

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Strasbourg, 16 May 2014

**DH-BIO/ abr RAP 5**

**COMMITTEE ON BIOETHICS**

**(DH-BIO)**

**5<sup>th</sup> MEETING**

**Strasbourg, 5-7 May 2014**

**ABRIDGED REPORT**

### **Adoption of the agenda**

1. The Committee on Bioethics (DH-BIO) held its 5<sup>th</sup> meeting in Strasbourg from 5 to 7 May 2014. The agenda of the meeting and the list of participants appear in Appendix I and Appendix II to this abridged report.
2. On 5 May, the Launching Conference of the Guide on the decision-making process regarding medical treatment in end-of-life situations, was held under the auspices of the Austrian Chairmanship of the Committee of Ministers of the Council of Europe. The programme of the conference appears in Appendix III to this abridged report. The video recording of the conference is available on line: [www.coe.int/bioethics](http://www.coe.int/bioethics)

### **Chart of signatures and ratifications of the Convention on Human Rights and Biomedicine, the Protocol on the Prohibition of Cloning Human Beings, the Protocol concerning Transplantation of Organs and Tissues of Human Origin, the Protocol concerning Biomedical Research and the Protocol concerning Genetic Testing for Health Purposes**

3. The DH-BIO took note of the information sent in written form on the current process towards signature and/or ratification of the Oviedo Convention and/or its Additional Protocols in some member or observer states.

### **Developments in the field of bioethics**

4. The DH-BIO took note of the developments in the field of bioethics within the member states, as well as in international organisations. It was also informed of the relevant developments in other Council of Europe bodies.

### **Predictivity, genetic testing and insurance**

5. The DH-BIO held a preliminary exchange of views on the draft Recommendation on the use for insurance purposes of personal health-related information, in particular information of a genetic and predictive nature, in the light of the comments made by delegations. It examined in particular the scope of the Recommendation.
6. The majority of delegations were in favour of the current wording of the scope not limiting it to genetic data.
7. Regarding the way forward, the DH-BIO agreed with the approach proposed by the Bureau:
  - the organisation of a consultation meeting with interested delegations with the aim of preparing a revised version for examination by the plenary committee;
  - the designation of a rapporteur (within the DH-BIO) who would be entrusted with the task of preparing, with the assistance of the Secretariat, a revised version in the light of the comments from delegations and taking account of the opinion of the T-PD which would be examined at the consultation meeting.

**Those DH-BIO members interested in acting as rapporteur were invited to inform the Secretariat at the latest by 1 June 2014.**

The DH-BIO entrusted the Bureau with the task of designating the rapporteur in case several members of the committee expressed a wish to undertake this function.
8. Moreover, it was agreed that the Bureau would propose a date for the consultation meeting, if possible before the next plenary meeting.
9. **Delegations which had not already done so were invited to send their comments on the draft Recommendation, accompanied where appropriate by drafting proposals, as soon as possible and at the latest by 20 June 2014.**

### **Genetic testing for health purposes: information document on genetic testing, in particular its nature and possible implications of its results**

10. The DH-BIO was informed that the information document on genetic testing had now been translated into 28 non-official languages thanks mainly to the help and support of the European Society of Human Genetics (ESHG) and EuroGentest. The different language versions are available on the site: [www.coe.int/bioethics](http://www.coe.int/bioethics).

### **Re-examination of Recommendation (2006) 4 on research on biological materials of human origin**

11. The public consultation on the working document presenting a draft revised Recommendation was launched in March 2014. Comments must be sent to the Secretariat by 15 August 2014.
12. The DH-BIO agreed to invite the Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD) to make comments on the working document which had been made public for consultation. These comments should be sent to the Secretariat **by 20 September at the latest**, so that they could be examined by the Bureau at its meeting on 29-30 September 2014.

### **Additional Protocol on the protection of the human rights and dignity of persons with mental disorders with regard to involuntary placement and involuntary treatment**

13. The DH-BