions under which it should bc stored;
5. « not for intravenous injection »;
6. in the case of the dried product, that it should bc used immediately after reconstitution.

5. Human Fibrinogen

Human fibrinogen is a dried preparation of the soluble constituent of liquid human plasma which, on the addition of thrombin, is transformed to fibrin. The processing method used should be one which produces a material meeting the requirements herein prescribed and which minimises the risk of transmitting homologous serum jaundice.

During preparation no antiseptic or bacteriostatic substance shall be added. The final product shall be freeze-dried. No less than 60 % of the total protein present shall be contained in the clot formed by the addition of thrombin.

Solubility – When the appropriate volume of the recommended solvent is added, the fibrinogen must be soluble, and form a colourless solution.

Identification

1. By precipitation test with specific antisera, it must be shown to contain only human plasma proteins;
2. the freshly reconstituted product has the property of clotting on the addition of thrombin.

Sterility – The final product after reconstitution should be sterile, when examined by a suitable bacteriological method.

Loss of weight on drying – When dried over phosphorus pentoxide at a pressure not exceeding 0.02 mm. of mercury for 24 hours it must not lose more than 0.5 per cent of its weight.

Storage – Human fibrinogen shall be kept in an atmosphere of nitrogen or in a vacuum in a sterile container sealed so as to exclude micro-organisms and, as far as possible, moisture, protected from light and stored at the temperature recommended.

Labelling – The label on the container shall state :

1. the amount of fibrinogen contained in it and the nature and percentage of any other material introduced;
2. the volume and composition of the solvent;
3. the dates of preparation and expiry;
4. the conditions under which it should be stored;
5. that it should be used immediately after reconstitution.

[…]

2.3.6. Agreement on the temporary importation, free of duty, of medical, surgical and laboratory equipment for use on free loan in hospitals and other medical institutions for purposes of diagnosis or treatment *European Treaty Series - No. 33* Strasbourg, 28.IV.1960

[…]

Article 1

1 The Contracting Parties shall, provided that they have sufficient stocks for their own needs, make medical, surgical and laboratory equipment available on free loan to such other Contracting Parties as may, in exceptional circumstances, have urgent need of it; such equipment shall, upon request, be sent to the Party concerned and shall subsequently be returned.

2 Each Contracting Party benefiting under the terms of the previous paragraph shall grant all possible facilities for the importation on a temporary basis of the equipment loaned.

Article 2

1 The period of temporary importation shall not exceed six months in the first instance but may, with the agreement of the exporting country, be extended for a further period subject to the same conditions.

2 The above facilities shall be granted only in respect of medical, surgical and laboratory equipment for use in hospitals and other medical institutions. They shall include the issue of any licences required for the temporary importation of such equipment and the suspension of import duties and import taxes (including all duties and taxes whatsoever chargeable by reason of importation) other than charges for actual expenses incurred by the authorities of the country of temporary importation.

Article 3

Notwithstanding the provisions of Articles 1 and 2 above, the competent authorities of the importing State may take such measures as may be necessary either to ensure the re-exportation of any such equipment imported on a temporary basis, once the exceptional circumstances shall have ceased to exist or the time-limit provided for under paragraph 1 of Article 2 above has elapsed, whichever is the earlier, or to ensure payment of any import duties and import taxes which become payable in the case of any failure to re-export the equipment.

Article 4

The provisions of this Agreement shall not prejudice more favourable provisions for the temporary importation of the equipment referred to in Article 1, contained in the laws or

regulations of any Contracting Party or in any convention, treaty or agreement in force between two or more Contracting Parties to the present Agreement.

Article 5

1 This Agreement shall be open to the signature of members of the Council of Europe, who may become Parties to it by:

a signature without reservation in respect of ratification, or

b signature with reservation in respect of ratification, followed by ratification.

2 Instruments of ratification shall be deposited with the Secretary General of the Council of Europe.

Article 6

1 This Agreement shall enter into force three months after the date on which three members of the Council shall, in accordance with Article 5, have signed the Agreement without reservation in respect of ratification or shall have ratified it.

2 In the case of any member of the Council who subsequently shall sign the Agreement without reservation in respect of ratification or who shall ratify it, the Agreement shall enter into force three months after the date of such signature or of the deposit of the instrument of ratification.

Article 7

The Committee of Ministers of the Council of Europe may invite any non-member State to accede to this Agreement. Such accession shall take effect three months after the date on which the instrument of accession was deposited with the Secretary General of the Council of Europe.

Article 8

The Secretary General of the Council of Europe shall notify members of the Council and acceding States:

a of the date of entry into force of this Agreement and the names of any members who have signed without reservation in respect of ratification or who have ratified it;

b of the deposit of any instrument of accession in accordance with Article 7.

Article 9

1 This Agreement shall remain in force indefinitely.

2 Any Contracting Party may withdraw from the Agreement by giving one year's notice to that effect to the Secretary General of the Council of Europe.

In witness whereof the undersigned, being duly authorised thereto, have signed this Agreement.

Done at Strasbourg, this 28th day of April 1960, in English and French, both texts being equally authoritative, in a single copy which shall remain deposited in the archives of the Council of Europe. The Secretary General shall send certified copies to each of the signatory and acceding governments.

2.3.7. European social charter *European Treaty Series - No. 35* Turin, 18.X.1961

[…]

Part I

The Contracting Parties accept as the aim of their policy, to be pursued by all appropriate means, both national and international in character, the attainment of conditions in which the following rights and principles may be effectively realised:

1 Everyone shall have the opportunity to earn his living in an occupation freely entered upon.

2 All workers have the right to just conditions of work.

3 All workers have the right to safe and healthy working conditions.

4 All workers have the right to a fair remuneration sufficient for a decent standard of living for themselves and their families.

5 All workers and employers have the right to freedom of association in national or international organisations for the protection of their economic and social interests.

6 All workers and employers have the right to bargain collectively.

7 Children and young persons have the right to a special protection against the physical and moral hazards to which they are exposed.

8 Employed women, in case of maternity, and other employed women as appropriate, have the right to a special protection in their work.

9 Everyone has the right to appropriate facilities for vocational guidance with a view to helping him choose an occupation suited to his personal aptitude and interests.

10 Everyone has the right to appropriate facilities for vocational training.

11 Everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable.

12 All workers and their dependents have the right to social security.

13 Anyone without adequate resources has the right to social and medical assistance.

14 Everyone has the right to benefit from social welfare services.

15 Disabled persons have the right to vocational training, rehabilitation and resettlement, whatever the origin and nature of their disability.

16 The family as a fundamental unit of society has the right to appropriate social, legal and economic protection to ensure its full development.

17 Mothers and children, irrespective of marital status and family relations, have the right to appropriate social and economic protection.

18 The nationals of any one of the Contracting Parties have the right to engage in any gainful occupation in the territory of any one of the others on a footing of equality with the nationals of the latter, subject to restrictions based on cogent economic or social reasons.

19 Migrant workers who are nationals of a Contracting Party and their families have the right to protection and assistance in the territory of any other Contracting Party.

Part II

The Contracting Parties undertake, as provided for in Part III, to consider themselves bound by the obligations laid down in the following articles and paragraphs.

Article 1 – The right to work

With a view to ensuring the effective exercise of the right to work, the Contracting Parties undertake:

1 to accept as one of their primary aims and responsibilities the achievement and maintenance of as high and stable a level of employment as possible, with a view to the attainment of full employment;

2 to protect effectively the right of the worker to earn his living in an occupation freely entered upon;

3 to establish or maintain free employment services for all workers;

4 to provide or promote appropriate vocational guidance, training and rehabilitation.

Article 2 – The right to just conditions of work

With a view to ensuring the effective exercise of the right to just conditions of work, the Contracting Parties undertake:

1 to provide for reasonable daily and weekly working hours, the working week to be progressively reduced to the extent that the increase of productivity and other relevant factors permit;

2 to provide for public holidays with pay;

3 to provide for a minimum of two weeks annual holiday with pay;

4 to provide for additional paid holidays or reduced working hours for workers engaged in dangerous or unhealthy occupations as prescribed;

5 to ensure a weekly rest period which shall, as far as possible, coincide with the day recognised by tradition or custom in the country or region concerned as a day of rest.

Article 3 – The right to safe and healthy working conditions

With a view to ensuring the effective exercise of the right to safe and healthy working conditions, the Contracting Parties undertake:

1 to issue safety and health regulations;

2 to provide for the enforcement of such regulations by measures of supervision;

3 to consult, as appropriate, employers' and workers' organisations on measures intended to improve industrial safety and health.

Article 4 – The right to a fair remuneration

With a view to ensuring the effective exercise of the right to a fair remuneration, the Contracting Parties undertake:

1 to recognise the right of workers to a remuneration such as will give them and their families a decent standard of living;

2 to recognise the right of workers to an increased rate of remuneration for overtime work, subject to exceptions in particular cases;

3 to recognise the right of men and women workers to equal pay for work of equal value;

4 to recognise the right of all workers to a reasonable period of notice for termination of employment;

5 to permit deductions from wages only under conditions and to the extent prescribed by national laws or regulations or fixed by collective agreements or arbitration awards.

The exercise of these rights shall be achieved by freely concluded collective agreements, by statutory wage-fixing machinery, or by other means appropriate to national conditions.

Article 5 – The right to organise

With a view to ensuring or promoting the freedom of workers and employers to form local, national or international organisations for the protection of their economic and social interests and to join those organisations, the Contracting Parties undertake that national law shall not be such as to impair, nor shall it be so applied as to impair, this freedom. The extent to which the guarantees provided for in this article shall apply to the police shall be determined by national laws or regulations. The principle governing the application to the members of the armed forces of these guarantees and the extent to which they shall apply to persons in this category shall equally be determined by national laws or regulations.

Article 6 – The right to bargain collectively

With a view to ensuring the effective exercise of the right to bargain collectively, the Contracting Parties undertake:

1 to promote joint consultation between workers and employers;

2 to promote, where necessary and appropriate, machinery for voluntary negotiations between employers or employers' organisations and workers' organisations, with a view to the regulation of terms and conditions of employment by means of collective agreements;

3 to promote the establishment and use of appropriate machinery for conciliation and voluntary arbitration for the settlement of labour disputes;

and recognise:

4 the right of workers and employers to collective action in cases of conflicts of interest, including the right to strike, subject to obligations that might arise out of collective agreements previously entered into.

Article 7 – The right of children and young persons to protection

With a view to ensuring the effective exercise of the right of children and young persons to protection, the Contracting Parties undertake:

1 to provide that the minimum age of admission to employment shall be 15 years, subject to exceptions for children employed in prescribed light work without harm to their health, morals or education;

2 to provide that a higher minimum age of admission to employment shall be fixed with respect to prescribed occupations regarded as dangerous or unhealthy;

3 to provide that persons who are still subject to compulsory education shall not be employed in such work as would deprive them of the full benefit of their education;

4 to provide that the working hours of persons under 16 years of age shall be limited in accordance with the needs of their development, and particularly with their need for vocational training;

5 to recognise the right of young workers and apprentices to a fair wage or other appropriate allowances;

6 to provide that the time spent by young persons in vocational training during the normal working hours with the consent of the employer shall be treated as forming part of the working day;

7 to provide that employed persons of under 18 years of age shall be entitled to not less than three weeks' annual holiday with pay;

8 to provide that persons under 18 years of age shall not be employed in night work with the exception of certain occupations provided for by national laws or regulations;

9 to provide that persons under 18 years of age employed in occupations prescribed by national laws or regulations shall be subject to regular medical control;

10 to ensure special protection against physical and moral dangers to which children and young persons are exposed, and particularly against those resulting directly or indirectly from their work.

Article 8 – The right of employed women to protection

With a view to ensuring the effective exercise of the right of employed women to protection, the Contracting Parties undertake:

1 to provide either by paid leave, by adequate social security benefits or by benefits from public funds for women to take leave before and after childbirth up to a total of at least 12 weeks;

2 to consider it as unlawful for an employer to give a woman notice of dismissal during her absence on maternity leave or to give her notice of dismissal at such a time that the notice would expire during such absence;

3 to provide that mothers who are nursing their infants shall be entitled to sufficient time off for this purpose;

4 a to regulate the employment of women workers on night work in industrial employment;

b to prohibit the employment of women workers in underground mining, and, as appropriate, on all other work which is unsuitable for them by reason of its dangerous, unhealthy, or arduous nature.

Article 9 – The right to vocational guidance

With a view to ensuring the effective exercise of the right to vocational guidance, the Contracting Parties undertake to provide or promote, as necessary, a service which will assist all persons, including the handicapped, to solve problems related to occupational choice and progress, with due regard to the individual's characteristics and their relation to occupational opportunity: this assistance should be available free of charge, both to young persons, including school children, and to adults.

Article 10 – The right to vocational training

With a view to ensuring the effective exercise of the right to vocational training, the Contracting Parties undertake:

1 to provide or promote, as necessary, the technical and vocational training of all persons, including the handicapped, in consultation with employers' and workers' organisations, and to grant facilities for access to higher technical and university education, based solely on individual aptitude;

2 to provide or promote a system of apprenticeship and other systematic arrangements for training young boys and girls in their various employments;

3 to provide or promote, as necessary:

a adequate and readily available training facilities for adult workers;

b special facilities for the re-training of adult workers needed as a result of technological development or new trends in employment;

4 to encourage the full utilisation of the facilities provided by appropriate measures such as:

a reducing or abolishing any fees or charges;

b granting financial assistance in appropriate cases;

c including in the normal working hours time spent on supplementary training taken by the worker, at the request of his employer, during employment;

d ensuring, through adequate supervision, in consultation with the employers' and workers' organisations, the efficiency of apprenticeship and other training arrangements for young workers, and the adequate protection of young workers generally.

Article 11 – The right to protection of health

With a view to ensuring the effective exercise of the right to protection of health, the Contracting Parties undertake, either directly or in co-operation with public or private organisations, to take appropriate measures designed *inter alia*:

1 to remove as far as possible the causes of ill-health;

2 to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health;

3 to prevent as far as possible epidemic, endemic and other diseases.

Article 12 – The right to social security

With a view to ensuring the effective exercise of the right to social security, the Contracting Parties undertake:

1 to establish or maintain a system of social security;

2 to maintain the social security system at a satisfactory level at least equal to that required for ratification of International Labour Convention (No. 102) Concerning Minimum Standards of Social Security;

3 to endeavour to raise progressively the system of social security to a higher level;

4 to take steps, by the conclusion of appropriate bilateral and multilateral agreements, or by other means, and subject to the conditions laid down in such agreements, in order to ensure:

a equal treatment with their own nationals of the nationals of other Contracting Parties in respect of social security rights, including the retention of benefits arising out of social security legislation, whatever movements the persons protected may undertake between the territories of the Contracting Parties;

b the granting, maintenance and resumption of social security rights by such means as the accumulation of insurance or employment periods completed under the legislation of each of the Contracting Parties.

Article 13 – The right to social and medical assistance

With a view to ensuring the effective exercise of the right to social and medical assistance, the Contracting Parties undertake:

1 to ensure that any person who is without adequate resources and who is unable to secure such resources either by his own efforts or from other sources, in particular by benefits under a social security scheme, be granted adequate assistance, and, in case of sickness, the care necessitated by his condition;

2 to ensure that persons receiving such assistance shall not, for that reason, suffer from a diminution of their political or social rights;

3 to provide that everyone may receive by appropriate public or private services such advice and personal help as may be required to prevent, to remove, or to alleviate personal or family want;

4 to apply the provisions referred to in paragraphs 1, 2 and 3 of this article on an equal footing with their nationals to nationals of other Contracting Parties lawfully within their territories, in accordance with their obligations under the European Convention on Social and Medical Assistance, signed at Paris on 11th December 1953.

Article 14 – The right to benefit from social welfare services

With a view to ensuring the effective exercise of the right to benefit from social welfare services, the Contracting Parties undertake:

1 to promote or provide services which, by using methods of social work, would contribute to the welfare and development of both individuals and groups in the community, and to their adjustment to the social environment;

2 to encourage the participation of individuals and voluntary or other organisations in the establishment and maintenance of such services.

Article 15 – The right of physically or mentally disabled persons to vocational training, rehabilitation and social resettlement

With a view to ensuring the effective exercise of the right of the physically or mentally disabled to vocational training, rehabilitation and resettlement, the Contracting Parties undertake:

1 to take adequate measures for the provision of training facilities, including, where necessary, specialised institutions, public or private;

2 to take adequate measures for the placing of disabled persons in employment, such as specialised placing services, facilities for sheltered employment and measures to encourage employers to admit disabled persons to employment.

Article 16 – The right of the family to social, legal and economic protection

With a view to ensuring the necessary conditions for the full development of the family, which is a fundamental unit of society, the Contracting Parties undertake to promote the economic, legal and social protection of family life by such means as social and family benefits, fiscal arrangements, provision of family housing, benefits for the newly married, and other appropriate means.

Article 17 – The right of mothers and children to social and economic protection

With a view to ensuring the effective exercise of the right of mothers and children to social and economic protection, the Contracting Parties will take all appropriate and necessary measures to that end, including the establishment or maintenance of appropriate institutions or services.

Article 18 – The right to engage in a gainful occupation in the territory of other Contracting Parties

With a view to ensuring the effective exercise of the right to engage in a gainful occupation in the territory of any other Contracting Party, the Contracting Parties undertake:

1 to apply existing regulations in a spirit of liberality;

2 to simplify existing formalities and to reduce or abolish chancery dues and other charges payable by foreign workers or their employers;

3 to liberalise, individually or collectively, regulations governing the employment of foreign workers;

and recognise:

4 the right of their nationals to leave the country to engage in a gainful occupation in the territories of the other Contracting Parties.

Article 19 – The right of migrant workers and their families to protection and assistance

With a view to ensuring the effective exercise of the right of migrant workers and their families to protection and assistance in the territory of any other Contracting Party, the Contracting Parties undertake:

1 to maintain or to satisfy themselves that there are maintained adequate and free services to assist such workers, particularly in obtaining accurate information, and to take all appropriate steps, so far as national laws and regulations permit, against misleading propaganda relating to emigration and immigration;

2 to adopt appropriate measures within their own jurisdiction to facilitate the departure, journey and reception of such workers and their families, and to provide, within their own jurisdiction, appropriate services for health, medical attention and good hygienic conditions during the journey;

3 to promote co-operation, as appropriate, between social services, public and private, in emigration and immigration countries;

4 to secure for such workers lawfully within their territories, insofar as such matters are regulated by law or regulations or are subject to the control of administrative authorities, treatment not less favourable than that of their own nationals in respect of the following matters:

a remuneration and other employment and working conditions;

b membership of trade unions and enjoyment of the benefits of collective bargaining;

c accommodation;

5 to secure for such workers lawfully within their territories treatment not less favourable than that of their own nationals with regard to employment taxes, dues or contributions payable in respect of employed persons;

6 to facilitate as far as possible the reunion of the family of a foreign worker permitted to establish himself in the territory;

7 to secure for such workers lawfully within their territories treatment not less favourable than that of their own nationals in respect of legal proceedings relating to matters referred to in this article;

8 to secure that such workers lawfully residing within their territories are not expelled unless they endanger national security or offend against public interest or morality;

9 to permit, within legal limits, the transfer of such parts of the earnings and savings of such workers as they may desire;

10 to extend the protection and assistance provided for in this article to self-employed migrants insofar as such measures apply.

Part III

Article 20 – Undertakings

1 Each of the Contracting Parties undertakes:

a to consider Part I of this Charter as a declaration of the aims which it will pursue by all appropriate means, as stated in the introductory paragraph of that part;

b to consider itself bound by at least five of the following articles of Part II of this Charter: Articles 1, 5, 6, 12, 13, 16 and 19;

c in addition to the articles selected by it in accordance with the preceding sub-paragraph, to consider itself bound by such a number of articles or numbered paragraphs of Part II of the Charter as it may select, provided that the total number of articles or numbered paragraphs by which it is bound is not less than 10 articles or 45 numbered paragraphs.

2 The articles or paragraphs selected in accordance with sub-paragraphs b and c of paragraph 1 of this article shall be notified to the Secretary General of the Council of Europe at the time when the instrument of ratification or approval of the Contracting Party concerned is deposited.

3 Any Contracting Party may, at a later date, declare by notification to the Secretary General that it considers itself bound by any articles or any numbered paragraphs of Part II of the Charter which it has not already accepted under the terms of paragraph 1 of this article. Such undertakings subsequently given shall be deemed to be an integral part of the ratification or

approval, and shall have the same effect as from the thirtieth day after the date of the notification.

4 The Secretary General shall communicate to all the signatory governments and to the Director General of the International Labour Office any notification which he shall have received pursuant to this part of the Charter.

5 Each Contracting Party shall maintain a system of labour inspection appropriate to national conditions.

Part IV

Article 21 – Reports concerning accepted provisions

The Contracting Parties shall send to the Secretary General of the Council of Europe a report at two-yearly intervals, in a form to be determined by the Committee of Ministers, concerning the application of such provisions of Part II of the Charter as they have accepted.

Article 22 – Reports concerning provisions which are not accepted

The Contracting Parties shall send to the Secretary General, at appropriate intervals as requested by the Committee of Ministers, reports relating to the provisions of Part II of the Charter which they did not accept at the time of their ratification or approval or in a subsequent notification. The Committee of Ministers shall determine from time to time in respect of which provisions such reports shall be requested and the form of the reports to be provided.

Article 23 – Communication of copies

1 Each Contracting Party shall communicate copies of its reports referred to in Articles 21 and 22 to such of its national organisations as are members of the international organisations of employers and trade unions to be invited under Article 27, paragraph 2, to be represented at meetings of the Sub-committee of the Governmental Social Committee.

2 The Contracting Parties shall forward to the Secretary General any comments on the said reports received from these national organisations, if so requested by them.

Article 24 – Examination of the reports

The reports sent to the Secretary General in accordance with Articles 21 and 22 shall be examined by a Committee of Experts, who shall have also before them any comments forwarded to the Secretary General in accordance with paragraph 2 of Article 23.

Article 25 – Committee of Experts

1 The Committee of Experts shall consist of not more than seven members appointed by the Committee of Ministers from a list of independent experts of the highest integrity and of recognised competence in international social questions, nominated by the Contracting Parties.

2 The members of the committee shall be appointed for a period of six years. They may be reappointed. However, of the members first appointed, the terms of office of two members shall expire at the end of four years.

3 The members whose terms of office are to expire at the end of the initial period of four years shall be chosen by lot by the Committee of Ministers immediately after the first appointment has been made.

4 A member of the Committee of Experts appointed to replace a member whose term of office has not expired shall hold office for the remainder of his predecessor's term.

Article 26 – Participation of the International Labour Organisation

The International Labour Organisation shall be invited to nominate a representative to participate in a consultative capacity in the deliberations of the Committee of Experts.

Article 27 – Sub-committee of the Governmental Social Committee

1 The reports of the Contracting Parties and the conclusions of the Committee of Experts shall be submitted for examination to a sub-committee of the Governmental Social Committee of the Council of Europe.

2 The sub-committee shall be composed of one representative of each of the Contracting Parties. It shall invite no more than two international organisations of employers and no more than two international trade union organisations as it may designate to be represented as observers in a consultative capacity at its meetings. Moreover, it may consult no more than two

representatives of international non-governmental organisations having consultative status with the Council of Europe, in respect of questions with which the organisations are particularly qualified to deal, such as social welfare, and the economic and social protection of the family.

3 The sub-committee shall present to the Committee of Ministers a report containing its conclusions and append the report of the Committee of Experts.

Article 28 – Consultative Assembly

The Secretary General of the Council of Europe shall transmit to the Consultative Assembly the conclusions of the Committee of Experts. The Consultative Assembly shall communicate its views on these conclusions to the Committee of Ministers.

Article 29 – Committee of Ministers

By a majority of two-thirds of the members entitled to sit on the Committee, the Committee of Ministers may, on the basis of the report of the sub-committee, and after consultation with the Consultative Assembly, make to each Contracting Party any necessary recommendations.

Part V

Article 30 – Derogations in time of war or public emergency

1 In time of war or other public emergency threatening the life of the nation any Contracting Party may take measures derogating from its obligations under this Charter to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with its other obligations under international law.

2 Any Contracting Party which has availed itself of this right of derogation shall, within a reasonable lapse of time, keep the Secretary General of the Council of Europe fully informed of the measures taken and of the reasons therefor. It shall likewise inform the Secretary General when such measures have ceased to operate and the provisions of the Charter which it has accepted are again being fully executed.

3 The Secretary General shall in turn inform other Contracting Parties and the Director General of the International Labour Office of all communications received in accordance with paragraph 2 of this article.

Article 31 – Restrictions

1 The rights and principles set forth in Part I when effectively realised, and their effective exercise as provided for in Part II, shall not be subject to any restrictions or limitations not specified in those parts, except such as are prescribed by law and are necessary in a democratic society for the protection of the rights and freedoms of others or for the protection of public interest, national security, public health, or morals.

2 The restrictions permitted under this Charter to the rights and obligations set forth herein shall not be applied for any purpose other than that for which they have been prescribed.

Article 32 – Relations between the Charter and domestic law or international agreements

The provisions of this Charter shall not prejudice the provisions of domestic law or of any bilateral or multilateral treaties, conventions or agreements which are already in force, or may come into force, under which more favourable treatment would be accorded to the persons protected.

Article 33 – Implementation by collective agreements

1 In member States where the provisions of paragraphs 1, 2, 3, 4 and 5 of Article 2, paragraphs 4, 6 and 7 of Article 7 and paragraphs 1, 2, 3 and 4 of Article 10 of Part II of this Charter are matters normally left to agreements between employers or employers' organisations and workers' organisations, or are normally carried out otherwise than by law, the undertakings of those paragraphs may be given and compliance with them shall be treated as effective if their provisions are applied through such agreements or other means to the great majority of the workers concerned.

2 In member States where these provisions are normally the subject of legislation, the undertakings concerned may likewise be given, and compliance with them shall be regarded as effective if the provisions are applied by law to the great majority of the workers concerned.

Article 34 – Territorial application

1 This Charter shall apply to the metropolitan territory of each Contracting Party. Each signatory government may, at the time of signature or of the deposit of its instrument of ratification or approval, specify, by declaration addressed to the Secretary General of the

Council of Europe, the territory which shall be considered to be its metropolitan territory for this purpose.

2 Any Contracting Party may, at the time of ratification or approval of this Charter or at any time thereafter, declare by notification addressed to the Secretary General of the Council of Europe, that the Charter shall extend in whole or in part to a non-metropolitan territory or territories specified in the said declaration for whose international relations it is responsible or for which it assumes international responsibility. It shall specify in the declaration the articles or paragraphs of Part II of the Charter which it accepts as binding in respect of the territories named in the declaration.

3 The Charter shall extend to the territory or territories named in the aforesaid declaration as from the thirtieth day after the date on which the Secretary General shall have received notification of such declaration.

4 Any Contracting Party may declare at a later date, by notification addressed to the Secretary General of the Council of Europe, that, in respect of one or more of the territories to which the Charter has been extended in accordance with paragraph 2 of this article, it accepts as binding any articles or any numbered paragraphs which it has not already accepted in respect of that territory or territories. Such undertakings subsequently given shall be deemed to be an integral part of the original declaration in respect of the territory concerned, and shall have the same effect as from the thirtieth day after the date of the notification.

5 The Secretary General shall communicate to the other signatory governments and to the Director General of the International Labour Office any notification transmitted to him in accordance with this article.

Article 35 – Signature, ratification and entry into force

1 This Charter shall be open for signature by the members of the Council of Europe. It shall be ratified or approved. Instruments of ratification or approval shall be deposited with the Secretary General of the Council of Europe.

2 This Charter shall come into force as from the thirtieth day after the date of deposit of the fifth instrument of ratification or approval.

3 In respect of any signatory government ratifying subsequently, the Charter shall come into force as from the thirtieth day after the date of deposit of its instrument of ratification or approval.

4 The Secretary General shall notify all the members of the Council of Europe and the Director General of the International Labour Office of the entry into force of the Charter, the names of the Contracting Parties which have ratified or approved it and the subsequent deposit of any instruments of ratification or approval.

Article 36 – Amendments

Any member of the Council of Europe may propose amendments to this Charter in a communication addressed to the Secretary General of the Council of Europe. The Secretary General shall transmit to the other members of the Council of Europe any amendments so proposed, which shall then be considered by the Committee of Ministers and submitted to the Consultative Assembly for opinion. Any amendments approved by the Committee of Ministers shall enter into force as from the thirtieth day after all the Contracting Parties have informed the Secretary General of their acceptance. The Secretary General shall notify all the members of the Council of Europe and the Director General of the International Labour Office of the entry into force of such amendments.

Article 37 – Denunciation

1 Any Contracting Party may denounce this Charter only at the end of a period of five years from the date on which the Charter entered into force for it, or at the end of any successive period of two years, and, in each case, after giving six months notice to the Secretary General of the Council of Europe who shall inform the other Parties and the Director General of the International Labour Office accordingly. Such denunciation shall not affect the validity of the Charter in respect of the other Contracting Parties provided that at all times there are not less than five such Contracting Parties.

2 Any Contracting Party may, in accordance with the provisions set out in the preceding paragraph, denounce any article or paragraph of Part II of the Charter accepted by it provided that the number of articles or paragraphs by which this Contracting Party is bound shall never be less than 10 in the former case and 45 in the latter and that this number of articles or paragraphs shall continue to include the articles selected by the Contracting Party among those to which special reference is made in Article 20, paragraph 1, sub-paragraph b.

3 Any Contracting Party may denounce the present Charter or any of the articles or paragraphs of Part II of the Charter, under the conditions specified in paragraph 1 of this article in respect of any territory to which the said Charter is applicable by virtue of a declaration made in accordance with paragraph 2 of Article 34.

Article 38 – Appendix

The appendix to this Charter shall form an integral part of it.

In witness whereof, the undersigned, being duly authorised thereto, have signed this Charter.

Done at Turin, this 18th day of October 1961, in English and French, both texts being equally authoritative, in a single copy which shall be deposited within the archives of the Council of Europe. The Secretary General shall transmit certified copies to each of the Signatories.

APPENDIX TO THE SOCIAL CHARTER

Scope of the Social Charter in terms of persons protected

1 Without prejudice to Article 12, paragraph 4, and Article 13, paragraph 4, the persons covered by Articles 1 to 17 include foreigners only insofar as they are nationals of other Contracting Parties lawfully resident or working regularly within the territory of the Contracting Party concerned, subject to the understanding that these articles are to be interpreted in the light of the provisions of Articles 18 and 19.

This interpretation would not prejudice the extension of similar facilities to other persons by any of the Contracting Parties.

2 Each Contracting Party will grant to refugees as defined in the Convention relating to the Status of Refugees, signed at Geneva on 28th July 1951, and lawfully staying in its territory, treatment as favourable as possible, and in any case not less favourable than under the obligations accepted by the Contracting Party under the said Convention and under any other existing international instruments applicable to those refugees.

Part I, paragraph 18, and Part II, Article 18, paragraph 1

It is understood that these provisions are not concerned with the question of entry into the territories of the Contracting Parties and do not prejudice the provisions of the European Convention on Establishment, signed at Paris on 13th December 1955.

Part II

Article 1, paragraph 2

This provision shall not be interpreted as prohibiting or authorising any union security clause or practice.

Article 4, paragraph 4

This provision shall be so understood as not to prohibit immediate dismissal for any serious offence.

Article 4, paragraph 5

It is understood that a Contracting Party may give the undertaking required in this paragraph if the great majority of workers are not permitted to suffer deductions from wages either by law or through collective agreements or arbitration awards, the exceptions being those persons not so covered.

Article 6, paragraph 4

It is understood that each Contracting Party may, insofar as it is concerned, regulate the exercise of the right to strike by law, provided that any further restriction that this might place on the right can be justified under the terms of Article 31.

Article 7, paragraph 8

It is understood that a Contracting Party may give the undertaking required in this paragraph if it fulfils the spirit of the undertaking by providing by law that the great majority of persons under 18 years of age shall not be employed in night work.

Article 12, paragraph 4

The words “and subject to the conditions laid down in such agreements” in the introduction to this paragraph are taken to imply *inter alia* that with regard to benefits which are available independently of any insurance contribution a Contracting Party may require the completion of a prescribed period of residence before granting such benefits to nationals of other Contracting Parties.

Article 13, paragraph 4

Governments not Parties to the European Convention on Social and Medical Assistance may ratify the Social Charter in respect of this paragraph provided that they grant to nationals of other Contracting Parties a treatment which is in conformity with the provisions of the said Convention.

Article 19, paragraph 6

For the purpose of this provision, the term “family of a foreign worker” is understood to mean at least his wife and dependent children under the age of 21 years.

Part III

It is understood that the Charter contains legal obligations of an international character, the application of which is submitted solely to the supervision provided for in Part IV thereof.

Article 20, paragraph 1

It is understood that the “numbered paragraphs” may include articles consisting of only one paragraph.

Part V

Article 30

The term “in time of war or other public emergency” shall be so understood as to cover also the threat of war.

2.3.8. European agreement on mutual assistance in the matter of special medical treatments and climatic facilities *European Treaty Series - No. 38* Strasbourg, 14.V.1962

[…]

Article 1

The provisions of this Agreement shall apply to persons residing in the territory of one of the Contracting Parties who are eligible for compulsory or optional medical benefits:

a under social security schemes, whether general or special, contributory or non-contributory, including special schemes for civil servants or persons treated as such and schemes relating to employer's obligations in regard to medical benefits; or

b under social and medical assistance schemes; or

c under schemes of benefits for victims of war or its consequences.

Article 2

Each Contracting Party shall endeavour to have admitted to medical establishments or spas in its territory which can provide appropriate medical treatment any persons referred to in Article 1, for the medical treatment required which they need but which is not available in the territory of the Contracting Party where they reside, in accordance with a certificate issued by the doctor designated by the institution to which the patient is affiliated.

Article 3

1 Each Contracting Party shall determine the competent authority or authorities responsible for implementing in its own territory the provisions of this Agreement.

2 Each competent authority may, where necessary, conclude with the competent authority or authorities of one or more of the other Contracting Parties administrative arrangements governing the implementation of this Agreement.

3 Each Contracting Party shall notify the Secretary General of the Council of Europe of the name and address of its appointed competent authority or authorities; the Secretary General shall communicate this information to the other members of the Council of Europe and to the government of any State acceding to this Agreement.

Article 4

1 Each competent authority may, for the purpose of implementing the provisions of this Agreement, appoint one or more bodies to work in conjunction with the body or bodies appointed by the competent authorities of the other Contracting Parties.

2 The liaison authorities of two or more Contracting Parties may co-operate in drawing up standard forms for the completion of the formalities necessary for implementing the provisions of this Agreement.

3 Each competent authority shall communicate to the competent authorities of the other Contracting Parties the name and address of the liaison authority or authorities appointed under the terms of paragraph 1 of this article.

4 Should the competent authority or authorities of one of the Contracting Parties not appoint the liaison authority referred to in paragraph 1 of this article, the functions assigned to liaison authorities in paragraph 2 of Article 4 and Articles 5 to 7 of this Agreement shall be assumed by the said competent authority or authorities.

Article 5

Applications for admission for the medical treatment referred to in Article 2 shall be submitted by the liaison authority to which the person referred to in Article 1 is subject. In each case, this authority shall have powers of verification and appraisal. Admission of the applicant is subject to the agreement of the liaison authority of the country where treatment is to be given. This liaison authority shall, at the request of the liaison authority to which the person is subject, supply the necessary information on the probable total of the expenses referred to in Article 6, paragraph 2, second sub-paragraph. Each case may form the subject of special regulations laid down by agreement between the liaison authorities.

Article 6

1 All expenses arising out of the medical treatment referred to in Article 2, including travelling expenses and, provided that the institution to which the beneficiary is affiliated gives its approval or in cases of urgency, expenses incurred as a result of illness, accident or arising from any other need for medical care during such treatment or the journey made for this purpose, shall be paid or refunded by that institution according to the rules laid down in the following paragraphs of this article.

2 That institution shall refund travelling expenses directly to the beneficiary so far as the rules of that institution permit.

It shall pay in full other expenses, through the liaison authorities concerned, to the medical establishments, spas and doctors providing the medical treatment or to any establishment or person entitled to payment for medical care.

3 The liaison authorities of two or more Contracting Parties may, by negotiation, lay down methods of assessing the amounts to be paid in accordance with the second sub-paragraph of

paragraph 2 above. For this purpose no account can be taken of charges higher than those applicable to persons affiliated to the institution competent for the place of treatment and corresponding to the institution to which the person in question is affiliated; the liaison authorities concerned may, however, jointly agree to waive this rule in special cases.

4 The institution to which the beneficiary is affiliated shall, if the need arises, be reimbursed by the latter in respect of that part of the expenses which, according to the national legislation applied by that institution, has to be borne by the beneficiary.

Article 7

The benefits to which a person referred to in Article 1 is entitled for himself or members of his family under the law of the Contracting Party where he resides shall continue to be granted. Cash benefits to which the person himself is entitled may be paid to him through the liaison authorities in the manner jointly agreed upon by the latter.

Article 8

The provisions of this Agreement shall not prejudice the provisions of municipal law, bilateral or multilateral treaties, conventions or agreements, or the regulations of the European Economic Community which are already in force or may come into force, under which more favourable treatment would be accorded to the persons referred to in Article 1.

Article 9

Each Contracting Party may, on signing this Agreement or on depositing its instrument of ratification or approval or accession, declare that it excludes from the benefits of this Agreement persons resident in its territory who are eligible for the medical benefits referred to in Article 1.

Article 10

This Agreement shall be open to the signature of members of the Council of Europe, who may become Parties to it by:

a signature without reservation in respect of ratification or approval, or

b signature with reservation in respect of ratification or approval, followed by ratification or approval.

Instruments of ratification or approval shall be deposited with the Secretary General of the Council of Europe.

Article 11

This Agreement shall enter into force one month after the date on which three members of the Council shall, in accordance with Article 10, have signed the Agreement without reservation in respect of ratification or approval or shall have ratified or approved it.

In the case of any member of the Council who subsequently shall sign the Agreement without reservation in respect of ratification or approval or who shall ratify or approve it, the Agreement shall enter into force one month after the date of such signature or the date of deposit of the instrument of ratification or approval.

Article 12

After this Agreement has entered into force, the Committee of Ministers of the Council of Europe may invite any non-member State of the Council to accede to it. Such accession shall take effect one month after the date on which the instrument of accession was deposited with the Secretary General of the Council of Europe.

Article 13

The Secretary General of the Council of Europe shall notify members of the Council and the governments of acceding States:

a of the date of entry into force of this Agreement and the names of members who have signed without reservation in respect of ratification or approval or who have ratified or approved it;

b of the deposit of any instrument of accession in accordance with Article 12;

c of any declaration received in accordance with Article 9;

d of any notification received in accordance with Article 14 and of its effective date.

Article 14

This Agreement shall remain in force indefinitely.

Any Contracting Party may terminate its own application of the agreement by giving one year's notice to that effect to the Secretary General of the Council of Europe.

In witness whereof the undersigned, duly authorised thereto by their respective governments, have signed the present Agreement.

Done at Strasbourg, this 14th day of May 1962, in English and French, both texts being equally authoritative, in a single copy which shall remain deposited in the archives of the Council of Europe. The Secretary General shall transmit certified copies to each of the signatory and acceding governments.

2.3.9. European agreementon the exchanges of blood-grouping reagents *European Treaty Series - No. 39*

Strasbourg, 14.V.1962

The signatory governments of the member States of the Council of Europe,

Considering that blood-grouping reagents are not available in unlimited quantities;

Considering that it is most desirable that member countries, in a spirit of European solidarity, should assist one another in the supply of these blood-grouping reagents, should the need arise;

Considering that such mutual assistance is only possible if the character and use of such blood-grouping reagents are subject to rules laid down jointly by the member countries and if the necessary import facilities and exemptions are granted,

Have agreed as follows:

Article 1

For the purposes of this Agreement, the expression “blood-grouping reagents” refers to reagents of human, animal and plant and other origin, used for blood-grouping and for the detection of blood incompatibilities.

Any Contracting Party may, by a declaration addressed to the Secretary General of the Council of Europe, when signing this Agreement or depositing its instrument of ratification or approval, or accession, limit the application of this Agreement to blood-grouping reagents of human

origin. This declaration may be withdrawn at any time, by notification addressed to the Secretary General of the Council of Europe.

Article 2

The Contracting Parties undertake, provided that they have sufficient stocks for their own needs, to make blood-grouping reagents available to other Parties who are in urgent need of them and to charge only those costs of collection, processing and carriage of such substances and the cost (if any) of their purchase.

Article 3

Blood-grouping reagents shall be made available to the other Contracting Parties subject to the condition that no profit is made on them, that they shall be used solely for medical purposes and shall be delivered only to bodies designated by the governments concerned.

Article 4

The Contracting Parties shall certify that the provisions as laid down in the Protocol to this Agreement have been observed.

They shall also comply with any rules to which they have subscribed with regard to international standardisation in this field.

All consignments of blood-grouping reagents shall be accompanied by a certificate to the effect that they were prepared in accordance with the specifications in the Protocol. This certificate shall be based on the model to be found in the Annex to the Protocol.

The Protocol and its Annex constitute an administrative arrangement and may be amended or supplemented by the governments of the Parties to this Agreement.

Article 5

The Contracting Parties shall take all necessary measures to exempt from all import duties the blood-grouping reagents placed at their disposal by the other Parties.

They shall also take all necessary measures to provide for the speedy delivery of these substances, by the most direct route, to the consignees referred to in Article 3 of this Agreement.

Article 6

The Contracting Parties shall forward to one another, through the Secretary General of the Council of Europe, a list of the bodies empowered to issue certificates as provided in Article 4 of this Agreement.

They shall also forward a list of bodies empowered to distribute imported blood-grouping reagents. Wherever possible these bodies should be the same as those referred to in Article 6 of the European Agreement on the Exchange of Therapeutic Substances of Human Origin.

Article 7

The present Agreement shall be open to the signature of Members of the Council of Europe, who may become Parties to it either by :

a signature without reservation in respect of ratification or approval, or

b signature with reservation in respect of ratification or approval, followed by ratification or approval.

Instruments of ratification or approval shall be deposited with the Secretary General of the Council of Europe.

Article 8

The present Agreement shall enter into force one month after the date on which three Members of the Council shall, in accordance with Article 7, have signed the Agreement without reservation in respect of ratification or approval or shall have ratified or approved it.

In the case of any Member of the Council who shall subsequently sign the Agreement without reservation in respect of ratification or approval or who shall ratify or approve it, the Agreement shall enter into force one month after the date of such signature or the date of deposit of the instrument of ratification or approval.

Article 9

After the entry into force of this Agreement, the Committee of Ministers of the Council of Europe may invite any non-member State to accede to the present Agreement. Such accession shall take effect one month after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 10

The Secretary General of the Council of Europe shall notify Members of the Council and acceding States :

a of the date of entry into force of this Agreement and of the names of any Members who have signed without reservation in respect of ratification or approval or who have ratified or approved it;

b of the deposit of any instrument of accession in accordance with Article 9;

c of any declaration or notification received in accordance with the provisions of Article 1, paragraph 2;

d of any notification received in accordance with Article 11 and its effective date;

e of any amendment of the Protocol and of its Annex under Article 4, paragraph 4.

Article 11

The present Agreement shall remain in force indefinitely.

Any Contracting Party may terminate its own application of the Agreement by giving one year's notice to that effect to the Secretary General of the Council of Europe.

In witness whereof the undersigned, duly authorised thereto by their respective Governments, have signed the present Agreement.

Done at Strasbourg, this 14th day of May 1962, in English and French, both texts being equally authoritative, in a single copy which shall remain deposited in the archives of the Council of Europe. The Secretary General shall transmit certified copies to each of the signatory and

2.3.10. EUROPEAN AGREEMENT ON THE INSTRUCTION AND EDUCATION OF NURSES *European Treaty Series - No. 59* Strasbourg, 25.X.1967

The member States of the Council of Europe, signatory hereto,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members for the purpose, among others, of facilitating their social progress and promoting the social well-being of their populations by means of appropriate action;

Having regard to the Conventions furthering this purpose already concluded within the framework of the Council, in particular the European Social Charter, signed on 18th October 1961, and the European Convention on Establishment, signed on 13th December 1955;

Being convinced that the conclusion of a regional Agreement on the harmonisation of the instruction and education of nurses will promote social progress and guarantee the standard of the nurses required for their establishment in the territory of other Contracting Parties on an equal footing with those countries' nationals;

Considering it necessary to lay down minimal standards,

Have agreed as follows:

Article 1

1 Each Contracting Party shall apply or, if the education of nurses is not under its direct control, recommend the competent authority to apply the provisions governing the instruction and education of nurses set out in Annex I to this Agreement.

2 For the purpose of this Agreement, nurses shall be intended to include only “general trained nurses”, male or female. Those nurses whose training is solely within the field of public health, infants' and sick children's nursing, obstetrics or mental health are excluded.

Article 2

Each Contracting Party shall communicate to the Secretary General of the Council of Europe a list of its authorities or other bodies authorised to certify the accomplishment of a nurse's instruction and education satisfying at least the standards laid down in Annex I to this Agreement.

Article 3

1 After the entry into force of this Agreement in accordance with Article 5, the Committee of Ministers of the Council of Europe sitting with its membership limited to the representatives of the Contracting Parties, shall be responsible for the further elaboration of the regulations contained in Annex I to this Agreement in accordance with the current developments in this field.

2 Any modification or extension of the regulations contained in Annex I unanimously approved by the Committee of Ministers referred to in the preceding paragraph shall be communicated by the Secretary General of the Council of Europe to the Contracting Parties and shall enter into force three months after the date on which the Secretary General is notified by the Contracting Parties of their approval of the modification or extension.

Article 4

1 This Agreement shall be open to signature by the member States of the Council of Europe, who may become Parties to it either by:

a signature without reservation in respect of ratification or acceptance, or

b signature with reservation in respect of ratification or acceptance, followed by ratification or acceptance.

2 Instruments of ratification or acceptance shall be deposited with the Secretary General of the Council of Europe.

Article 5

1 This Agreement shall enter into force three months after the date on which three member States of the Council shall have become Parties to the Agreement, in accordance with the provisions of Article 4.

2 As regards any member States who shall subsequently sign the Agreement without reservation in respect of ratification or acceptance or who shall ratify or accept it, the Agreement shall enter into force three months after the date of such signature or after the date of deposit of the instrument of ratification or acceptance.

Article 6

1 After the entry into force of this Agreement, the Committee of Ministers of the Council of Europe may invite any non-member State to accede thereto.

2 Such accession shall be effected by depositing with the Secretary General of the Council of Europe an instrument of accession which shall take effect three months after the date of its deposit.

Article 7

1 Any Contracting Party may, at the time of signature or when depositing its instrument of ratification, acceptance or accession, declare that it avails itself of one or more of the reservations provided for in Annex II to this Agreement.

2 Any Contracting Party may wholly or partly withdraw a reservation it has made in accordance with the foregoing paragraph by means of a declaration addressed to the Secretary General of the Council of Europe, which shall become effective as from the date of its receipt.

Article 8

The annexes shall be an integral part of this Agreement.

Article 9

1 Any Contracting Party may at the time of signature or when depositing its instrument of ratification, acceptance or accession, specify the territory or territories to which this Agreement shall apply.

2 Any Contracting Party may, when depositing its instrument of ratification, acceptance or accession or at any later date by declaration addressed to the Secretary General of the Council of Europe, extend this agreement to any other territory or territories specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings.

3 Any declaration made in pursuance of the preceding paragraph may, in respect of any territory mentioned in such declaration, be withdrawn according to the procedure laid down in Article 10 of this Agreement.

Article 10

1 This Agreement shall remain in force indefinitely.

2 Any Contracting Party may, in so far as it is concerned, denounce this Agreement by means of a notification addressed to the Secretary General of the Council of Europe.

3 Such denunciation shall take effect six months after the date of receipt by the Secretary General of such notification.

Article 11

The Secretary General of the Council of Europe shall notify the member States of the Council and any State which has acceded to this Agreement of:

a any signature without reservation in respect of ratification or acceptance;

b any signature with reservation in respect of ratification or acceptance;

c the deposit of any instrument of ratification, acceptance or accession;

d any date of entry into force of the modifications or extensions referred to in Article 3.2;

e any date of entry into force of this Agreement in accordance with Article 5;

f any communication received in pursuance of the provisions of Article 2;

g any notification received in pursuance of the provisions of Article 7;

h any declaration received in pursuance of the provisions of Article 9;

i any notification received in pursuance of the provisions of Article 10 and the date on which denunciation takes effect.

In witness whereof the undersigned, being duly authorised thereto, have signed this Agreement.

Done at Strasbourg, this 25th day of October 1967, in English and French, both texts being equally authoritative, in a single copy which shall remain deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each of the signatory and acceding States.

ANNEX I

Minimal standards for the instruction and education of nurses

Chapter I – Definition of the functions of general trained nurses

1 The general trained nurse exercises in conformity with the national legislation the following essential functions:

a giving skilled nursing care to persons as required in accordance with the physical, emotional and spiritual needs of the patient, whether that care is given in health institutions, homes, schools, places of work;

b observing physical and emotional situations and conditions which have significant bearing on health and communicating those observations to other members of the health team;

c training and giving guidance to auxiliary personnel who are required to fulfil the nursing service needs of all health agencies.

2 This also involves an evaluation of the nursing needs of a particular patient and assigning personnel in accordance with the needs of that patient at a particular time.

Chapter II – Educational standard required of candidates for admission to schools of nursing

Candidates for admission to schools of nursing shall normally have reached a cultural and intellectual standard equivalent to at least that of the 10th year of general education. They shall therefore either possess a recognised school certificate signifying the completion of such general education, or must have passed an official entrance examination of an equivalent standard.

Chapter III – Duration and content of the educational programme

Nurses shall have a minimum of 4 600 hours basic nursing education. At least half the total time shall be devoted to clinical instruction (practical experience) (see B below). However, the number of hours of theoretical and formal instruction (see A below) shall not be less than one third of the total educational programme.

A – Theoretical and formal instruction

Instruction shall include all aspects of nursing, as well as the prevention of sickness, health education, rehabilitation, drug action and administration of drugs and problems of nutrition and dietetics, and also first aid, resuscitation and the theory of blood transfusion.

Theory and practice shall be co-ordinated and integrated throughout the programme.

The subjects to be included in the curriculum may be grouped under two headings:

1 Nursing

– Professional orientation and ethics

– General principles of health and nursing

– Principles of nursing care in relation to:

– general medicine and medical specialities

– general surgery and surgical specialities

– care of children and pediatrics

– maternity care

– mental health and psychiatry

– care of the aged and geriatrics.

2 Fundamental sciences

– Anatomy and physiology

– General pathology

– Bacteriology, virology, parasitology

– Biophysics and biochemistry

– Hygiene:

– preventive medicine

– health education.

– Social sciences:

– sociology

– psychology

– principles of administration

– principles of teaching

– social and health legislation

– legal aspects of nursing.

B – Clinical instruction (practical experience)

Practical experience shall cover all aspects of the nurse's role, including the prevention of sickness, health education, first aid, resuscitation and blood transfusion.

It shall include:

– General medicine and medical specialities

– General surgery and surgical specialities

– Care of children and pediatrics

– Maternity care

– Mental health and psychiatry (in a specialised service if possible)

– Care of the aged and geriatrics.

The following factors shall be taken into account in choosing such fields:

1 The experience gained shall be of educational value. It is therefore necessary to have:

– sufficient trained staff to ensure that the nursing care is satisfactory;

– adequate and satisfactory physical facilities, equipment and supplies for the nursing care of patients.

2 In all departments or units to which student nurses are assigned during the practical experience there shall be at all times at least one qualified nurse to provide supervision, and sufficient additional staff to ensure that the student does not undertake tasks which have no nursing educational value.

3 Qualified nurses in departments or units approved as fields of practical experience shall assist in the supervision and instruction of the students for whom the tutorial staff is responsible.

Chapter IV – Requirements for the organisation of the school of nursing

In order that the proposed schemes of nursing education may be adequately carried out the organisation and operation of the school has to meet the following requirements:

A – Administration of the school of nursing

The administration of the school shall be placed under the direction of a medical practitioner or a nurse who is competent in teaching and administration.

B – Teaching staff

The instruction shall be given by qualified teachers: doctors, nurses and specialists in various disciplines. Each school should have on its staff at least one qualified nurse who has received training of at least one year's duration which qualified her in the teaching of nursing.

C – School finances

The sum of money available to meet expenditure directly attributable to nurse training, e.g. salaries of tutors and cost of teaching equipment, should be clearly identifiable.

Chapter V – Evidence of completion of the education programme

A – A school record shall be kept for each student, the authenticity of which would be guaranteed by the competent authority stating:

– details of courses attended

– test and examination results

– an appreciation of the personal and professional aptitudes revealed by the student in the course of the studies.

B – The final examination shall comprise written, practical and oral tests, and its successful result should be certificated.

ANNEX II

Any Contracting Party may declare that it reserves the right:

1 to derogate from the provisions of Chapter II of Annex I by providing that candidates may have reached a cultural and intellectual standard equivalent to eight years of general education;

2 to derogate from the provisions of Chapter II of Annex I by providing that candidates need not possess a recognised school certificate;

3 to derogate from the provisions of Chapter III of Annex I by providing a number of hours of theoretical and formal instruction other than that referred to in that chapter;

4 to derogate from the provisions of Chapter III of Annex I:

i by retaining as optional subjects in the curriculum and in practical training, maternity care, mental health and psychiatry and care of the aged and geriatrics, or

ii by providing that clinical instruction shall not cover mental health and psychiatry.

RECOMMENDATIONS

I – Minimum age required for admission to schools of nursing

No hard and fast minimum age for admission to a school of nursing should be laid down. In countries where general education is included in the programme, the age of entry may be considerably lower than when such general education is regarded as a prerequisite. Maturity also depends on social and climatic conditions.

In general, students should not come in contact with patients and with the hospital atmosphere until an age varying from 17 to 19 according to the country.

II – Educational standard required of candidates for admission to schools of nursing (cf. Agreement, Annex I, Chapter II)

The duration of 10 years of general education is not obligatory if the educational standard reached after a shorter duration has an equivalent cultural and intellectual level.

III – Duration and content of educational programme (cf. Agreement, Annex I, Chapter III, first paragraph)

If the total number of hours of education are more than 4,600 the proportions indicated need only be respected in relation to the minimum number of hours.

IV – Practical experience (cf. Agreement, Annex I, Chapter III, B)

a Fields of practical experience should be proposed by the director of the school and approved by the competent authority of each country.

b Practical experience should be organised by the director of the school and placed under the supervision of the tutorial staff of the school.

c The provision No. 2, which requires the existence of “sufficient additional staff to ensure that the student does not undertake tasks which have no nursing educational value”, has the purpose of guaranteeing that the nursing students are not given work which does not enter into their field of education and which should be carried out by other personnel.

d As far as possible the nurses mentioned under No. 3 should have received education in teaching nursing and administration.

e The following factors should also be taken into consideration:

– number of patients in the department or unit,

– variety of clinical conditions presented by the patients,

– efficiency of administration of the department or unit,

– existence of programmes of in-service education for the nursing staff of the department or unit,

– the maximum desirable number of students in the department or unit,

– the teaching methods employed.

V – Requirements for the organisation of the school of nursing (cf. Agreement, Annex I, Chapter IV)

a Administration of the school of nursing

Administration of the school of nursing should normally have the support and advice of a body composed of nurses trained to give instruction and representatives of other disciplines such as medicine, general education, administration and the social sciences.

b Teaching staff

There should be tutors responsible for the application of the co-ordination of theoretical and practical instruction. Tutors should be nurses prepared to give theoretical and practical instruction and supervise practical experience. They should contribute to the students' education and professional training. The number of tutors should be related to the number of students in order to ensure proper instruction and supervision. A proportion of 15 students to each tutor is proposed.

c Facilities for the school of nursing

Adequate space should be available for the number of students in the school. The following teaching facilities should be provided: class and demonstration rooms, small rooms for group work, library and laboratory. Individual office space should be available according to the number of full-time administrative and teaching staff.

d Teaching equipment Adequate equipment to enable modern methods of teaching to be used extensively should be provided. Particular emphasis should be placed on the availability of audio-visual aids.

VI –Documents to be produced by the nurse A.

A certificate (diploma or other document) authenticated by the government of the country of issue or by the designated authority in that country.

B An extract of the school record

This extract should comprise:

– the nurse's civil status,

– courses attended,

– results obtained.

C Evidence of linguistic ability

2.3.11. European agreement on the restriction of the use of certain detergents in washing and cleaning products *European Treaty Series - No. 64* Strasbourg, 16.IX.1968

Text amended according to the provisions of the Protocol of amendment (ETS No. 115) as from its entry into force on 1 November 1984.

The Governments of the Kingdom of Belgium, the Kingdom of Denmark, the French Republic, the Federal Republic of Germany, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Swiss Confederation and the United Kingdom of Great Britain and Northern Ireland,

Considering that the Parties to the Brussels Treaty of 17th March 1948, as amended on 23rd October 1954, resolved to strengthen the social ties by which they are united and to make every effort in common, both by direct consultation and in specialised Agencies, to raise the standard of living of their peoples and promote the harmonious development of social services in their respective countries;

Considering that the social activities governed by the Brussels Treaty and carried on, until 1959, under the auspices of the Brussels Treaty Organisation and the Western European Union are now conducted within the framework of the Council of Europe, in accordance with the decision taken on 21st October 1959 by the Council of Western European Union and with Resolution (59) 23 adopted on 16th November 1959 by the Committee of Ministers of the Council of Europe;

Considering that the Swiss Confederation and the Kingdom of Denmark have participated since 6th May 1964 and 2nd April 1968 respectively in activities in the field of public health carried on under the aforesaid resolution;

Whereas the aim of the Council of Europe is to achieve greater unity between its members, so as to further economic and social progress by agreements and by common action in economic, social, cultural, scientific, legal and administrative matters;

Whereas the said governments have striven to encourage progress as far as may be practicable not only in social matters but in the related field of public health, and have undertaken to harmonise their national legislations in pursuance of the action mentioned in the foregoing paragraph;

Whereas it is becoming increasingly necessary to secure harmonisation of the laws on the control of fresh water pollution;

Being convinced that appropriate measures are essential not only from the standpoint of human needs but also to ensure the protection of nature in general, the paramount objectives being to protect effectively:

a the supply of water for the population, for industry, for agriculture and for other business occupations;

b the natural aquatic fauna and flora, and in particular so far as they contribute to human well-being;

c the unhindered enjoyment of places devoted to leisure and sport;

Observing that the general household and industrial use of certain types of detergents might cause considerable prejudice to these interests;

Feeling, therefore, that some restriction must be put on the use of such products,

Have agreed as follows:

Article 1 [115]

This Agreement applies to any washing and cleaning product (detergent) the composition of which has been specially devised with a view to developing its detergent properties and which may be made up of surfactants, adjuvants, intensifying agents, fillers, additives and other auxiliary constituents.

Article 2

The use of products of the kind referred to in Article 1 shall not, under conditions of normal use, adversely affect man and the environment.

Article 3

1 The Contracting Parties undertake to adopt measures as effective as possible in the light of the available techniques, including legislation if it is necessary, to ensure that in their respective territories:

a no products of the kind referred to in Article 1 are put on the market unless the anionic and non-ionic surfactants which they contain are at least 80% susceptible to biological degradation as determined by the best practical techniques, such as the OECD reference method or any other method providing equivalent results;

b the same objectives be achieved when considered appropriate with regard to cationic and ampholytic surfactants;

c appropriate measurement and control procedures are implemented to guarantee compliance with the provisions of sub-paragraphs a and b of this paragraph.

[115] Text amended pursuant to the provisions of the Protocol of amendment (ETS no. 115).

2 The Contracting Parties may exempt the following surfactants, in the absence of suitable substitutes, from the requirements of paragraph 1:

a low-foaming alkene oxide additives on such substances as alcohols, alkylphenols, glycols, polyols, fatty acids, amides or amines, used in dish-washing products;

b surfactants mentioned under sub-paragraph a of this paragraph, and alkali-resistant terminally blocked alkyl and alkyl-aryl polyglycol ethers, used in cleaning agents for the food, beverage and metal working industries.

Article 3bis

The Contracting Parties undertake to intensify their research leading to a better understanding and assessment of the biological degradability of surfactants and to encourage, where necessary, the research for phosphate substitutes.

Article 3 ter [116]

The Contracting Parties shall, every five years, or more frequently if one of the Parties should so request, hold multilateral consultations within the Council of Europe to examine the application of this Agreement, and the advisability of revising it or extending any of its provisions. These consultations shall take place at meetings convened by the Secretary General of the Council of Europe. The Contracting Parties shall communicate the name of their representative to the Secretary General of the Council of Europe at least two months before the meetings.

Article 4

1 This Agreement shall be open to signature by member States of the Council of Europe which take part in the activities in the field of public health referred to in Resolution (59) 23 mentioned in the Preamble hereto. They may become Parties to it by either:

a signature without reservation in respect of ratification or acceptance, or

b signature with reservation in respect of ratification or acceptance, followed by ratification or acceptance.

[116] Text amended pursuant to the provisions of the Protocol of amendment (ETS no. 115).

2 Instruments of ratification or acceptance shall be deposited with the Secretary General of the Council of Europe.

Article 5

1 This Agreement shall enter into force one month after the date on which three member States of the Council shall have become Parties to the Agreement, in accordance with the provisions of Article 4.

2 As regards any member States who shall subsequently sign the Agreement without reservation in respect of ratification or acceptance or who shall ratify or accept it, the Agreement shall enter into force one month after the date of such signature or after the date of deposit of the instrument of ratification or acceptance.

Article 6

1 After the entry into force of this Agreement,

a any member State of the Council of Europe which does not take part in the activities in the field of public health referred to in Resolution (59) 23 mentioned in the Preamble to this Agreement, may accede thereto;

b the Committee of Ministers of the Council of Europe may invite any State not a member of the Council to accede to this Agreement provided that the resolution containing such invitation receives the unanimous agreement by member States of the Council of Europe which take part in the activities in the field of public health referred to in Resolution (59) 23 mentioned in the Preamble to this Agreement.

2 Such accession shall be effected by depositing with the Secretary General of the Council of Europe an instrument of accession which shall take effect one month after the date of its deposit.

Article 7

1 Any Contracting Party may at the time of signature or when depositing its instrument of ratification, acceptance or accession, specify the territory or territories to which this Agreement shall apply.

2 Any Contracting Party may, when depositing its instrument of ratification, acceptance or accession or at any later date, by declaration addressed to the Secretary General of the Council of Europe, extend this Agreement to any other territory or territories specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings.

3 Any declaration made in pursuance of the preceding paragraph may, in respect of any territory mentioned in such declaration, be with drawn according to the procedure laid down in Article 8 of this Agreement.

Article 8

1 This Agreement shall remain in force indefinitely.

2 Any Contracting Party may, in so far as it is concerned, denounce this Agreement by means of a notification addressed to the Secretary General of the Council of Europe.

3 Such denunciation shall take effect six months after the date of receipt by the Secretary General of such notification.

Article 9

The Secretary General of the Council of Europe shall notify the member States of the Council and any State which has acceded to this Agreement, of:

a any signature without reservation in respect of ratification or acceptance;

b any signature with reservation in respect of ratification or acceptance;

c the deposit of any instrument of ratification, acceptance or accession;

d any date of entry into force of this Agreement in accordance with Article 5 thereof;

e any declaration received in pursuance of the provisions of paragraphs 2 and 3 of Article 7;

f any notification received in pursuance of the provisions of Article 8 and the date on which denunciation takes effect.

In witness whereof the undersigned, being duly authorised thereto, have signed this Agreement.

Done at Strasbourg, this 16th day of September 1968, in the English and French languages, both texts being equally authoritative, in a single copy which shall remain deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each of the signatory and acceding States.

2.4. History of the Convention

The necessity to ensure protection of human rights at the international level became a significant issue after World War II. The proclamation of the Universal Declaration of Human Rights by the General Assembly of the United Nations in 1948 was the first major milestone for the protection of human rights. The United Nations did not limit the protection of human rights to this document – the Member States were encouraged to introduce their own means and regulations on this matter while respecting the provisions of the Declaration.

After the Universal Declaration of Human Rights was proclaimed the newly-formed Council of Europe took upon itself the task of creating the first regional expression of the protection of human rights described in its provisions[117]. The Convention for the Protection of Human Rights and Fundamental Freedoms was proclaimed on 4 November 1950. It was designed to contrast the prewar Nazism and fascism as well as the postwar Spanish and Portugese dictatorships and the Soviet Union's communism[118]. Therefore its original provisions were introduced to provide a protection against introducing totalitarian government systems in the Member States of the Council of Europe and guarantee that another world war never happens again[119].

The Convention was focused on abstract and general definitions of civil and social rights, thus limiting its matter in comparison with the United Nations' Universal Declaration of Human

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117 J. Reiss, Protocol No. 14 ECHR and the Russian Non-ratification: the Current State of affairs, Harvard Human Rights Journal Vol. 22, p. 293.

118 L. Wildhaber, European Union, European Convention of Human Rights and Human Rights Protection in Europe, Ritsumeikan Law Review No. 26, 2009, p. 156.

119 L. Wildhaber, The European Court of Human Rights: The Past, the Present, the Future, American University International Law Review Vol. 22, No. 4, p. 522.

Rights. The decision to determine the Convention's provisions in such way was a reflection of the traditions of the Member States and enabled them to interpret the Convention flexibly[120].

This flexibility allowed the Member States and the European Court of Human Rights to interpret the Convention according to the definitions and expectations appropriate for the given time period. However some changes in society, law and execution of the Convention required significant changes. Thus protocols to the Convention were introduced and ratified by the Contracting Parties. The matter of those protocols covered additional rights to be added to the Convention[121], modifications to the procedures governed by the Convention[122] and to the powers of the Court[123].

Protocols No. 11 and No. 14 are considered to be the most important to the Convention's legal existence. Their introduction resulted from the growing significance of the European Court of Human Rights, the accompanying rising number of cases filed with the Court and the restrictions on individual applications.

The necessity to introduce Protocol No. 11 to the Convention for the Protection of Human Rights and Fundamental Freedoms arose as the former communist nations of Central and Eastern Europe joined the Council of Europe and signed the Convention for the Protection of Human Rights and Fundamental Freedoms. However it is pointed out that at that time the right of individual applications was optional for the Contracting Parties[124] - thus the citizens of the Member States had no means of effectively addressing the breach of their rights. As will be described later through the provisions of Protocol No.11, proclaimed on 11 May 1994, the Court was thoroughly reformed and the right to an individual application was granted to the citizens of the Contracting Parties. However these amendments proved to be inadequate to the circumstances. The problems with the efficiency of the system of enforcing the rights granted by the Convention were solved with the adoption of Protocol No.14 on 13 May 2004. This Protocol introduced several measures to counter the arising problems including a settlement procedure and the possibility for the Court to explain its judgment’s provisions.

120 L. Wildhaber, European Union..., op. cit., p. 156.

121 e.g. Protocol No. 4 to the Convention – 16 September 1963.

122 e.g. Protocol No. 3 to the Convention – 6 May 1963.

123 e.g. Protocol No. 11 to the Convention – 11 May 1994.

124 J. Reiss, op.cit., p. 297.

However it has been pointed out that the "true heart"[125] of Protocol No.14 lies within the provisions of its Articles 6 and 7 which introduce the single-judge formation and the proceedings on admissibility, thoroughly described later in Chapter V. This greatly increased the Court's efficiency[126]. Protocol No.14 also contained provisions dealing with similar cases arising from structural problems in a Contracting Party. The introduction of the a new admissibility criterion – a significant disadvantage suffered by the applicant unless otherwise required due to respect for human rights – was initially considered controversial[127] but proved to be the effect of a compromise between various options suggested while preparing the draft of the Protocol.

Those measures were again proved to be inadequate – in 2008 the number of cases rose to over 100,000, with almost 90% of them not meeting admissibility criteria[128]. This led the Council of Europe to organize the High Level Conference on the Future of the European Court of Human Rights in February 2010. During this Conference the Interlaken Declaration was adopted. It contains the assumptions on which further changes to the procedure should be based with the final evaluation of the improvements planned for 2019. The Declaration emphasizes the need to thoroughly and efficiently examine every case and to ensure that the Member State inform their authorities about human rights protection standards and provide measures of enforcing them as well as inform their citizens about the admissibility criteria.

2.4. The Convention's Matter

The Convention's Matter is divided into three easily distinguishable parts – the rights and freedoms, the procedure connected with their enforcement and other provisions.

It is obvious that the rights and freedoms protected by the Convention are among human rights. As such every individual is entitled to them as he is born and states are obliged to respect them.

[125] Ibid., p. 300.

[126] Ibid.

[127] Ibid, p. 302.

[128] B. Gronowska, „Europejski Trybunał Praw Człowieka. W poszukiwaniu efektywnej ochrony praw jednostki", Toruń 2011, p. 87.

The rights and freedoms covered by the Convention are classified as First Generation Human Rights[129]. As a result they are all associated with liberty and states are prohibited from interfering with them (while they are obliged to take certain actions to enable the respect of human rights of the second and third generations).

The right to life is emphasized by being mentioned first in the Convention. The Convention states that no one can be deprived of his live with the exception of an execution of a penalty after being convicted by a court if such penalty is provided by the law. The Convention introduces several exceptions to this rule – deprivation of life is allowed, if excessive force isn't used, if it is a result of actions in defense of any person from unlawful violence or aimed at either a lawful arrest or preventing an escape of a lawfully detained person as well as for the purpose of quelling a riot or insurrection. It must be pointed out that Protocol No. 6 to the Convention of 28 April 1983 expressly and without the possibility of derogation abolished the death penalty, except in time of war, while Protocol No. 13 of 3 May 2002 introduced a general abolishment of the death penalty.

According to the Convention torture, inhuman and degrading treatment or punishment is prohibited. The Convention also prohibits slavery, holding persons in servitude and force or compulsory labor. It is however pointed out that work done during detention, military service, service exacted in an emergency to the community and any other service resulting from normal civic obligations are not considered forced or compulsory labor.

The Convention affirms the right to liberty and security by stating that depriving one of his liberty is allowed only in case of a lawful detention of a criminal or a suspect, detention of a minor aimed at educational supervision, detention for the prevention of spreading infectious diseases, alcoholics, drug addicts or persons of unsound mind. The Convention also obliges the authorities to inform the arrested person of the reasons for the arrest and charges against him and to bring him before a judge or other authority, as well as to hold a trial within a reasonable time.

The right to a fair trial is extensively described in the Convention. It states that everyone is entitled to a fair and public hearing both in civil and in criminal proceedings. The hearing must be held within a reasonable time by an independent or impartial authority established by

[129] Adam Wiśniewski, „Prawa człowieka" in: J. Zajadło, „Leksykon współczesnej teorii i filozofii prawa. 100 podstawowych pojęć", Warszawa 2007, p. 260.

law. The judgment is to be pronounced publicly but the Convention provides several exceptions[130] due to e.g. morals or national security. Everyone charged with a criminal offence is presumed innocent and has the right to be informed without delay and in detail of the accusation against him. He is to be provided with time and facilities necessary for the preparation of his defense – he can defend himself in person or he may choose a professional representative (legal assistance is free if the interests of justice require it) – he must also be provided with an interpreter if he does not know the language of the Court. Punishment is to be carried out only for actions constituting criminal offence under law at the time they were committed. Additionally Protocol No. 7 of 22 November 1984 granted everyone convicted of a criminal offence the right to appeal his case and ensured that no one shall be tried or punished twice for the same offence.

Interference by public authorities with the right to respect of private and family life, home or correspondence is prohibited except cases in which it is in accordance with the law and the principals of democratic society if such interference is required for the reasons stated in Article 8 paragraph 2 of the Convention.

The Convention guarantees everyone freedom of thought, conscience and religion. It is specified that this right encompasses the right to change religions or beliefs as well as the right to manifest one's religion publicly and privately not only in worship but also in teaching, practice and observance. Any limits to these rights must be introduced by law and must arise from reasons stated in Article 9 paragraph 2 of the Convention.

The right to freedom of expression according to the Convention includes freedom to have opinions and to receive information regardless of frontiers and without any interference or censorship from the state. It is however stated that licensing of broadcasting, television and cinema is allowed, while other actions might be connected with necessary formalities, conditions or restrictions.

Everyone has the freedom of peacefully assembling and associating with others, which specifically includes being a member of trade unions, however lawful restrictions imposed by the authorities are allowed. The Convention also affirms that men and women of marriageable age are allowed to marry and found a family, while equality between spouses was guaranteed by the aforementioned Protocol No. 7 to the Convention.

[130] Article 6 paragraph 1 of the Convention.

The right to an effective remedy is the final right described in the Convention. It grants everyone who was a victim of a violation of the rights set forth in the Convention the possibility of receiving effective remedy before a national authority even if the violation was committed by a person acting in an official capacity. Thus the Convention itself regulates the consequences of its breach.

The Convention also contains several clauses dealing with the restrictions and derogations of the abovementioned rights. It emphasizes that the rights set forth in it are to be enjoyed by everyone regardless of their sex, race, color, language, religion, opinions, origin, association, property or other status. Thus the Convention confirms that those rights are universal. However it must be pointed out that the Convention allows for the derogation of the rights in time of war or a public emergency threatening the life of the nation. The right to life, the prohibition of torture, slavery, forced labor and punishment without law cannot be derogated. The freedom of expression, assembly and association as well as the prohibition of discrimination in the enjoyment of rights can be restricted by a Contracting Party to limit the political activity of aliens. The Convention emphasizes that the limits cannot be applied to a greater extent than stated in the Convention and any restrictions cannot be applied for reasons other than those expressed in the Convention.

The Convention sets the base of functioning of the European Court of Human Rights. It determines the number of judges, the criteria and terms of office, the election procedure and the institutions necessary to aid the judges (described later in Chapter 5). The basis of the Court's organization, including the establishment and competence of the Plenary Court, its President, single-judge formations, Committees, Chambers and Grand Chamber is laid out in the Convention along with the general rules regarding the proceedings, including admissibility criteria, hearings, settlements and judgments.

Other issues covered by the Convention include the possibility of the Secretary General of the Council of Europe requesting explanation on the implementation of the Convention from a Contracting Party. Means of settlement of disputes arising from the Convention other than those specified in it (e.g. provided for in other treaties, declarations etc.) are excluded.

Moreover the Protocols to the Convention introduced other protected rights. Protocol of 20 March 1952 introduced the right to peaceful enjoyment and the prohibition of depravation of one's possessions as well as right to education and to free elections. Protocol No. 4 of 16 September 1963 emphasized that no one shall be imprisoned due to inability to fulfill a

contractual obligation, introduced the freedom of movement and choosing one's residence as well as prohibited states from the expulsion of nationals and the collective expulsion of aliens.

2.5. Structure of the Convention

The Convention consists of the preamble and 59 Articles divided into three sections. Article 1 – the obligation to respect human rights precedes Section I – Rights and freedoms. This section spans Articles 2-18 describing each of the protected rights and the conditions of their derogation or restriction. Section II – European Court of Human Rights consists of Articles 19-51 and deals with the Court's judges, structure and proceedings. Section III – Miscellaneous Provisions includes Articles 52-59 dealing with the Convention's territorial application, reservations, denunciation, signature and ratification.

Changes introduced in the Protocols to the Convention became a part of the text of the Convention except Protocol of 20 March 1952, Protocol No. 4 of 16 September 1963, Protocol No. 6 of 28 April 1983, Protocol No. 7 of 22 September 1984, Protocol No. 12 of 4 November 2000 and Protocol no. 13 of 3 May 2002. These Protocols introduced additional rights without changing the structure of the Convention itself and thus their texts function independently of the Convention. However it must be remembered that legally their provisions have become a part of the Convention[131].

[131] See: Article 5 of Protocol of 20 March 1952, Article 6 of Protocol No.4, Article 6 of Protocol No. 6, Article 7 of Protocol No. 7, Article 3 of Protocol No.12, Article 5 of Protocol No.13.

2.6. Contracting Parties – signatories of the Convention.

The Convention for the Protection of Human Rights and Fundamental Freedoms [132]

States	Signature	Ratification	Entry into force
Albania	13/7/1995	2/10/1996	2/10/1996
Andorra	10/11/1994	22/1/1996	22/1/1996
Armenia	25/1/2001	26/4/2002	26/4/2002
Austria	13/12/1957	3/9/1958	3/9/1958
Azerbaijan	25/1/2001	15/4/2002	15/4/2002
Belgium	4/11/1950	14/6/1955	14/6/1955
Bosnia and Herzegovina	24/4/2002	12/7/2002	12/7/2002
Bulgaria	7/5/1992	7/9/1992	7/9/1992
Croatia	6/11/1996	5/11/1997	5/11/1997
Cyprus	16/12/1961	6/10/1962	6/10/1962
Czech Republic	21/2/1991	18/3/1992	1/1/1993
Denmark	4/11/1950	13/4/1953	3/9/1953
Estonia	14/5/1993	16/4/1996	16/4/1996
Finland	5/5/1989	10/5/1990	10/5/1990
France	4/11/1950	3/5/1974	3/5/1974
Georgia	27/4/1999	20/5/1999	20/5/1999
Germany	4/11/1950	5/12/1952	3/9/1953
Greece	28/11/1950	28/11/1974	28/11/1974
Hungary	6/11/1990	5/11/1992	5/11/1992
Iceland	4/11/1950	29/6/1953	3/9/1953
Ireland	4/11/1950	25/2/1953	3/9/1953

[132] http://conventions.coe.int as of 01.01.2013.

Italy	4/11/1950	26/10/1955	26/10/1955
Latvia	10/2/1995	27/6/1997	27/6/1997
Liechtenstein	23/11/1978	8/9/1982	8/9/1982
Lithuania	14/5/1993	20/6/1995	20/6/1995
Luxembourg	4/11/1950	3/9/1953	3/9/1953
Malta	12/12/1966	23/1/1967	23/1/1967
Moldova	13/7/1995	12/9/1997	12/9/1997
Monaco	5/10/2004	30/11/2005	30/11/2005
Montenegro	3/4/2003	3/3/2004	6/6/2006
Netherlands	4/11/1950	31/8/1954	31/8/1954
Norway	4/11/1950	15/1/1952	3/9/1953
Poland	26/11/1991	19/1/1993	19/1/1993
Portugal	22/9/1976	9/11/1978	9/11/1978
Romania	7/10/1993	20/6/1994	20/6/1994
Russia	28/2/1996	5/5/1998	5/5/1998
San Marino	16/11/1988	22/3/1989	22/3/1989
Serbia	3/4/2003	3/3/2004	3/3/2004
Slovakia	21/2/1991	18/3/1992	1/1/1993
Slovenia	14/5/1993	28/6/1994	28/6/1994
Spain	24/11/1977	4/10/1979	4/10/1979
Sweden	28/11/1950	4/2/1952	3/9/1953
Switzerland	21/12/1972	28/11/1974	28/11/1974
The former Yugoslav Republic of Macedonia	9/11/1995	10/4/1997	10/4/1997
Turkey	4/11/1950	18/5/1954	18/5/1954
Ukraine	9/11/1995	11/9/1997	11/9/1997
United Kingdom	4/11/1950	8/3/1951	3/9/1953

Protocol No. 11 to the Convention for the Protection of Human Rights and Fundamental Freedoms, restructuring the control machinery established thereby[133]

States	Signature	Ratification	Entry into force
Albania	13/7/1995	2/10/1996	1/11/1998
Andorra	10/11/1994	22/1/1996	1/11/1998
Armenia	25/1/2001	26/4/2002	26/4/2002
Austria	11/5/1994	3/8/1995	1/11/1998
Azerbaijan	25/1/2001	15/4/2002	15/4/2002
Belgium	11/5/1994	10/1/1997	1/11/1998
Bosnia and Herzegovina	24/4/2002	12/7/2002	12/7/2002
Bulgaria	11/5/1994	3/11/1994	1/11/1998
Croatia	6/11/1996	5/11/1997	1/11/1998
Cyprus	11/5/1994	28/6/1995	1/11/1998
Czech Republic	11/5/1994	28/4/1995	1/11/1998
Denmark	11/5/1994	18/7/1996	1/11/1998
Estonia	11/5/1994	16/4/1996	1/11/1998
Finland	11/5/1994	12/1/1996	1/11/1998
France	11/5/1994	3/4/1996	1/11/1998
Georgia	27/4/1999	20/5/1999	20/5/1999
Germany	11/5/1994	2/10/1995	1/11/1998
Greece	11/5/1994	9/1/1997	1/11/1998
Hungary	11/5/1994	26/4/1995	1/11/1998
Iceland	11/5/1994	29/6/1995	1/11/1998
Ireland	11/5/1994	16/12/1996	1/11/1998

[133] http://conventions.coe.int as of 01.01.2013.

Italy	21/12/1994	1/10/1997	1/11/1998
Latvia	10/2/1995	27/6/1997	1/11/1998
Liechtenstein	11/5/1994	14/11/1995	1/11/1998
Lithuania	11/5/1994	20/6/1995	1/11/1998
Luxembourg	11/5/1994	10/9/1996	1/11/1998
Malta	11/5/1994	11/5/1995	1/11/1998
Moldova	13/7/1995	12/9/1997	1/11/1998
Monaco	5/10/2004	30/11/2005	30/11/2005
Montenegro	3/4/2003	3/3/2004	6/6/2006
Netherlands	11/5/1994	21/1/1997	1/11/1998
Norway	11/5/1994	24/7/1995	1/11/1998
Poland	11/5/1994	20/5/1997	1/11/1998
Portugal	11/5/1994	14/5/1997	1/11/1998
Romania	11/5/1994	11/8/1995	1/11/1998
Russia	28/2/1996	5/5/1998	1/11/1998
San Marino	11/5/1994	5/12/1996	1/11/1998
Serbia	3/4/2003	3/3/2004	3/3/2004
Slovakia	11/5/1994	28/9/1994	1/11/1998
Slovenia	11/5/1994	28/6/1994	1/11/1998
Spain	11/5/1994	16/12/1996	1/11/1998
Sweden	11/5/1994	21/4/1995	1/11/1998
Switzerland	11/5/1994	13/7/1995	1/11/1998
The former Yugoslav Republic of Macedonia	9/11/1995	10/4/1997	1/11/1998
Turkey	11/5/1994	11/7/1997	1/11/1998
Ukraine	9/11/1995	11/9/1997	1/11/1998
United Kingdom	11/5/1994	9/12/1994	1/11/1998

Protocol No. 14 to the Convention for the Protection of Human Rights and Fundamental Freedoms, amending the control system of the Convention[134]

States	Signature	Ratification	Entry into force
Albania	10/11/2004	3/2/2006	1/6/2010
Andorra	12/11/2004	17/7/2006	1/6/2010
Armenia	13/5/2004	7/1/2005	1/6/2010
Austria	10/11/2004	23/1/2006	1/6/2010
Azerbaijan	16/2/2005	19/5/2006	1/6/2010
Belgium	20/4/2005	14/9/2006	1/6/2010
Bosnia and Herzegovina	10/11/2004	19/5/2006	1/6/2010
Bulgaria	23/9/2005	17/11/2005	1/6/2010
Croatia	13/5/2004	30/1/2006	1/6/2010
Cyprus	15/12/2004	17/11/2005	1/6/2010
Czech Republic	29/6/2005	19/5/2006	1/6/2010
Denmark	13/5/2004	10/11/2004	1/6/2010
Estonia	13/5/2004	26/1/2006	1/6/2010
Finland	29/11/2004	7/3/2006	1/6/2010
France	13/5/2004	7/6/2006	1/6/2010
Georgia	13/5/2004	10/11/2004	1/6/2010
Germany	10/11/2004	11/4/2006	1/6/2010
Greece	13/5/2004	5/8/2005	1/6/2010
Hungary	7/4/2005	21/12/2005	1/6/2010
Iceland	13/5/2004	16/5/2005	1/6/2010
Ireland	13/5/2004	10/11/2004	1/6/2010

[134] http://conventions.coe.int as of 01.01.2013

Italy	13/5/2004	7/3/2006	1/6/2010
Latvia	13/5/2004	28/3/2006	1/6/2010
Liechtenstein	20/9/2004	7/9/2005	1/6/2010
Lithuania	10/11/2004	1/7/2005	1/6/2010
Luxembourg	13/5/2004	21/3/2006	1/6/2010
Malta	4/10/2004	4/10/2004	1/6/2010
Moldova	10/11/2004	22/8/2005	1/6/2010
Monaco	10/11/2004	10/3/2006	1/6/2010
Montenegro	10/11/2004	6/9/2005	1/6/2010
Netherlands	13/5/2004	2/2/2006	1/6/2010
Norway	13/5/2004	10/11/2004	1/6/2010
Poland	10/11/2004	12/10/2006	1/6/2010
Portugal	27/5/2004	19/5/2006	1/6/2010
Romania	13/5/2004	16/5/2005	1/6/2010
Russia	4/5/2006	18/2/2010	1/6/2010
San Marino	16/5/2005	2/2/2006	1/6/2010
Serbia	10/11/2004	6/9/2005	1/6/2010
Slovakia	22/10/2004	16/5/2005	1/6/2010
Slovenia	13/5/2004	29/6/2005	1/6/2010
Spain	10/5/2005	15/3/2006	1/6/2010
Sweden	3/9/2004	17/11/2005	1/6/2010
Switzerland	13/5/2004	25/4/2006	1/6/2010
The former Yugoslav Republic of Macedonia	15/9/2004	15/6/2005	1/6/2010
Turkey	6/10/2004	2/10/2006	1/6/2010
Ukraine	10/11/2004	27/3/2006	1/6/2010
United Kingdom	13/7/2004	28/1/2005	1/6/2010

Chapter 3. The European Court of Human Rights

Piotr Pietrzak, Ewa Adamska-Pietrzak

3.1. Evolution of the Court

The signing of the European Convention on Human Rights required the introduction of measures designed to enforce the fulfilment of obligations included in it. Thus the European Court of Human Rights was established under the auspices of the Council of Europe on 21 January 1959 by the signatories of the Convention according to its Article 19. The Court's first session took place on 23-28 February 1959, while the first judgement was passed on 14 November 1960[135].

It should be pointed out that despite the similarities in law and culture of the contracting states the creation of the Court was the subject of long negotiations and the resulting organisation and procedure was viewed as imperfect but based on concession between the parties[136]. Thus at first the Court gathered only during its sessions and individuals had no direct access to it.

The original text of the Convention introduced two institutions tasked with "ensuring the observance of the engagement undertaken"[137] by the parties: the Court and the European Commission of Human Rights (hereinafter: "the Commission").

The Commission consisted of one member from each of the contracting states elected for a period of six years by the European Council's Committee of Ministers from a list prepared by the Bureau of the Consultative Assembly. Any signatory was entitled to report other party's breach of the Convention. Individuals or their organizations were entitled to file petitions to the Secretary-General of the Council of Europe who was allowed to forward them to the Commission only if the party accused of breaching the Convention recognized the Commission's authority to receive it[138] and only on the condition of exhausting all the legal

[135] Lawless v. Ireland, Application no 332/57.

[136] B. Gronowska, „Europejski Trybunał Praw Człowieka. W poszukiwaniu efektywnej ochrony praw jednostki", Torun 2011, p. 39.

[137] Article 19 of the European Convention on Human Rights as of 21 January 1959.

[138] Article 25 of the European Convention on Human Rights as of 21 January 1959.

domestic remedies. Upon accepting the petition the Commission's task was to ascertain the facts by examining the petition and, if necessary, conducting the investigation in order to secure "a friendly settlement of the matter"[139]. The aforementioned activities were conducted by a Sub-Commission consisting of seven members of the Commission and one person selected by each of the concerned parties, if they exercised their right to appoint them. Reaching a settlement resulted in the Sub-Commission's report sent not only to the parties concerned, but also to the Committee of Ministers and to the Secretary-General of the Council of Europe. If a settlement was not reached, the Commission was required to draft a report that included an opinion whether a breach of the State's obligations under the Convention was discovered. Referring this report to the Committee of Ministers was one of the conditions for the case to be brought before the Court. According to the Convention if the case was not brought to the Court within a period of three months from the date of the Report's transmission to the Committee of Ministers, the Committee of Ministers was to decide whether there a violation of the Convention had taken place.

The original text of the Convention stated that the Court consisted of one member from each of the contracting states elected for a period of nine years by the Consultative Assembly from a list assembled by Members of the Council of Europe. The Convention introduced the requirement for the candidates to be of high moral character and either possess the qualifications required for appointment to high judicial office in one of the signatory states or be jurisconsults of recognized competence. The cases were considered by a Chamber of the Court composed of seven judges. Article 44 of the Convention in its original form stated that the contracting parties and the Commission were the only entities entitled to bring a case before the Court. The concerned states were to declare whether they recognized the Court's compulsory jurisdiction. Furthermore the Court could have dealt with a case only after the Commission acknowledged the failure of its efforts to achieve a friendly settlement and only within the period of three months after the Commission's report transfer to the Committee of Ministers. Allowing the Committee of Ministers to decide whether a violation had taken place caused a significant lengthening of the procedures[140]. The Convention also specified that its party was allowed to bring a case before the Court after it had acknowledged its compulsory jurisdiction only if its party's national was alleged to be the victim of the breach, it referred the case to the Commission or the complaint had been lodged against this party. The Court

[139] Article 28 b) of the European Convention on Human Rights as of 21 January 1959.

[140] B. Gronowska, op.cit., p. 42-43.

was allowed to afford satisfaction to the injured party of the case if a decision or measure taken by a legal authority of the given state was found to be in conflict with the Convention and the law of that state did not offer full reparation. It is important to point out that the contracting parties were obliged to abide to the decision of the Court and the Committee of Ministers was to supervise the judgment's execution.

Thus an individual was not allowed to file his case directly to the Court. Moreover a person who was a victim of a breach of the Convention was not allowed to file any petitions to the Court while the Court was not allowed to listen to this person's statements. On the other hand the Committee of Ministers while supervising the execution of the Court's decision was allowed to consider the information from the victim to determine whether the compensation was adequate. Individuals received the right to file a case to the Court in 1990 with the signing of Protocol no. 9 to the Convention.

The increasing number of the Convention's signatories and the lengthening of individual procedures forced a number of changes to the regulations governing the above described procedure. The amendments introduced from 1994 to 2004 were aimed to improve the protection of human rights and shortening the time required to consider the Court's cases. Committees, Chambers and the Grand Chamber were introduced to the internal organization of the Court. In exceptional cases the parties of the case were granted the right to appeal the judgment of the Chamber and to refer their case to the Grand Chamber. Other amendments in the above period include the introduction of a non-discrimination clause. The effects of this clause were somewhat limited by the fact that most of the Council of Europe's member states refused to sign Protocol no. 12 to the Convention to avoid the accusations of discrimination in regard to the social and economic rights.

In 1997 the introduction of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine[141] extended the jurisdiction of the Court to include advisory opinions on legal questions concerning the interpretation of that convention at the request of the government of a party of this convention or the Steering Committee on Bioethics appointed with accordance to Article 29 of this convention.

The introduced changes proved to be insufficient for the Court to efficiently consider the presented cases. This caused the Council of Europe to introduce Protocol no.14 to the

[141] Signed in Oviedo on 4 April 1997, also called the Convention on Human Rights and Biomedicine.

Convention aimed at further simplifying and shortening the procedure. The included amendments are the basis of the Court's current procedure.

3.2. The Court's structure

The Court functions on a permanent basis in order to ensure the observance of the engagements undertaken by the signatories in the Convention as amended by the Protocols. The seat of the Court is at the seat of the Council of Europe in Strasbourg, but the Court may perform its functions elsewhere in a Member State of the Council of Europe. During the examination of a case the Court may decide to carry out investigations or other functions elsewhere by one or more members. The plenary sessions of the Court are convened by its President whenever it is required by the Convention or the Rules of the Court and always when at least one-third of the members of the Court request it. The plenary Court is in session when two-thirds of the elected judges are present. All expenses of the Court are borne by the Council of Europe.

The Court's Grand Chamber, the Chambers and the Committees sit full time although the President of the Court may propose the Court to fix session periods each year.

The number of judges of the Court is equal to the number of the signatories of the Convention. The requirements to be appointed a judge have not changed since the establishment of the Court – the judges have to be of high moral character and must either possess the qualifications for appointment to high judicial office in their country or be jurisconsults of recognized competence.

To ensure the objectivity of the judges the Convention states that they shall sit on the Court in their individual capacity and they are prohibited from engaging in activities that are incompatible with their impartiality, independence or full-time office as determined by the Court itself. Furthermore on 23 June 2008 the Court adopted a Resolution on Judicial Ethics (hereinafter: the Resolution) which confirms that the judges are independent of all external authority or influence while exercising their judicial functions. The Resolution also obliges the judges to refrain from any activities, memberships and other situations, that may have an effect on their independence. The judges are also required not only to exercise their function impartially but also to ensure the appearance of impartiality. Thus they must but be diligent to avoid both conflicts of interest and situations that may be reasonably perceived as causing a conflict of interest. In order to assure compliance with the aforementioned rules the Judges

are required to inform the President of the Court about all their additional activities. Furthermore the judges may accept decorations and honours only where it does not cause reasonable doubt as to their independence or impartiality and only after informing the President of the Court. They are also prohibited from accepting any gift, favour or advantage that could cast doubt on their independence or impartiality. It should also be mentioned that Rule 4.2 of the Rules of the Court[142] prohibits a former judge from representing a party or a third party in proceedings before the Court if the application was lodged when he was still holding office.

The Resolution also points out that the judges should act in consistency with the high moral character required by the Convention at all times and therefore their conduct should uphold the standing and reputation of the Court. Despite the fact that the judges should possess high qualifications already at the time of their election, the Resolution obliges them to constantly develop their professional skills in order to maintain their level of competence throughout their term of office.

The Parliamentary Assembly of the Council of Europe elects each judge for a period of nine years from a list of three candidates selected by each party of the convention. The judges cannot be reelected and their term of office expires when they reach 70 years of age. According to Article 23 of the Convention the judges should hold their office until replaced but they should also continue to deal with cases that they already have under consideration. The Convention states that other judges may decide (by a majority of two-thirds) that a judge ceased to fulfill the required conditions – only then a judge may be dismissed from office but he or she must first be heard by the Court.

The Rules of the Court clarify that the judge's term of office begins from the date of taking up office which should happen no later than three months after the election. In case the office becomes vacant later than three months after the election, the judge's term of office begins on the day of the vacancy. The judges are replaced on the day their successor takes the oath or makes the declaration according to Rule 3 of the Rules of Court.

The Court elects its President, two Vice-Presidents and Presidents of the Sections, while each Section elects its Vice-President. The President of the Court directs the Court, represents it, guides the Court's relations with the Council of Europe and presides at: the Court's plenary meetings, Grand Chamber's meetings and meetings of the panel of five judges. In his tasks the President is assisted by the Bureau (composed of the President himself, the Vice-

[142] As of 1 September 2012.

Presidents and the Presidents of the Sections) and the Vice-Presidents. The Presidents of the Sections presides at the Section's and Chambers' meetings.

In order to assist the Court in translation, legal and administrative work (including processing applications lodged by individuals) the Convention established a Registry composed of Section Registries and other departments necessary for performing of its functions. The Registrar is responsible for the Registry's activities and organization as well as functioning of the Court's archives and replying to the requests for information on the Court and its work. The plenary Court elects the Registrar and two Deputy Registrars for a period of five years from candidates of high moral character possessing sufficient linguistic, managerial and legal knowledge. The Registry also includes non-judicial rapporteurs who assist the Court sitting in a single-judge formation.

The Court's structure is composed of the Grand Chamber, Sections, Chambers and Committees.

The Grand Chamber's duties include:

- jurisdiction in cases in which a Chamber relinquished its jurisdiction due to serious questions on interpretation of the Convention according to Article 30 of the Convention,
- deciding cases referred by the parties according to Article 43 of the Convention,
- examining requests for determining whether a party has failed to fulfill its obligation resulting from the Court's judgments according to Article 46 § 4 of the Convention,
- preparing advisory opinions on the interpretation of the Convention for the Committee of Ministers according to Article 47 of the Convention.

The Grand Chamber is composed of seventeen judges and no less than three substitute judges and includes the President and the Vice-Presidents of the Court as well as the Presidents of the Sections. The judges are designated by a drawing of lots by the President of the Court witnessed by the Registrar. If a Vice-President of the Court or a President of the Section is unavailable to attend a Grand Chamber session, he is replaced by the Vice-President of the relevant Section.

In cases referred to the Grand Chamber according to Article 30 of the Convention the Grand Chamber includes the members of the Chamber which relinquished jurisdiction. In cases referred under Article 43, the Grand Chamber cannot include a judge who took part in rendering the judgments in the referred case, except the President of the Chamber, he judge who sat in respect of the Party concerned or a judge who ruled only on the admissibility of the application. While examining a request made in accordance with Article 46 § 4 of the

Convention the Grand Chamber must include the judges which rendered the judgment in the case concerned.

It is necessary to point out that cases referred under Article 43 of the Convention are first considered by a panel of five judges that includes the President of the Court (or a Vice-President if the President is unavailable), two Presidents of Sections, two judges from the other Sections and two substitute judges – if this panel accepts the request, the Grand Chamber decides the case.

The designated judges are required to sit in the Grand Chamber until the proceedings in the given case are completed. Thus they are obliged to participate in the case even after their term of office ends. In case a judge is unable to sit in the Grand Chamber, he is replaced by the designated substitute judge.

The Court's Sections are set up by the plenary Court for a period of three years according to a proposal by the President of the Court. The Rules of the Court state that there are to be at least four Sections. The sections are to be geographically and gender balanced and their composition reflects the variety of legal systems among the Contracting parties. As of 20 January 2013 the Court is composed of five sections[143]. Each judge is required to be a member of one of the Sections.

Article 26 § 1 of the Convention provides for a Chamber of the Court consisting of seven judges of a Section. Those judges include the President of the Section and a judge elected in respect of any concerned signatory of the Convention as well as judges of the Section elected by its President. The judges of the Section who are not elected to the Chamber sit in the Chamber's case as substitute judges. The President of the Section may dispense a judge from attending meetings concerning only preparatory or procedural matters. If the dispensed judge is the one elected in respect of any contracting party concerned, the party is deemed to have appointed the first substitute judge for such meeting. During the consideration of a case a judge elected in respect of the Contracting Party concerned sits as a member of the Chamber.

A Committee is composed of three judges from the same Section. The President of the Court decides on the number of Committees to be set up. They are constituted for a period of twelve months and then their composition changes by rotation among the judges of each Section, excluding the President of the Section. In a case a judge is unable to sit, any other judge of the Section, including its President, can be called upon to sit on the Committee.

[143] http://www.echr.coe.int as of 20 January 2013.

Article 26 § 1 of the Convention introduces the single-judge formation. The President of the Court determines the number of single judges and appoints them for a period of twelve months after consulting his decision with the Bureau. Each appointed single judge examines applications in respect of Contracting Parties as drawn up by the President of the Court. The President of the Court and the Presidents of the Sections cannot be appointed as single judges. It is necessary to point out that being appointed as a single judge obliges the judge to carry out these duties along with his regular duties as a member of a Section.

A judge who is prevented from taking in a sitting is required to give notice to the President of the Chamber as soon as possible. A judge may withdraw from considering a case if:

- he has personal interest in the case – this includes a family, personal or professional relationship with a party,
- he acted in the case previously – including but not limited to acting as a representative of a party, as a party or as a member of a national or international court or commission,
- he is engaged in any activities which are incompatible with his independence or impartiality in the given case,
- he had publicly expressed opinions that are capable of negatively affecting his impartiality,
- for any other reason his independence or impartiality may be doubted.

If a judge withdraws for one of the abovementioned reasons, he is obliged to notify the President of the Chamber (or – in case of a single judge or a member of a Committee – to the President of the Section). If the existence of one of those reasons is doubted by the judge or the President of the Chamber the issue is decided by the Chamber. Prior to voting on the issue the Chamber hears the judge concerned. During deliberations and voting the judge concerned is replaced by the first substitute judge of the Chamber.

If a judge elected in respect of a Contracting Party is unable to sit, withdraws or is exempted the Contracting Party appoints an ad hoc judge or is invited to indicate a judge from among the other elected judges. If it decides to appoint an ad hoc judge the President of the Chamber is obliged to choose him from a list of three to five persons submitted by the Contracting Party to be eligible to serve as ad hoc judges for a period of two years. Such an ad hoc judge must comply with the requirements stated in Article 21 § 1 of the Convention. The Contracting Party is presumed to have waived the rights of appointment if it does not reply within a thirty-day period or if does not provide the Registrar with the list of candidates for the position. Furthermore if two or more Contracting Parties have common interest in a given

case, the President of the Chamber is entitled to invite them to appoint a single common-interest judge. If there is no agreement, the President himself selects this judge.

Deliberations of the Court are done in private and shall remain secret. Only the judges take part in them, while the Registrar and other members of the Court's Registry are present if their assistance is necessary. The decisions of the Court are taken by majority of the judges present. In case of a tie a new vote is taken and if another tie happens, the President has the deciding vote. Votes are generally taken by a show of hands.

If a decision on a point of procedure or another issue is necessary outside of the Court's scheduled meeting, the President is allowed to prepare a draft of the decision and circulate it among the judges, while setting a deadline for their comments. In the absence of an objection, the proposal is considered to have been adopted at the deadline's expiry.

3.3. The Procedure

The official languages of the Court are English and French however all communications and submissions to the Court in regard to an individual application by a person, non-governmental organization or group of individuals claiming to be a victim of a violation of the Convention may be in any of the official languages of the Parties of the Convention. However all communications in respect of a hearing or after the Contracting party is noticed of an application shall be done in English or French unless the President of the Chamber allows to continue the use of one of the languages of the Contracting Parties. In the latter case the Registrar is responsible for supplying the interpretation and translation to English or French. In exceptional cases the President of the Chamber may allow the continuance of the use of a language on the condition that the applicant bears all or part of the casts of the interpretation and translation. The President's decision is valid un all proceedings in the given case including referrals to the Grand Chamber and revisions of the judgment.

The Contracting Party is obliged to address and communicate with the Court in English or French. However the President of the Chamber is allowed to grant the Party a leave to use one of its official languages. The Party is then responsible for filing a translation of its written submissions in the period scheduled by the President of the Chamber as well as covering the expenses of interpreting its oral submissions. Moreover the President of the Chamber is entitled to ask the Contracting Party to provide a translation of its submissions in the official language of that Party in order to ensure that they are understood by the applicant. All

witnesses, experts and other persons appearing before the Court are entitled to use their own languages if their knowledge of English or French is insufficient. In such cases the Registrar makes the necessary arrangements in order to provide interpretation or translation.

All hearings are public however the Court may decide otherwise in exceptional circumstances. The documents deposited with the Court's Registry in connection with an application are accessible to the public with the exception of documents to which public access has been restricted by the President of the Chamber because of morals, public order, national security, interests of juveniles or private life of a person concerned. Any request for such confidentiality must specify reasons and point out whether they affect all the documents or parts of the documents. All decisions and judgments of the Chamber are public, while information on decisions taken by single-judge formations and by the Committees are made accessible periodically.

The Contracting Parties are represented by Agents, assisted by advocates and advisers. Persons and other entities entitled to file an individual application present them themselves or through a representative. However after the Contracting Party is notified of the application the applicant must be represented by an advocate authorized to practice and residing in one of the Parties of the Convention, unless the President of the Chamber decides otherwise. However the representative or the applicant if he presents his own case is obliged either to have a sufficient understanding of English or French or to be granted the leave to use one of the official languages of the Contracting Parties.

Communications are considered to be addressed to the Parties even if they are addressed to the Agents or advocates. For communication, notifying or summoning a person other than the parties or their representatives the Court may consider it necessary to acquire assistance of the Government of the State on whose territory such communication is to have effect. In such cases the President of the Court should contact the Government directly in order to secure the necessary facilities.

According to the Rules of the Court[144] the Court determines the order of dealing with the cases with the regard to the importance and urgency of the raised issue based on the criteria fixed by the Court itself. In any case of urgency the Registrar, after acquiring authorization from the President of the Chamber, is allowed to inform a Contracting Party of the application and its contents. The Chamber may order the joinder of at least two applications – either of its own motion or at the request of the cases' parties. Moreover the

[144] Rule 41 of the Rules of the Court.

President of the Chamber may order the proceedings in applications assigned to the same Chamber to be conducted simultaneously.

The Chamber is allowed to strike an application out of its list of cases at any time if it comes to the conclusion that the applicant will not pursue his application, the matter is resolved or it is no longer necessary to examine the application and the respect for human rights does not require otherwise. However the Court is allowed to restore an application if it is justified by the circumstances. An applicant Contracting Party may notify the Registrar that it does not have the intention to proceed with the case – the Chamber may strike such an application out only if other Contracting Parties concerned agree to such discontinuance. If a friendly settlement is reached according to Article 39 of the Convention, the Court issues a decision on striking out the application – this decision is forwarded to the Committee of Ministers, which is responsible for supervising its execution. In other cases the application shall be struck out in the form of a judgment if it was previously declared admissible or in the form of a decision if it was declared inadmissible. The judgments on striking out applications are forwarded to the Committee of Ministers, which supervises the execution of provisions attached to the discontinuance of the case.

A Contracting Party one of whose nationals is an applicant in a case is entitled to submit its comments and take part in the proceedings – it must notify the Registrar of its decision no later than twelve weeks after it was informed of the case. Furthermore the President of the Court may invite a Contracting Party or any concerned person to submit written comments or take part in the hearings if it is required for the proper administration of justice. The Council of Europe Commissioner for Human Rights is allowed to take part in the proceedings in such scope if the case is considered by one of the Chambers or the Grand Chamber. He may do it himself or he may indicate the employee of his office to represent him in the proceedings.

The parties and the Contracting Parties are obliged to fully cooperate with the Court during the proceedings. When a party does not comply with the Court's order concerning the proceedings, the President of the Chamber is allowed to take any steps that he deems appropriate, however neither the Convention nor the Rules of the Court specify the kinds of actions that may be considered as appropriate steps. If a party does not adduce evidence, provide the Court with requested information or otherwise does not participate effectively in the proceedings, the Court may take appropriate actions except discontinuing the examination of the application. A representative of a party may be excluded from the proceedings if he makes abusive, frivolous, vexatious, misleading or prolix submissions.

While examining the case the Chamber simultaneously considers any questions of procedure that require its decision.

At any stage of the proceedings the Court may assist the parties in securing a friendly settlement of the case based on the respect for human rights. If such a settlement is reached the Court strikes the case out of its list.

When it deems it necessary, at the request of a party or other person concerned the Chamber may introduce interim measures that should be adopted in the interest of the parties or in order to secure proper conduct of the proceedings. Moreover immediate notice of such measures may be given to the Committee of Ministers.

Any application filed by a Contracting Party or an individual must be submitted in written form and signed by the party or its representative (in case of an organization or group of individuals – by the persons competent to represent this entity). The rules of the Court specify the information that must be contained in the application[145], including a statement of the facts, alleged violations and the applicant's compliance with the admissibility criteria. Individual applicants who wish their identity to remain undisclosed to the public must justify it in the application. Failure to comply with the requirements for the contents of the application set out in Rule 47 §1 and §2 of the Rules of the Court may be the basis for the Court not to examine the case. An applicant is oblige to inform the Court of any change of address as well as any circumstances relevant to the case.

In case of an Inter-State application the Chamber[146] selects at least one of its judges as Judge Rapporteur who is tasked with submitting a report of the applications admissibility and any other documents that may assist the Chamber and its President in performing their functions. If an individual application contains material that is sufficient for the Court to determine that this application is inadmissible or should be struck out of the list a single-judge formation considers the case. On the other hand if a case seems justified the President of the Section designates a Judge Rapporteur who examines the application. In addition to submitting documents that may assist the Chamber and its President in performing their functions connected with examination of an individual application the Judge Rapporteur may request the parties to submit additional relevant documents and information. He also decides whether the application will be considered by a single-judge formation, by a committee or by a Chamber.

[145] Rule 46-47 of the Rules of the Court.

[146] Or the Grand Chamber under Article 40 or Article 43 of the Convention.

The examination of an application begins with the analysis of its admissibility according to Article 35 of the Convention. The Court is obliged to determine whether all domestic remedies have been exhausted as well as whether a six-month period from the date of the final decision has not passed. Furthermore the Court cannot deal with anonymous applications or applications that are substantially the same as a matter that has already been examined or is under examination by the Court. Article 35 of the Convention also states that the Court may declare an application inadmissible if it is found to be incompatible with the provisions of the Convention, manifestly ill-founded, an abuse of right to an application or the applicant has not suffered a significant disadvantage. After an inter-state application is filed, the President of the Court notifies the Contracting Party concerned and assigns the application to one of the Court's Sections. The Contracting Party is then invited to provide its observations on the admissibility of the application. The Chamber schedules an admissibility hearing if a Contracting Party requests it or if it decides that such hearing is necessary. In case of an individual application, the President of the Court assigns it to a Section. A single judge assesses its admissibility and may declare it inadmissible or strike it out of the Court's list of cases. Furthermore the Committee may declare an individual application inadmissible at any stage of the proceedings by an unanimous vote. The Chamber is also allowed to declare an application inadmissible and may hold a hearing on an application's admissibility. If no decision on the application's inadmissibility has been made, the Chamber shall decide the application's admissibility together with its merits, although the Court may, at any stage of the proceedings, decide to take a separate decision on the application's admissibility.

If a Chamber decides that an inter-state application is admissible, its President sets the time-limits for submitting evidence and filing observations. A hearing on the merits of the case is scheduled if the Contracting Parties request it or if the Chamber decides that it is necessary.

After an individual application is declared admissible the Chamber or its President may invite the parties to submit evidence and observations in a set time-limit that must be the same for all parties. The Chamber may also decide to schedule a hearing on the case's merits.

Article 41 of the Convention entitles the injured party to be afforded just satisfaction if the internal law of the Contracting Party allows only partial compensation. However the applicant must make a specific claim to obtain just satisfaction. This claim shall include its itemized particulars as well as relevant documents and must be filed in the time-limit fixed for the submission of observations. The Chamber may reject a claim that does not comply with

the aforementioned requirements. The Contracting Party concerned is allowed to comment on the applicant's claim.

If the facts described in an application reveal a structural or systemic dysfunction in a Contracting Party and there is a high possibility of similar applications being filed to the Court, the Court, after obtaining the views of the parties, may decide to initiate a pilot-judgment procedure and adopt a pilot judgment. In such judgment the Court is obliged to identify the problem and determine the remedial measures required to be taken by the Contracting Party. The Court may also specify the time in which the measures are to be introduced. A pilot-judgment procedure does not rule out a friendly-settlement agreement, however the parties must include a declaration by the Contracting Party on the implementation of the remedial measures.

After an application is declared admissible the Registrar is obliged to attempt to convince the parties to secure a friendly settlement. As stated above the proceedings connected with such settlement are confidential and because of that no statements, communications or offers made during the attempt to secure a settlement cannot be referred to during the contentious proceedings. A friendly settlement results in the Chamber striking the case out of the Court's list. If an applicant refuses the terms of a proposal for a friendly settlement the Contracting Party can request the Court to strike the case out of its list. Such request must be made publicly and must include a declaration that a violation of the Convention had taken place together with the proposal for adequate redress and any remedial measures necessary. In exceptional cases such request may be filed without the proceedings for reaching a friendly settlement. If the Court finds such request sufficient it is allowed to strike the case out of the list regardless of the applicants opinion.

The President of the Chamber organizes and directs the Court's hearings as well as determines the order in which the Parties are called upon to speak. It is important to point out that a judge may ask questions to any persons appearing before the Court. The President of the Chamber may direct the Registrar to be responsible for making a record of the hearing which includes the Chamber's composition, a list of persons appearing before the Court and the text of all submissions, questions replies and rulings. The representatives of the Parties are allowed, in a set time-limit, to make corrections that do not affect the sense and bearing of what was said.

The Rules of the Court specify that a judgment must contain: the names of the judges and the Registrar or Deputy registrar concerned, the dates of its adoption and delivery, description of the parties and the names of their Agents, advocates and advisers, the procedure

followed, the facts of the case, the parties submissions, the reasons for the judgment, operative provisions, the decision on the costs, the number of judges constituting the majority[147]. Furthermore the judges are entitled to a separate opinion (either concurring or dissenting with the judgment) or a statement of dissent which becomes a part of the judgment. All judgments are signed by the President of the Chamber or Committee and the Registrar. The Chamber's judgment may be delivered by reading it out during a public hearing. All judgments are transmitted to the Committee of Ministers. The Registrar sends copies to the parties, to the Secretary General of the Council of Europe, to any third parties and other persons concerned, while the original signed and sealed copy of the judgment is placed in the Court's archives. The judgment is given in either English or French unless the Court decides that it should be given in both official languages.

A party is allowed to make a request for an interpretation of a judgment within a period of one year from its delivery or notification. Such a request is filed with the Registry and must clearly and precisely state which point of the judgment's operative provisions requires interpretation. The Chamber may refuse the request if it decides that interpretation is not required. If the Chamber does not refuse, the Registrar is obliged to notify the parties and inform them about the possibility to submit written comments within a specified time limit. The Chamber may also hold a hearing on this matter. The interpretation is delivered in the form of a judgment.

If a party discovers a fact which was unknown to the Court at the time of the judgment and could not reasonably be known to the Court, but which may have a decisive influence the party, within sixth months after gaining knowledge of such fact, may file a request for the Court to revise such judgment. Such request must specify the judgment in question and describe the new facts in a way that shows that the conditions for the revision have been met as well as include all documents relevant to the request. The Chamber may refuse the request if it decides that there is no reason to warrant considering it. If it does not refuse the Registrar notifies the parties and invites them to submit written comments within a specified time limit. The revision is delivered in the form of a judgment.

The rules regarding applications apply also to the advisory opinions on legal questions concerning the interpretation of the Convention given by the Court in accordance with Articles 47-49 of the Convention at the request of the Committee of Ministers. Such requests must be filed with the Registrar and shall state the question on which the opinion is sought.

[147] Rule 74 of the Rules of the Court

Such question must not relate to the content or scope of the rights and freedoms defined in Section 1 of the Convention. On receiving the request the Registrar transmits its copy to all members of the Court and informs the Contracting Parties that they are allowed to submit written comments in a time limit set by the President of the Court. After receiving written comments the President of the Court may decide that an oral hearing is necessary for the Contracting Parties to develop their comments. A Grand Chamber is constituted to consider the request for an advisory opinion. If it decides that the request is not within its competence it is obliged to issue a reasoned decision. The Grand Chamber gives an opinion or a reasoned decision by a majority vote. Such an opinion or decision may be read out I one of the official languages of the Court at a public hearing. The Court is obliged to give reasons for an advisory opinion. If a judge does not concur with an opinion, he is entitled to deliver a separate opinion.

The Contracting Parties are obliged to abide by the final judgment of the Court in all cases to which they are parties.

Chapter 4. The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine

Krzysztof Sobczak, Ewa Bandurska, Marzena Zarzeczna-Baran, Lubomira Wengler

4.1. European Convention on Bioethics. The genesis. The subject matter

The European Convention on Bioethics, in fact "Convention on Protection for the Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (CETS no. 64), was signed on 4th of April 1997 in Spanish city Oviedo, and entered into force on 1st of December 1999. It has been signed by 34 countries and ratified, till this moment, by 20 countries. Four additional protocols have been adopted to the above act:

1. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1988, CETS no. 168) – opened for signature on January, 24th 2002, in force since May 1st, 2006.

2. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2002, CETS no. 186) - opened for signature on January 24th 2002, in force since May 1st, 2006.

3. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research (2005, CETS no. 195) - opened for signature on January 25th, 2005, in force since September 1st, 2007.

4. Additional Protocol to the Convention on Human Rights and Bioethics, concerning Genetic Testing for Health Purposes (2008, CETS no. 203) – opened for signature on November 27th 2008, not in force.

The convention is a direct effect of work of Steering Committee on Bioethics (CDBI). Steering Committee has stated to work under this act's project as a part of a working group in March 1992. In July 1994 the outputs of this work have been presented to the public consultations and the Parliamentary Assembly of the Council of Europe (PACE). On the

grounds of the opinion issued by the Parliamentary Assembly of the Council of Europe recommending "general revision" [148] of the project, on the 2nd of February 1995 the CDBI started further work on it, which was completed on the 7th of June 1996. On the 26th of September 1996 Parliamentary Assembly of the Council of Europe gave a positive opinion on presented document, which resulted directly in its adoption on the 19th of November 1996 by the Committee of Ministers of the Council of Europe[149].

The direct reason for creation of the Convention was a need to provide legal and ethical framework in aspect of law regulations, concerning human rights and development of biomedical sciences. The discussion on the need of developing some standards started in late 60s of the twentieth century. The convention is therefore, on the one hand the first document about the character and legal consequences, which is summing up many years of debating, on the other- it sets specific guidelines for further debate by formulating the fundamental standards in subject of solutions in progress in the biomedical and biotechnology sciences. The form, as adopted in Convention, is not describing any concrete bioethical vision or ethical explants of accepted norms.[150] By referring to the axiology of promoting human rights (regarding the Convention for the Protection of Human Rights and Fundamental Freedoms from 4th of November 1950, what is emphasized in the preamble Universal Declaration of Human Rights, announced by General Assembly of the United Nations on 10th of December 1948; European Social Charter from 18th October 1961; International Covenant on Civil and Political Rights from 16th December 1966; Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data from 28th January 1981; the Convention on the Rights of a Child from 20th November 1989) there are some fundamental rules described:

I. Protection of dignity, integrity and respecting of rights of every human being in relation to biomedical development (CETS no. 164, art. 1).

II. The primacy of the individual's wellbeing over social and scientific interests

III. Fair distribution of goods and accessibility to medical care of appropriate quality (CETS No.164, art. 3).

[148] Nawrot O., Ludzka biogeneza w standardach bioetycznych Rady Europy, Warszawa 2011, p. 91

[149] Biesaga T., Europejska Konwencja Bioetyczna, [w:] Medycyna Praktyczna (2006): 11-12, s. 24.

[150] Grzymkowska M., Konwencja o prawach człowieka i biomedycynie, document available on website: http://www.hfhrpol.waw.pl/precedens/images/stories/konwencja_overview.pdf, Access on December, 2nd, 2002.

IV. Respecting rules and rights applicable with the intervention in the health field (CETS No. 164, art. 4).

4.2. General characteristics of European Convention on Bioethics

On the grounds of the adopted principles, contents of the Convention and the Additional Protocols regulate and set standards for ethics in the following areas:

1. Patients' rights.

a. With regard to an agreement for medical procedures: It is required to obtain a free and informed patient's consent to make a decision about medical intervention, which is expressed by the patient on the basis of information on the purpose, nature of the intervention and on its consequences and the estimated risk of complications (CETS No. 164, article 5). For the minors, the intervention may take place if and only when it is directly beneficial and the consent was obtained from the legal representative or established institutions. In the text of the Convention is also emphasized the obligation of active participation of juvenile in decision making (CETS No. 164, Art. 6). On protection of rights of patients, who do not have the capacity to consent (unable to give informed consent due to mental disorders) in article 7 of the text of the Convention (CETS No. 164) is allowed the possibility of medical intervention if and only if the absence of this intervention creates a risk of harm to the health of such person and that during the whole therapeutic effect, will be preserved an adequate supervision and certain rights. In case of emergency medical intervention it is permitted to act without the consent of the patient, if the medical effect is intended to achieve "health benefits to an individual" (CETS No. 164, Art. 8) [151]. Article 9 of the Convention (CETS No. 164) refers to necessity to respect the will of the patient who had previously expressed own position with respect to the use of medical intervention or its abandonment and for medical reasons is not able at the time to formulate this will.

[151] The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (CETS No. 164), document available on website: http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/ETS164Polish.pdf, record from December 2nd, 2012.

b. With regard to privacy and the right to information: Article no. 10 of the Convention (CETS No. 164), requires the respect of privacy "with respect to health information"[152] and providing all information related to health, apart from not informing those patients who did not wish to get such information.

2. Genetic regulations:

The Convention prohibits all forms of discrimination based on genetic heritage (CETS No. 164, Art. 11). Research and genetic tests, which are designed to diagnose diseases or are carried out in order to determine the inborn predisposition or susceptibility to some diseases, may be carried out only in terms of health or scientific research (CETS No. 164, Art. 12). Interventions in the human genome can be made to the prevention, therapeutic and diagnostic matters if and only when the result is not genetic modification in descendants (CETS No. 164, Art. 13). In Article 14 of the Convention (CETS No. 164) it is prohibited to choose gender of the baby by using the techniques of assisted fertilization, except where that choice allows "to avoid a serious hereditary disease dependent on child's sex." [153].

3. Medical research on people:

a. Protection of persons undergoing research: The Convention allows for research and human experiments, specifying at the same time the necessary conditions for such activities: lack of any alternative of comparable effectiveness; the estimated risk of intervention cannot be disproportionate to the potential benefits of the research; the formal condition about allowing certain test or experiment by the appropriate institutional bioethics board has been fulfilled; the persons undergoing research have been informed about their rights, their free and informed consent has been obtained (CETS No 164, art. 16).

b. Protection of persons not able to give consent to the research: the Convention allows experiments and medical research if the criteria listed in CETS No 164, article 16 are fulfilled (the active and formal agreement, which the patient is unable to express is replaced by a double negative condition- meaning "a person undergoing tests does not oppose to

[152] Ibidem.

[153] Ibidem.

the procedure" [154] and positive, formal expression of legal representative or established institutions and assuming that the research has the aim of significant improvement in the individual's condition, disease or disorder and there is no possibility to conduct the experiment on people with full capacity of giving consent. In the case of experiments and studies that do not provide a direct benefit to patients without full capacity to consent, they may be carried out if, and only when the above conditions are met (with the exception of direct benefit) and additional two parameters are obtained: studies create minimal risk and burden to the patient and the outcome may provide a significant and practical improvement in the scientific understanding and medical practice.

4. Protection of embryos formed by assisted fertilization in vitro.

The Convention shall require the provision of adequate protection of embryos formed through in vitro procedure and identifies a ban on creating embryos for scientific purposes (CETS No. 164, Article18).

5. Transplantation

a. With regard to people able to consent: the Convention determines the necessity to get consent for removal of organs or tissue from a living person for transplantation purposes. This procedure can be carried out only if there is a therapeutic benefit for the recipient and if there is no possibility for post mortem transplantation and no other alternative therapeutic method of comparable effectiveness. (CETS No. 164, art. 19).

b. With regard to people unable to consent: the Convention prohibits organs removal from people who cannot consent. Under special condition it is only possible to remove regenerative tissue from a person, who is not able to consent only when: the recipient is a brother or sister of the donor; the transplantation is a lifesaving procedure; the consent was obtained from the legal representative or established institutions; the donor does not object to the planned transplantation procedure (CETS No 164, art. 20).

6. The commercial use of medicine

Nor human body or its parts cannot be used to obtain any financial profits.

[154] Ibidem.

The contents of the Explanatory Protocol (CETS No. 164 - Explanatory Report) of the Convention presents generally formulated intention of the need to build upon the achievements and progress in the biomedical sciences only for the benefit of present and future generations. Axiology is, according to the text realized in three perspectives:

- First: Specifies the primacy of the individual in relation to science and society in a way that offers protection of the unit from illegal interference into the body, prohibits the commercialization of the human body and its parts, determine the limits of the use of genetic testing;

- Second: it emphasizes the need to involve society through a public debate into defining and discussing the problems arising from the progress of biomedical sciences;

- Third: concerning human species, the need for creating rules and ethical principles that ensure protection of human genetic identity[155].

The Convention is an agreement on the nature and legal effects, it means that its signing is associated with the establishment of a specific law[156].
Consequences on violation of the Convention are defined in Chapter XIII (CETS No. 164), and state that signing the Convection is associated with a commitment to ensure the legal protection of its principles and in case of their negligence, it presents applicable legal sanctions and possibilities to obtain appropriate compensation. An institution, which prepares opinions and interprets the regulations of the Convention is European Court of Human Rights (CETS No. 164, Art. 29). It requires emphasizing, that in the text of the Convention (CETS No. 164, Art. 28) is noted the need to take public debate because of the dynamic changes that occur in the field of biomedical sciences. The implications for medical, economic, ethical and legal aspects should be subjected consulting and evaluation. According to Professor Safjan:"without exaggeration one can say that we are dealing with a completely new approach for the creation of standards for the future and solving complex legal and ethical dilemmas, and even in some sense, with demand of using new methodology of innovative rules creation in areas of social controversy. The adopted assumptions, concerning the necessity of public

[155] The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (CETS No. 164), The exploratory Protocol.Document available on website: http://conventions.coe.int/Treaty/EN/Reports/Html/164.htm, Protocol from December 2nd, 2012.

[156] Safjan M., Prawo polskie a Europejska Konwencja Bioetyczna, [w:] Prawo medyczne (2000): 5, p. 2.

debate, mean first: the basic problems, reserved previously to be solved by the scientists and sages, are right know supposed to be an element of a debate of <profane> people off streets and the ordinary people[157].

According to the text, this act states that its ratification is available for countries which are not members of the Counsil of Europe (CETS No. 164, art. 34). This notation, can with whole responsibility be interpreted as an attempt of forming an universal axiology terms of biomedical and biotechnological problems. The countries that become a Parties to an Agreement, may legally establish a representative in the Steering Committee on Bioethics (CDBI), which has the active voice. The representatives of a country which is not Party to this Convention can only have the observer's status (CETS No. 164, art. 32, p.3). the Convention text, according to the article 32, p.4 (CETS No. 164) has to be systematically examined, and all the changes of the text require a specific legislative procedures.

The Convention's construction in article 32 (CETS No. 164) assumes that all the issues presented in this act can be specified in selected areas, through amendments of the rules. In the Explanatory Report of the Convention we can read that: the document sets only the most important and significant rules. All additional rules and standards, more specific questions should be discussed in additional protocols. The Convention therefore should set a common fundament for protection of peoples' laws and dignity…".[158]. According to this intention, the additional protocols state:

1. The Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings emphasis that development of biomedical and bio-technological sciences can create, in close future, the possibility of cloning human beings. Because of this fact, the article 1 (CETS no. 168) states that: any intervention aiming at creation of a human being identical to other human being, living or dead, is forbidden" [159]. It results from the rule that any instrumentalisation of human beings, which could occur

[157] Ibidem, p. 3.

[158] The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (CETS No. 164), The exploratory Protocol. Document available on website: http://conventions.coe.int/Treaty/EN/Reports/Html/164.htm, Protocol from December 2nd, 2012.

[159] The Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings (CETS nr 168), European Parliament, Document available on website http://conventions.coe.int/Treaty/en/Treaties/Html/168.htm, record from December, 2nd 2012.

while creation of genetically identical human beings is contrary to human dignity and constitutes an abuse done by the science.

2. The Additional Protocol to the Convention on Human Rights and biomedicine, concerning transplantation of organs and tissues of human origin emphasis in the introduction that the development of medicine in transplantation area helped to save human's lives and improving quality of life. The cooperation of European countries through common promotion of information about role and importance of transplantation for the public opinion, is supposed to be initial to following more effective ways to obtain human organs and tissues. The axiology, which is a fundament of this assumption, determines that commercialization of human body and its fragments is forbidden (it is stated by the articles 21 and 22) (CETS no. 186) and it is strongly needed to protect human's rights and freedoms of donors. According to the mentioned articles, the commercialization is not: a compensation of losses of earnings and having additional expenditures by the living donors who acted for the recipients; a fee for medical services rendered in connection with transplantation; compensation of damage occurring as a resulting from the organs or tissues removal from living persons [160].

3. The Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being concerning Biomedical Research (CETS no. 195) emphasis in the article 3, that the interests and welfare of the human being participating in research is more important than the interest of society or science. The fundament of this assumption is acceptance of autonomy of an individual, who has got a inalienable right to undergo or an objection to undergo a medical examination. The Protocol emphasis, that all research undertaken, which can be undertaken only when there is no other method of comparable effectiveness, must protect rights of humans beings and cannot interfere their rights and dignity. Besides, every participant of a medical research, has a right to know the aim of the research, the experiment's schedule, and risks and benefits estimations[161].

[160] The Additional Protocol to the Convention on Human Rights and biomedicine, concerning transplantation of organs and tissues of human origin (CETS nr 186),European Parliament, Document available on website http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm, record from December, 2nd 2012.

[161] The Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being concerning Biomedical Research (CETS nr 195),
[w:] European Parliament, Document available on website
http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm, record from December, 2nd 2012.

4. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being concerning Genetic Testing for Health Purposes (CETS no. 203) states that, according to the present doubts and fears about the inappropriate use of genetic research, especially the information obtained in that way, the general rule should be respecting human dignity and avoiding all forms of discrimination, especially on the base of genetic features. The article 3 emphasis in the context of genetic test, the primacy of human being, stating that: "The interests and welfare of the human being participating in research shall prevail over the sole interest of society or science"[162].

Poland has signed the Convention on July 5th, 1999. The real works on the contents included in the act were officially undertaken since April 7, 2008, as a result of the decision of the Prime Minister, who established The Team for Bioethics Convention. This Team's works took place between April 24 and June 9th, 2008. The result of the discussion was a report published on 28 October 2008, presenting a starting material for further discussion and work in parliament.

Within mention report, the members of the Team for the Bioethics Convention unanimously recommended:

1. The necessity of changes in Polish law, concerning protection of people unable to give their consent for medical intervention;

2. The necessity of forming in Polish system a law giving a possibility of prior expression of the will to abandonment of any aggressive medical treatment or therapy extending life of terminally ill patient against their will ("a testament of life", the institution of authorized representative to give a replacement consent) in the situation of a lack of such ability in the patient;

3. The requirement to create a framework for the cloning, the use of genetic engineering, and the status and protection of the embryo, gamete donation and assisted reproduction;

4. The requirement to undertake works upon and novelization of Transplantation Law;

5. The necessity of forming "a body initiating a debate on ethical, law and economic and social conditions of development of biomedicine and biotechnology (first called the Polish

[162] Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being concerning Genetic Testing for Health Purposes (CETS nr 203), [w:] European Parliament, Document available on website http://conventions.coe.int/Treaty/en/Treaties/Html/203.htm, record from December, 2nd 2012.

Bioethical Council). The Council should assure the knowledge and evaluation from the area of biomedicine and biotechnology for the government authorities, create reports and recommendations, initiate and review legislation in this area, present analysis of the results of its' implementation, formulate the standards and recommendations (good practice) in the area of scientific research from biomedicine and biotechnology, and representing Polish position in international bioethical debates[163].

The alternative recommendations were dealing with necessity of applying law regulations in such matters as: assisted procreation and activity and control of selected (licensed) centers in this range, the prohibition of forming humans embryos for medical research purposes, the prohibition interference into reproductive cells, the prohibition of trading human embryos and gametes, and the introduction of legal sanctions associated with the prohibitions set forth.

The Team has not managed to work out common and specific recommendations problems concerning: assisted fertilization and allogeneic donation, the possibility to create supernumerary embryos and pre-implantation genetic diagnosis.

In a letter dated on November, 12th, 2010, being a response of the Ministry of Justice to the position of the Helsinki Foundation for Human Rights concerning the position of polish government on the ratification of the Convention and overworking needed acts of law in the subject of bioethical problems defining the basic standards concerning the above issue. The Ministry of Justice has shown the reason of such situation in existence of significant differences between the requirements of the Convention and the state of Polish law. The Ministry has also stressed that because of the necessity to refine bioethical standards, which The Convention refers to and all controversy present in the public debate concerning this subject. This controversy builds a need to carry on a public debate on this subject and obtaining the position of society. Because of that, according to the Ministry of Justice, it is impossible to even approximately schedule the date of ratification of this Convention.

The Committee of Bioethics of the PAS (Polish Academy of Sciences) has also presented its position on the subject of necessity of public debate concerning documents requiring ratification, on the November, 17th, 2011. The Committee has appealed for a ratification of the

[163] The report of the of the Team for the Bioethics Convention, Office of the Prime Minister. Team for Bioethics Convention, Document available on website: http://www.federa.org.pl/dokumenty_pdf/invitro/Raport_bioetyka_11.2008.pdf, record from December, 16th, 2012.

Convention as soon as possible and pointed to lack of detailed legislation in the range of determining of human genome, the accurate guarantee of patients' rights protection, genetic counseling and prenatal care, reimplementation screening and prognostic tests.

A similar intention was present in the activity undertaken by the Ombudsman for Citizen Rights, who in a letter dated on August, 7th, 2012, asked for clarification on the position of the Government on the ratification of the Convention, the current status of work on the adaptation of Polish law and the calendar established by legislative action in this area . The Ombudsman pointed out that, in His opinion, there is an urgent need for decisive action to identify and implement "appropriate measures, both at the legislative level and in the field of medical practice and research"[164].

[164] Statement of the Ombudsman to the Prime Minister on the ratification of the European Convention on Bioethics from 7 August 2012, Document available on website: , http://www.sprawy-generalne.brpo.gov.pl/pdf/2008/01/577511/1662753.pdf, record from December, 16th, 2012 .

Chapter 5. European Bioethics Convention and Additional Protocols

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5.1. Convention the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine

The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

Preamble

The member States of the Council of Europe, the other States and the European Community, signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the European Social Charter of 18 October 1961;

Bearing in mind the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights of 16 December 1966;

Bearing in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing also in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine,

Have agreed as follows:

Chapter I – General provisions

Article 1 – Purpose and object

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.
Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

Article 2 – Primacy of the human being

The interests and welfare of the human being shall prevail over the sole interest of society or science.

Article 3 – Equitable access to health care

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

Article 4 – Professional standards

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

Chapter II – Consent

Article 5 – General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

Article 6 – Protection of persons not able to consent

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.
2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.
3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorisation procedure.
4. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 5.
5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

Article 7 – Protection of persons who have a mental disorder

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

Article 8 – Emergency situation

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 9 – Previously expressed wishes

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

Chapter III – Private life and right to information

Article 10 – Private life and right to information

1. Everyone has the right to respect for private life in relation to information about his or her health.
2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.
3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

Chapter IV – Human genome

Article 11 – Non-discrimination

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

Article 12 – Predictive genetic tests

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

Article 13 – Interventions on the human genome

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

Article 14 – Non-selection of sex

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

Chapter V – Scientific research

Article 15 – General rule

Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.

Article 16 – Protection of persons undergoing research

Research on a person may only be undertaken if all the following conditions are met:

i. there is no alternative of comparable effectiveness to research on humans;

ii. the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;

iii. the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;

iv. the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;

v. the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Article 17 – Protection of persons not able to consent to research

1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:

   i. the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled;

   ii. the results of the research have the potential to produce real and direct benefit to his or her health;

   iii. research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

iv. the necessary authorisation provided for under Article 6 has been given specifically and in writing; and

v. the person concerned does not object.

2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:

i. the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition;

ii. the research entails only minimal risk and minimal burden for the individual concerned.

Article 18 – Research on embryos *in vitro*

1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.

2. The creation of human embryos for research purposes is prohibited.

Chapter VI – Organ and tissue removal from living donors for transplantation purposes

Article 19 – General rule

1. Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

2. The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.

Article 20 – Protection of persons not able to consent to organ removal

1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.

2. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:

   i. there is no compatible donor available who has the capacity to consent;

   ii. the recipient is a brother or sister of the donor;

   iii. the donation must have the potential to be life-saving for the recipient;

   iv. the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the competent body;

   v. the potential donor concerned does not object.

Chapter VII – Prohibition of financial gain and disposal of a part of the human body

Article 21 – Prohibition of financial gain

The human body and its parts shall not, as such, give rise to financial gain.

Article 22 – Disposal of a removed part of the human body

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

Chapter VIII – Infringements of the provisions of the Convention

Article 23 – Infringement of the rights or principles

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Article 24 – Compensation for undue damage

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 25 – Sanctions

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

Chapter IX – Relation between this Convention and other provisions

Article 26 – Restrictions on the exercise of the rights

1. No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.
2. The restrictions contemplated in the preceding paragraph may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21.

Article 27 – Wider protection

None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention.

Chapter X – Public debate

Article 28 – Public debate

Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

Chapter XI – Interpretation and follow-up of the Convention

Article 29 – Interpretation of the Convention

The European Court of Human Rights may give, without direct reference to any specific proceedings pending in a court, advisory opinions on legal questions concerning the interpretation of the present Convention at the request of:

1. the Government of a Party, after having informed the other Parties;
2. the Committee set up by Article 32, with membership restricted to the Representatives of the Parties to this Convention, by a decision adopted by a two-thirds majority of votes cast.

Article 30 – Reports on the application of the Convention

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

Chapter XII – Protocols

Article 31 – Protocols

Protocols may be concluded in pursuance of Article 32, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying accepting or approving the Convention.

Chapter XIII – Amendments to the Convention

Article 32 – Amendments to the Convention

1. The tasks assigned to "the Committee" in the present article and in Article 29 shall be carried out by the Steering Committee on Bioethics (CDBI), or by any other committee designated to do so by the Committee of Ministers.
2. Without prejudice to the specific provisions of Article 29, each member State of the Council of Europe, as well as each Party to the present Convention which is not a member of the Council of Europe, may be represented and have one vote in the Committee when the Committee carries out the tasks assigned to it by the present Convention.
3. Any State referred to in Article 33 or invited to accede to the Convention in accordance with the provisions of Article 34 which is not Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.
4. In order to monitor scientific developments, the present Convention shall be examined within the Committee no later than five years from its entry into force and thereafter at such intervals as the Committee may determine.
5. Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, to the European Community, to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 33 and to any State invited to accede to it in accordance with the provisions of Article 34.
6. The Committee shall examine the proposal not earlier than two months after it has been forwarded by the Secretary General in accordance with paragraph 5. The Committee shall submit the text adopted by a two-thirds majority of the votes cast to the Committee of

Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

7. Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.
   In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

Chapter XIV – Final clauses

Article 33 – Signature, ratification and entry into force

1. This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration and by the European Community.
2. This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.
3. This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present article.
4. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 34 – Non-member States

1. After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, paragraph d, of the Statute of the Council of Europe, and by the unanimous

vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2. In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 35 – Territories

1. Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.
2. Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.
3. Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 36 – Reservations

1. Any State and the European Community may, when signing this Convention or when depositing the instrument of ratification, acceptance, approval or accession, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article.
2. Any reservation made under this article shall contain a brief statement of the relevant law.
3. Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 35, paragraph 2, may, in respect of the territory

concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4. Any Party which has made the reservation mentioned in this article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 37 – Denunciation

1. Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.
2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 38 – Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council, the European Community, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

1. any signature;
2. the deposit of any instrument of ratification, acceptance, approval or accession;
3. any date of entry into force of this Convention in accordance with Articles 33 or 34;
4. any amendment or Protocol adopted in accordance with Article 32, and the date on which such an amendment or Protocol enters into force;
5. any declaration made under the provisions of Article 35;
6. any reservation and withdrawal of reservation made in pursuance of the provisions of Article 36;
7. any other act, notification or communication relating to this Convention.
8. In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at Oviedo (Asturias), this 4th day of April 1997, in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each

member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.

5.2. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings.

The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

The member States of the Council of Europe, the other States and the European Community Signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine,

Noting scientific developments in the field of mammal cloning, particularly through embryo splitting and nuclear transfer;

Mindful of the progress that some cloning techniques themselves may bring to scientific knowledge and its medical application;

Considering that the cloning of human beings may become a technical possibility;

Having noted that embryo splitting may occur naturally and sometimes result in the birth of genetically identical twins;

Considering however that the instrumentalisation of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine;

Considering also the serious difficulties of a medical, psychological and social nature that such a deliberate biomedical practice might imply for all the individuals involved;

Considering the purpose of the Convention on Human Rights and Biomedicine, in particular the principle mentioned in Article 1 aiming to protect the dignity and identity of all human beings,

Have agreed as follows:

Article 1

1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
2. For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set.

Article 2

No derogation from the provisions of this Protocol shall be made under Article 26, paragraph 1, of the Convention.

Article 3

As between the Parties, the provisions of Articles 1 and 2 of this Protocol shall be regarded as additional articles to the Convention and all the provisions of the Convention shall apply accordingly.

Article 4

This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 5

1. This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 4.
2. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 6

1. After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.
2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 7

1. Any Party may at any time denounce this Protocol by means of a notification addressed to the Secretary General of the Council of Europe.
2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 8

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the Convention of:

1. any signature;
2. the deposit of any instrument of ratification, acceptance, approval or accession;
3. any date of entry into force of this Protocol in accordance with Articles 5 and 6;
4. any other act, notification or communication relating to this Protocol.

In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol.

Done at Paris, this twelfth day of January 1998, in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Protocol, to any State invited to accede to the Convention and to the European Community.

5.3. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research.

The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

Preamble

The member States of the Council of Europe, the other States and the European Community signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereinafter referred to as "Convention on Human Rights and Biomedicine"),

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Considering that the aim of the Convention on Human Rights and Biomedicine, as defined in Article 1, is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine;

Considering that progress in medical science, in particular in the field of organ and tissue transplantation, contributes to saving lives or greatly improving their quality;

Considering that transplantation of organs and tissues is an established part of the health services offered to the population;

Considering that, in view of the shortage of organs and tissues, appropriate action should be taken to increase organ and tissue donation, in particular by informing the public of the importance of organ and tissue transplantation and by promoting European co-operation in this field;

Considering moreover the ethical, psychological and socio-cultural problems inherent in the transplantation of organs and tissues;

Considering that the misuse of organ and tissue transplantation may lead to acts endangering human life, well being or dignity;

Considering that organ and tissue transplantation should take place under conditions protecting the rights and freedoms of donors, potential donors and recipients of organs and tissues and that institutions must be instrumental in ensuring such conditions;

Recognising that, in facilitating the transplantation of organs and tissues in the interest of patients in Europe, there is a need to protect individual rights and freedoms and to prevent the commercialisation of parts of the human body involved in organ and tissue procurement, exchange and allocation activities;

Taking into account previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Resolving to take such measures as are necessary to safeguard human dignity and the rights and fundamental freedoms of the individual with regard to organ and tissue transplantation,

Have agreed as follows:

Chapter I – Object and scope

Article 1 – Object

Parties to this Protocol shall protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to transplantation of organs and tissues of human origin.

Article 2 – Scope and definitions

1 This Protocol applies to the transplantation of organs and tissues of human origin carried out for therapeutic purposes.

2 The provisions of this Protocol applicable to tissues shall apply also to cells, including haematopoietic stem cells.

3 The Protocol does not apply:

a to reproductive organs and tissue;

b to embryonic or foetal organs and tissues;

c to blood and blood derivatives.

4 For the purposes of this Protocol:

– the term "*transplantation*" covers the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all procedures for preparation, preservation and storage;

– subject to the provisions of Article 20, the term "*removal*" refers to removal for the purposes of implantation.

Chapter II – General provisions

Article 3 – Transplantation system

1. Parties shall guarantee that a system exists to provide equitable access to transplantation services for patients.
2. Subject to the provisions of Chapter III, organs and, where appropriate, tissues shall be allocated only among patients on an official waiting list, in conformity with transparent, objective and duly justified rules according to medical criteria. The persons or bodies responsible for the allocation decision shall be designated within this framework.
3. In case of international organ exchange arrangements, the procedures must also ensure justified, effective distribution across the participating countries in a manner that takes into account the solidarity principle within each country.
4. The transplantation system shall ensure the collection and recording of the information required to ensure traceability of organs and tissues.

Article 4 – Professional standards

Any intervention in the field of organ or tissue transplantation must be carried out in accordance with relevant professional obligations and standards.

Article 5 – Information for the recipient

The recipient and, where appropriate, the person or body providing authorisation for the implantation shall beforehand be given appropriate information as to the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention.

Article 6 – Health and safety

All professionals involved in organ or tissue transplantation shall take all reasonable measures to minimise the risks of transmission of any disease to the recipient and to avoid any action which might affect the suitability of an organ or tissue for implantation.

Article 7 – Medical follow-up

Appropriate medical follow-up shall be offered to living donors and recipients after transplantation.

Article 8 – Information for health professionals and the public

Parties shall provide information for health professionals and for the public in general on the need for organs and tissues. They shall also provide information on the conditions relating to removal and implantation of organs and tissues, including matters relating to consent or authorisation, in particular with regard to removal from deceased persons.

Chapter III – Organ and tissue removal from living persons

Article 9 – General rule

Removal of organs or tissue from a living person may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

Article 10 – Potential organ donors

Organ removal from a living donor may be carried out for the benefit of a recipient with whom the donor has a close personal relationship as defined by law, or, in the absence of such relationship, only under the conditions defined by law and with the approval of an appropriate independent body.

Article 11 – Evaluation of risks for the donor

1. Before organ or tissue removal, appropriate medical investigations and interventions shall be carried out to evaluate and reduce physical and psychological risks to the health of the donor.
2. The removal may not be carried out if there is a serious risk to the life or health of the donor.

Article 12 – Information for the donor

1. The donor and, where appropriate, the person or body providing authorisation according to Article 14, paragraph 2, of this Protocol, shall beforehand be given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks.
2. They shall also be informed of the rights and the safeguards prescribed by law for the protection of the donor. In particular, they shall be informed of the right to have access to independent advice about such risks by a health professional having appropriate experience and who is not involved in the organ or tissue removal or subsequent transplantation procedures.

Article 13 – Consent of the living donor

1. Subject to Articles 14 and 15 of this Protocol, an organ or tissue may be removed from a living donor only after the person concerned has given free, informed and specific consent to it either in written form or before an official body.
2. The person concerned may freely withdraw consent at any time.

Article 14 – Protection of persons not able to consent to organ or tissue removal

1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 13 of this Protocol.

2. Exceptionally, and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:

i there is no compatible donor available who has the capacity to consent;

ii the recipient is a brother or sister of the donor;

iii the donation has the potential to be life-saving for the recipient;

iv the authorisation of his or her representative or an authority or a person or body provided for by law has been given specifically and in writing and with the approval of the competent body;

v the potential donor concerned does not object.

Article 15 – Cell removal from a living donor

The law may provide that the provisions of Article 14, paragraph 2, indents ii and iii, shall not apply to cells insofar as it is established that their removal only implies minimal risk and minimal burden for the donor.

Chapter IV – Organ and tissue removal from deceased persons

Article 16 – Certification of death

1. Organs or tissues shall not be removed from the body of a deceased person unless that person has been certified dead in accordance with the law.
2. The doctors certifying the death of a person shall not be the same doctors who participate directly in removal of organs or tissues from the deceased person, or subsequent transplantation procedures, or having responsibilities for the care of potential organ or tissue recipients.

Article 17 – Consent and authorisation

1. Organs or tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained.

2. The removal shall not be carried out if the deceased person had objected to it.

Article 18 – Respect for the human body

During removal the human body must be treated with respect and all reasonable measures shall be taken to restore the appearance of the corpse.

Article 19 – Promotion of donation

Parties shall take all appropriate measures to promote the donation of organs and tissues.

Chapter V – Implantation of an organ or tissue removed for a purpose other than donation for implantation

Article 20 – Implantation of an organ or tissue removed for a purpose other than donation for implantation

1 When an organ or tissue is removed from a person for a purpose other than donation for implantation, it may only be implanted if the consequences and possible risks have been explained to that person and his/her informed consent, or appropriate authorisation in the case of a person not able to consent, has been obtained .

2 All the provisions of this Protocol apply to the situations referred to in paragraph 1, except for those in Chapter III and IV.

Chapter VI – Prohibition of financial gain

Article 21 – Prohibition of financial gain

1. The human body and its parts shall not, as such, give rise to financial gain or comparable advantage.

The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular:

– compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations;

– payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;

– compensation in case of undue damage resulting from the removal of organs or tissues from living persons.

2. Advertising the need for, or availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage, shall be prohibited.

Article 22 – Prohibition of organ and tissue trafficking

Organ and tissue trafficking shall be prohibited.

Chapter VII – Confidentiality

Article 23 – Confidentiality

1 All personal data relating to the person from whom organs or tissues have been removed and those relating to the recipient shall be considered to be confidential. Such data may only be collected, processed and communicated according to the rules relating to professional confidentiality and personal data protection.

2 The provisions of paragraph 1 shall be interpreted without prejudice to the provisions making possible, subject to appropriate safeguards, the collection, processing and communication of the necessary information about the person from whom organs or tissues have been removed or the recipient(s) of organs and tissues in so far as this is required for medical purposes, including traceability, as provided for in Article 3 of this Protocol.

Chapter VIII – Infringements of the provisions of the Protocol

Article 24 – Infringements of rights or principles

Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Protocol at short notice.

Article 25 – Compensation for undue damage

The person who has suffered undue damage resulting from transplantation procedures is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 26 – Sanctions

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Protocol.

Chapter IX – Co-operation between Parties

Article 27 – Co-operation between Parties

1. Parties shall take appropriate measures to ensure that there is efficient co-operation between them on organ and tissue transplantation, *inter alia* through information exchange.

2. In particular, they shall undertake appropriate measures to facilitate the rapid and safe transportation of organs and tissues to and from their territory.

Chapter X – Relation between this Protocol and the Convention, and re-examination of the Protocol

Article 28 – Relation between this Protocol and the Convention

As between the Parties, the provisions of Articles 1 to 27 of this Protocol shall be regarded as additional articles to the Convention on Human Rights and Biomedicine, and all the provisions of that Convention shall apply accordingly.

Article 29 – Re-examination of the Protocol

In order to monitor scientific developments, the present Protocol shall be examined within the Committee referred to in Article 32 of the Convention on Human Rights and Biomedicine no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

Chapter XI – Final clauses

Article 30 – Signature and ratification

This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 31 – Entry into force

1 This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 30.

2 In respect of any signatory which subsequently expresses its consent to be bound by it, the Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 32 – Accession

1 After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.

2 Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 33 – Denunciation

1 Any Party may at any time denounce this Protocol by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 34 – Notification

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the Convention of:

a any signature;

b the deposit of any instrument of ratification, acceptance, approval or accession;

c any date of entry into force of this Protocol in accordance with Articles 31 and 32;

d any other act, notification or communication relating to this Protocol.

In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol.

Done at Strasbourg, this 24th day of January 2002, in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Protocol, to any State invited to accede to the Convention and to the European Community.

5.4. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research.

The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

Preamble

The member States of the Council of Europe, the other States and the European Community signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereinafter referred to as "the Convention"),

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Considering that the aim of the Convention, as defined in Article 1, is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine;

Considering that progress in medical and biological sciences, in particular advances obtained through biomedical research, contributes to saving lives and improving quality of life;

Conscious of the fact that the advancement of biomedical science and practice is dependent on knowledge and discovery which necessitates research on human beings;

Stressing that such research is often transdisciplinary and international;

Taking into account national and international professional standards in the field of biomedical research and the previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Convinced that biomedical research that is contrary to human dignity and human rights should never be carried out;

Stressing the paramount concern to be the protection of the human being participating in research;

Affirming that particular protection shall be given to human beings who may be vulnerable in the context of research;

Recognising that every person has a right to accept or refuse to undergo biomedical research and that no one should be forced to undergo such research;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to biomedical research,

Have agreed as follows:

Chapter I – Object and scope

Article 1 – Object and purpose

Parties to this Protocol shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to any research involving interventions on human beings in the field of biomedicine.

Article 2 – Scope

1. This Protocol covers the full range of research activities in the health field involving interventions on human beings.

2. This Protocol does not apply to research on embryos *in vitro*. It does apply to research on foetuses and embryos *in vivo*.

3. For the purposes of this Protocol, the term “intervention” includes:

i. a physical intervention, and

ii. any other intervention in so far as it involves a risk to the psychological health of the person concerned.

Chapter II – General provisions

Article 3 – Primacy of the human being

The interests and welfare of the human being participating in research shall prevail over the sole interest of society or science.

Article 4 – General rule

Research shall be carried out freely, subject to the provisions of this Protocol and the other legal provisions ensuring the protection of the human being.

Article 5 – Absence of alternatives

Research on human beings may only be undertaken if there is no alternative of comparable effectiveness.

Article 6 – Risks and benefits

1. Research shall not involve risks and burdens to the human being disproportionate to its potential benefits.

2. In addition, where the research does not have the potential to produce results of direct benefit to the health of the research participant, such research may only be undertaken if the research entails no more than acceptable risk and acceptable burden for the research participant. This shall be without prejudice to the provision contained in Article 15 paragraph 2, sub-paragraph ii for the protection of persons not able to consent to research.

Article 7 – Approval

Research may only be undertaken if the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of research, and multidisciplinary review of its ethical acceptability.

Article 8 – Scientific quality

Any research must be scientifically justified, meet generally accepted criteria of scientific quality and be carried out in accordance with relevant professional obligations and standards under the supervision of an appropriately qualified researcher.

Chapter III – Ethics committee

Article 9 – Independent examination by an ethics committee

1. Every research project shall be submitted for independent examination of its ethical acceptability to an ethics committee. Such projects shall be submitted to independent examination in each State in which any research activity is to take place.

2. The purpose of the multidisciplinary examination of the ethical acceptability of the research project shall be to protect the dignity, rights, safety and well-being of research participants. The assessment of the ethical acceptability shall draw on an appropriate range of expertise and experience adequately reflecting professional and lay views.

3. The ethics committee shall produce an opinion containing reasons for its conclusion.

Article 10 – Independence of the ethics committee

1. Parties to this Protocol shall take measures to assure the independence of the ethics committee. That body shall not be subject to undue external influences.

2. Members of the ethics committee shall declare all circumstances that might lead to a conflict of interest. Should such conflicts arise, those involved shall not participate in that review.

Article 11 – Information for the ethics committee

1. All information which is necessary for the ethical assessment of the research project shall be given in written form to the ethics committee.

2. In particular, information on items contained in the appendix to this Protocol shall be provided, in so far as it is relevant for the research project. The appendix may be amended by the Committee set up by Article 32 of the Convention by a two-thirds majority of the votes cast.

Article 12 – Undue influence

The ethics committee must be satisfied that no undue influence, including that of a financial nature, will be exerted on persons to participate in research. In this respect, particular attention must be given to vulnerable or dependent persons.

Chapter IV – Information and consent

Article 13 – Information for research participants

1. The persons being asked to participate in a research project shall be given adequate information in a comprehensible form. This information shall be documented.

2. The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee. Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research:

i. of the nature, extent and duration of the procedures involved, in particular, details of any burden imposed by the research project;

ii. of available preventive, diagnostic and therapeutic procedures;

iii. of the arrangements for responding to adverse events or the concerns of research participants;

iv. of arrangements to ensure respect for private life and ensure the confidentiality of personal data;

v. of arrangements for access to information relevant to the participant arising from the research and to its overall results;

vi. of the arrangements for fair compensation in the case of damage;

vii. of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials;

viii. of the source of funding of the research project.

3. In addition, the persons being asked to participate in a research project shall be informed of the rights and safeguards prescribed by law for their protection, and specifically of their right to refuse consent or to withdraw consent at any time without being subject to any form of discrimination, in particular regarding the right to medical care.

Article 14 – Consent

1. No research on a person may be carried out, subject to the provisions of both Chapter V and Article 19, without the informed, free, express, specific and documented consent of the person. Such consent may be freely withdrawn by the person at any phase of the research.

2. Refusal to give consent or the withdrawal of consent to participation in research shall not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.

3. Where the capacity of the person to give informed consent is in doubt, arrangements shall be in place to verify whether or not the person has such capacity.

Chapter V – Protection of persons not able to consent to research

Article 15 – Protection of persons not able to consent to research

1. Research on a person without the capacity to consent to research may be undertaken only if all the following specific conditions are met:

i. the results of the research have the potential to produce real and direct benefit to his or her health;

ii. research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

iii. the person undergoing research has been informed of his or her rights and the safeguards prescribed by law for his or her protection, unless this person is not in a state to receive the information;

iv. the necessary authorisation has been given specifically and in writing by the legal representative or an authority, person or body provided for by law, and after having received the information required by Article 16, taking into account the person’s previously expressed

wishes or objections. An adult not able to consent shall as far as possible take part in the authorisation procedure. The opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity;

v. the person concerned does not object.

2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs ii, iii, iv, and v above, and to the following additional conditions:

i. the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition;

ii. the research entails only minimal risk and minimal burden for the individual concerned; and any consideration of additional potential benefits of the research shall not be used to justify an increased level of risk or burden.

3. Objection to participation, refusal to give authorisation or the withdrawal of authorisation to participate in research shall not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.

Article 16 – Information prior to authorisation

1. Those being asked to authorise participation of a person in a research project shall be given adequate information in a comprehensible form. This information shall be documented.

2. The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee. They shall further be informed of the rights and safeguards prescribed by law for the protection of those not able to consent to research and specifically of the right to refuse or to withdraw authorisation at any time, without the person concerned being subject to any form of discrimination, in particular regarding the right to medical care. They shall be specifically informed according to the nature and purpose of the research of the items of information listed in Article 13.

3. The information shall also be provided to the individual concerned, unless this person is not in a state to receive the information.

Article 17 – Research with minimal risk and minimal burden

1. For the purposes of this Protocol it is deemed that the research bears a minimal risk if, having regard to the nature and scale of the intervention, it is to be expected that it will result, at the most, in a very slight and temporary negative impact on the health of the person concerned.

2. It is deemed that it bears a minimal burden if it is to be expected that the discomfort will be, at the most, temporary and very slight for the person concerned. In assessing the burden for an individual, a person enjoying the special confidence of the person concerned shall assess the burden where appropriate.

Chapter VI – Specific situations

Article 18 – Research during pregnancy or breastfeeding

1. Research on a pregnant woman which does not have the potential to produce results of direct benefit to her health, or to that of her embryo, foetus or child after birth, may only be undertaken if the following additional conditions are met:

i. the research has the aim of contributing to the ultimate attainment of results capable of conferring benefit to other women in relation to reproduction or to other embryos, foetuses or children;

ii. research of comparable effectiveness cannot be carried out on women who are not pregnant;

iii. the research entails only minimal risk and minimal burden.

2. Where research is undertaken on a breastfeeding woman, particular care shall be taken to avoid any adverse impact on the health of the child.

Article 19 – Research on persons in emergency clinical situations

1. The law shall determine whether, and under which protective additional conditions, research in emergency situations may take place when:

i. a person is not in a state to give consent, and

ii. because of the urgency of the situation, it is impossible to obtain in a sufficiently timely manner, authorisation from his or her representative or an authority or a person or body which would in the absence of an emergency situation be called upon to give authorisation.

2. The law shall include the following specific conditions:

i. research of comparable effectiveness cannot be carried out on persons in non-emergency situations;

ii. the research project may only be undertaken if it has been approved specifically for emergency situations by the competent body;

iii. any relevant previously expressed objections of the person known to the researcher shall be respected;

iv. where the research has not the potential to produce results of direct benefit to the health of the person concerned, it has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same category or afflicted with the same disease or disorder or having the same condition, and entails only minimal risk and minimal burden.

3. Persons participating in the emergency research project or, if applicable, their representatives shall be provided with all the relevant information concerning their participation in the research project as soon as possible. Consent or authorisation for continued participation shall be requested as soon as reasonably possible.

Article 20 – Research on persons deprived of liberty

Where the law allows research on persons deprived of liberty, such persons may participate in a research project in which the results do not have the potential to produce direct benefit to their health only if the following additional conditions are met:

i. research of comparable effectiveness cannot be carried out without the participation of persons deprived of liberty;

ii. the research has the aim of contributing to the ultimate attainment of results capable of conferring benefit to persons deprived of liberty;

iii. the research entails only minimal risk and minimal burden.

Chapter VII – Safety and supervision

Article 21 – Minimisation of risk and burden

1. All reasonable measures shall be taken to ensure safety and to minimise risk and burden for the research participants.

2. Research may only be carried out under the supervision of a clinical professional who possesses the necessary qualifications and experience.

Article 22 – Assessment of health status

1. The researcher shall take all necessary steps to assess the state of health of human beings prior to their inclusion in research, to ensure that those at increased risk in relation to participation in a specific project be excluded.

2. Where research is undertaken on persons in the reproductive stage of their lives, particular consideration shall be given to the possible adverse impact on a current or future pregnancy and the health of an embryo, foetus or child.

Article 23 – Non-interference with necessary clinical interventions

1. Research shall not delay nor deprive participants of medically necessary preventive, diagnostic or therapeutic procedures.

2. In research associated with prevention, diagnosis or treatment, participants assigned to control groups shall be assured of proven methods of prevention, diagnosis or treatment.

3. The use of placebo is permissible where there are no methods of proven effectiveness, or where withdrawal or withholding of such methods does not present an unacceptable risk or burden.

Article 24 – New developments

1. Parties to this Protocol shall take measures to ensure that the research project is re-examined if this is justified in the light of scientific developments or events arising in the course of the research.

2. The purpose of the re-examination is to establish whether:

i. the research needs to be discontinued or if changes to the research project are necessary for the research to continue;

ii. research participants, or if applicable their representatives, need to be informed of the developments or events;

iii. additional consent or authorisation for participation is required.

3. Any new information relevant to their participation shall be conveyed to the research participants, or, if applicable, to their representatives, in a timely manner.

4. The competent body shall be informed of the reasons for any premature termination of a research project.

Chapter VIII – Confidentiality and right to information

Article 25 – Confidentiality

1. Any information of a personal nature collected during biomedical research shall be considered as confidential and treated according to the rules relating to the protection of private life.

2. The law shall protect against inappropriate disclosure of any other information related to a research project that has been submitted to an ethics committee in compliance with this Protocol.

Article 26 – Right to information

1. Research participants shall be entitled to know any information collected on their health in conformity with the provisions of Article 10 of the Convention.

2. Other personal information collected for a research project will be accessible to them in conformity with the law on the protection of individuals with regard to processing of personal data.

Article 27 – Duty of care

If research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them. That shall be done within a framework of health care or counselling. In communication of such information, due care must be taken in order to protect confidentiality and to respect any wish of a participant not to receive such information.

Article 28 – Availability of results

1. On completion of the research, a report or summary shall be submitted to the ethics committee or the competent body.

2. The conclusions of the research shall be made available to participants in reasonable time, on request.

3. The researcher shall take appropriate measures to make public the results of research in reasonable time.

Chapter IX – Research in States not parties to this Protocol

Article 29 – Research in States not parties to this Protocol

Sponsors or researchers within the jurisdiction of a Party to this Protocol that plan to undertake or direct a research project in a State not party to this Protocol shall ensure that, without prejudice to the provisions applicable in that State, the research project complies with the principles on which the provisions of this Protocol are based. Where necessary, the Party shall take appropriate measures to that end.

Chapter X – Infringement of the provisions of the Protocol

Article 30 – Infringement of the rights or principles

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights or principles set forth in this Protocol at short notice.

Article 31 – Compensation for damage

The person who has suffered damage as a result of participation in research shall be entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 32 – Sanctions

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Protocol.

Chapter XI – Relation between this Protocol and other provisions and re-examination of the Protocol

Article 33 – Relation between this Protocol and the Convention

As between the Parties, the provisions of Articles 1 to 32 of this Protocol shall be regarded as additional articles to the Convention, and all the provisions of the Convention shall apply accordingly.

Article 34 – Wider protection

None of the provisions of this Protocol shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant research participants a wider measure of protection than is stipulated in this Protocol.

Article 35 – Re-examination of the Protocol

In order to monitor scientific developments, the present Protocol shall be examined within the Committee referred to in Article 32 of the Convention no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

Chapter XII – Final clauses

Article 36 – Signature and ratification

This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 37 – Entry into force

1. This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 36.

2. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 38 – Accession

1. After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.

2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 39 – Denunciation

1. Any Party may at any time denounce this Protocol by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 40 – Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the Protocol of:

a. any signature;

b. the deposit of any instrument of ratification, acceptance, approval or accession;

c. any date of entry into force of this Protocol in accordance with Articles 37 and 38;

d. any other act, notification or communication relating to this Protocol.

In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol.

Done at Strasbourg, this 25th day of January 2005, in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Protocol, to any State invited to accede to the Convention and to the European Community.

Appendix

Information to be given to the ethics committee

Information on the following items shall be provided to the ethics committee, in so far as it is relevant for the research project:

Description of the project

i. the name of the principal researcher, qualifications and experience of researchers and, where appropriate, the clinically responsible person, and funding arrangements;

ii. the aim and justification for the research based on the latest state of scientific knowledge;

iii. methods and procedures envisaged, including statistical and other analytical techniques;

iv. a comprehensive summary of the research project in lay language;

v. a statement of previous and concurrent submissions of the research project for assessment or approval and the outcome of those submissions;

Participants, consent and information

vi. justification for involving human beings in the research project;

vii. the criteria for inclusion or exclusion of the categories of persons for participation in the research project and how those persons are to be selected and recruited;

viii. reasons for the use or the absence of control groups;

ix. a description of the nature and degree of foreseeable risks that may be incurred through participating in research;

x. the nature, extent and duration of the interventions to be carried out on the research participants, and details of any burden imposed by the research project;

xi. arrangements to monitor, evaluate and react to contingencies that may have consequences for the present or future health of research participants;

xii. the timing and details of information for those persons who would participate in the research project and the means proposed for provision of this information;

xiii. documentation intended to be used to seek consent or, in the case of persons not able to consent, authorisation for participation in the research project;

xiv. arrangements to ensure respect for the private life of those persons who would participate in research and ensure the confidentiality of personal data;

xv. arrangements foreseen for information which may be generated and be relevant to the present or future health of those persons who would participate in research and their family members;

Other information

xvi. details of all payments and rewards to be made in the context of the research project;

xvii. details of all circumstances that might lead to conflicts of interest that may affect the independent judgement of the researchers;

xviii. details of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials;

xix. details of all other ethical issues, as perceived by the researcher;

xx. details of any insurance or indemnity to cover damage arising in the context of the research project.

The ethics committee may request additional information necessary for evaluation of the research project.

5.5.Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes.

The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

Preamble

The member States of the Council of Europe, the other States and the European Community, signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereinafter referred to as "the Convention on Human Rights and Biomedicine", ETS No. 164),

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Considering that the aim of the Convention on Human Rights and Biomedicine, as defined in Article 1, is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine;

Bearing in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108) of 28 January 1981;

Bearing in mind the work carried out by other intergovernmental organisations, in particular the Universal Declaration on the Human Genome and Human Rights, endorsed by the General Assembly of the United Nations on 9 December 1998;

Recalling that the human genome is shared by all human beings, thereby forming a mutual bond between them while slight variations contribute to the individuality of each human being;

Stressing the particular bond that exists between members of the same family;

Considering that progress in medical science can contribute to saving lives and improving their quality;

Acknowledging the benefit of genetics, in particular genetic testing, in the field of health;

Considering that genetic services in the field of health form an integral part of the health services offered to the population and recalling the importance of taking appropriate

measures, taking into account health needs and available resources, with a view to providing equitable access to genetic services of appropriate quality;

Aware also of the concerns that exist regarding possible improper use of genetic testing, in particular of the information generated thereby;

Reaffirming the fundamental principle of respect for human dignity and the prohibition of all forms of discrimination, in particular those based on genetic characteristics;

Taking into account national and international professional standards in the field of genetic services and the previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to genetic testing for health purposes,

Have agreed as follows:

Chapter I – Object and scope

Article 1 – Object and purpose

Parties to this Protocol shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the tests to which this Protocol applies in accordance with Article 2.

Article 2 – Scope

1. This Protocol applies to tests, which are carried out for health purposes, involving analysis of biological samples of human origin and aiming specifically to identify the genetic characteristics of a person which are inherited or acquired during early prenatal development (hereinafter referred to as “genetic tests”).

2. This Protocol does not apply:

a to genetic tests carried out on the human embryo or foetus;

b to genetic tests carried out for research purposes.

3. For the purposes of paragraph 1:

A. “analysis” refers to:

I chromosomal analysis,

II DNA or RNA analysis,

III analysis of any other element enabling information to be obtained which is equivalent to that obtained with the methods referred to in sub-paragraphs A..I. and A..II.;

B. “biological samples” refers to:

I. biological materials removed for the purpose of the test concerned,

II. biological materials previously removed for another purpose.

Chapter II – General provisions

Article 3 – Primacy of the human being

The interests and welfare of the human being concerned by genetic tests covered by this Protocol shall prevail over the sole interest of society or science.

Article 4 – Non-discrimination and non-stigmatisation

1 Any form of discrimination against a person, either as an individual or as a member of a group on grounds of his or her genetic heritage is prohibited.

2 Appropriate measures shall be taken in order to prevent stigmatisation of persons or groups in relation to genetic characteristics.

Chapter III – Genetic services

Article 5 – Quality of genetic services

Parties shall take the necessary measures to ensure that genetic services are of appropriate quality. In particular, they shall see to it that:

a genetic tests meet generally accepted criteria of scientific validity and clinical validity;

b a quality assurance programme is implemented in each laboratory and that laboratories are subject to regular monitoring;

c persons providing genetic services have appropriate qualifications to enable them to perform their role in accordance with professional obligations and standards.

Article 6 – Clinical utility

Clinical utility of a genetic test shall be an essential criterion for deciding to offer this test to a person or a group of persons.

Article 7 – Individualised supervision

1 A genetic test for health purposes may only be performed under individualised medical supervision.

2 Exceptions to the general rule referred to in paragraph 1 may be allowed by a Party, subject to appropriate measures being provided, taking into account the way the test will be carried out, to give effect to the other provisions of this Protocol.

However, such an exception may not be made with regard to genetic tests with important implications for the health of the persons concerned or members of their family or with important implications concerning procreation choices.

Chapter IV – Information, genetic counselling and consent

Article 8 – Information and genetic counselling

1. When a genetic test is envisaged, the person concerned shall be provided with prior appropriate information in particular on the purpose and the nature of the test, as well as the implications of its results.

2. For predictive genetic tests as referred to in Article 12 of the Convention on Human Rights and Biomedicine, appropriate genetic counselling shall also be available for the person concerned.

The tests concerned are:

– tests predictive of a monogenic disease,
– tests serving to detect a genetic predisposition or genetic susceptibility to a disease,
– tests serving to identify the subject as a healthy carrier of a gene responsible for a disease.

The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family, including possible implications concerning procreation choices.

Genetic counselling shall be given in a non-directive manner.

Article 9 – Consent

1. A genetic test may only be carried out after the person concerned has given free and informed consent to it.

Consent to tests referred to in Article 8, paragraph 2, shall be documented.

2. The person concerned may freely withdraw consent at any time.

Chapter V – Persons not able to consent

Article 10 – Protection of persons not able to consent

Subject to Article 13 of this Protocol, a genetic test on a person who does not have the capacity to consent may only be carried out for his or her direct benefit.

Where, according to law, a minor does not have the capacity to consent, a genetic test on this person shall be deferred until attainment of such capacity unless that delay would be detrimental to his or her health or well-being.

Article 11 – Information prior to authorisation, genetic counselling and support

1. When a genetic test is envisaged in respect of a person not able to consent, the person, authority or body whose authorisation is required shall be provided with prior appropriate information in particular with regard to the purpose and the nature of the test, as well as the implications of its results.

Appropriate prior information shall also be provided to the person not able to consent in respect of whom the test is envisaged, to the extent of his or her capacity to understand.

A qualified person shall be available to answer possible questions by the person, authority or body whose authorisation is required, and, if appropriate, the person in respect of whom the test is envisaged.

2. The provisions of Article 8, paragraph 2, shall apply in the case of persons not able to consent to the extent of their capacity to understand.

Where relevant, appropriate support shall be available for the person whose authorisation is required.

Article 12 – Authorisation

1. Where, according to law, a minor does not have the capacity to consent to a genetic test, that test may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

2. Where, according to law, an adult does not have the capacity to consent to a genetic test because of a mental disability, a disease or for similar reasons, that test may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

Wishes relating to a genetic test expressed previously by an adult at a time where he or she had capacity to consent shall be taken into account.

The individual concerned shall, to the extent of his or her capacity to understand, take part in the authorisation procedure.

3. Authorisation to tests referred to in Article 8, paragraph 2, shall be documented.

4. The authorisation referred to in paragraphs 1 and 2 above may be withdrawn at any time in the best interests of the person concerned.

Chapter VI – Tests for the benefit of family members

Article 13 – Tests on persons not able to consent

Exceptionally, and by derogation from the provisions of Article 6, paragraph 1, of the Convention on Human Rights and Biomedicine and of Article 10 of this Protocol, the law may allow a genetic test to be carried out, for the benefit of family members, on a person who does not have the capacity to consent, if the following conditions are met:

A. the purpose of the test is to allow the family member(s) concerned to obtain a preventive, diagnostic or therapeutic benefit that has been independently evaluated as important for their health, or to allow them to make an informed choice with respect to procreation;

B. the benefit envisaged cannot be obtained without carrying out this test;

C. the risk and burden of the intervention are minimal for the person who is undergoing the test;

D. the expected benefit has been independently evaluated as substantially outweighing the risk for private life that may arise from the collection, processing or communication of the results of the test;

E. the authorisation of the representative of the person not able to consent, or an authority or a person or body provided for by law has been given;

F. the person not able to consent shall, in proportion to his or her capacity to understand and degree of maturity, take part in the authorisation procedure. The test shall not be carried out if this person objects to it.

Article 14 – Tests on biological materials when it is not possible to contact the person concerned

When it is not possible, with reasonable efforts, to contact a person for a genetic test for the benefit of his or her family member(s) on his or her biological material previously removed for another purpose, the law may allow the test to be carried out in accordance with the principle of proportionality, where the expected benefit cannot be otherwise obtained and where the test cannot be deferred.

Provisions shall be made, in accordance with Article 22 of the Convention on Human Rights and Biomedicine, for the case where the person concerned has expressly opposed such test.

Article 15 – Tests on deceased persons

A genetic test for the benefit of other family members may be carried out on biological samples:

– removed from the body of a deceased person, or

– removed, when he or she was alive, from a person now deceased, only if the consent or authorisation required by law has been obtained.

Chapter VII – Private life and right to information

Article 16 – Respect for private life and right to information

1. Everyone has the right to respect for his or her private life, in particular to protection of his or her personal data derived from a genetic test.

2. Everyone undergoing a genetic test is entitled to know any information collected about his or her health derived from this test.

The conclusions drawn from the test shall be accessible to the person concerned in a comprehensible form.

3. The wish of a person not to be informed shall be respected.

4. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraphs 2 and 3 above in the interests of the person concerned.

Article 17 – Biological samples

Biological samples referred to in Article 2 shall only be used and stored in such conditions as to ensure their security and the confidentiality of the information which can be obtained therefrom.

Article 18 – Information relevant to family members

Where the results of a genetic test undertaken on a person can be relevant to the health of other family members, the person tested shall be informed.

Chapter VIII – Genetic screening programmes for health purposes

Article 19 – Genetic screening programmes for health purposes

A health screening programme involving the use of genetic tests may only be implemented if it has been approved by the competent body. This approval may only be given after independent evaluation of its ethical acceptability and fulfilment of the following specific conditions:

A. the programme is recognised for its health relevance for the whole population or section of population concerned;

B. the scientific validity and effectiveness of the programme have been established;

C. appropriate preventive or treatment measures in respect of the disease or disorder which is the subject of the screening, are available to the persons concerned;

D. appropriate measures are provided to ensure equitable access to the programme;

E. the programme provides measures to adequately inform the population or section of population concerned of the existence, purposes and means of accessing the screening programme as well as the voluntary nature of participation in it.

Chapter IX – Public information

Article 20 – Public information

Parties shall take appropriate measures to facilitate access for the public to objective general information on genetic tests, including their nature and the potential implications of their results.

Chapter X – Relation between this Protocol and other provisions and re-examination of the Protocol

Article 21 – Relation between this Protocol and the Convention

As between the Parties, the provisions of Articles 1 to 20 of this Protocol shall be regarded as additional articles to the Convention on Human Rights and Biomedicine, and all the provisions of the Convention shall apply accordingly.

Article 22 – Wider protection

None of the provisions of this Protocol shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant persons concerned by genetic testing for health purposes a

Article 23 – Re-examination of the Protocol wider measure of protection than is stipulated in this Protocol.

In order to monitor scientific developments, the present Protocol shall be examined within the Committee referred to in Article 32 of the Convention on Human Rights and Biomedicine no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

Chapter XI – Final clauses

Article 24 – Signature and ratification

This Protocol shall be open for signature by Signatories to the Convention on Human Rights and Biomedicine. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified,

accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 25 – Entry into force

1. This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 24.

2. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of the instrument of ratification, acceptance or approval.

Article 26 – Accession

1. After the entry into force of this Protocol, any State which has acceded to the Convention on Human Rights and Biomedicine may also accede to this Protocol.

2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 27 – Denunciation

1. Any Party may at any time denounce this Protocol by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 28 – Notification

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the Convention on Human Rights and Biomedicine of:

A. any signature;

B. the deposit of any instrument of ratification, acceptance, approval or accession;

C. any date of entry into force of this Protocol in accordance with Articles 25 and 26;

D. any other act, notification or communication relating to this Protocol.

In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol. Done at Strasbourg, this 27th day of November 2008, in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Protocol, to any State invited to accede to the Convention on Human Rights and Biomedicine and to the European Community.

5.6.The list of countries - signatories of the European Convention on Bioethics[165]

Member States of the Council of Europe	Signature	Ratification
Albania	30/3/2011	30/3/2011
Bosnia and Herzegovina	16/12/2005	11/5/2007
Bulgaria	31/5/2001	23/4/2003
Croatia	7/5/1999	28/11/2003
Cyprus	30/9/1998	20/3/2002
Czech Republic	24/6/1998	22/6/2001
Denmark	4/4/1997	10/8/1999
Estonia	4/4/1997	8/2/2002
Finland	4/4/1997	30/11/2009
France	4/4/1997	13/12/2011
Georgia	11/5/2000	22/11/2000
Greece	4/4/1997	6/10/1998
Hungary	7/5/1999	9/1/2002
Iceland	4/4/1997	12/10/2004
Italy	4/4/1997	

[165] http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=&CL=ENG

Latvia	4/4/1997	25/2/2010
Lithuania	4/4/1997	17/10/2002
Luxembourg	4/4/1997	
Moldova	6/5/1997	26/11/2002
Montenegro	9/2/2005	19/3/2010
Netherlands	4/4/1997	
Norway	4/4/1997	13/10/2006
Poland	7/5/1999	
Portugal	4/4/1997	13/8/2001
Romania	4/4/1997	24/4/2001
San Marino	4/4/1997	20/3/1998
Serbia	9/2/2005	10/2/2011
Slovakia	4/4/1997	15/1/1998
Slovenia	4/4/1997	5/11/1998
Spain	4/4/1997	1/9/1999
Sweden	4/4/1997	
Switzerland	7/5/1999	24/7/2008
The former Yugoslav Republic of Macedonia	4/4/1997	3/9/2009
Turkey	4/4/1997	2/7/2004
Ukraine	22/3/2002	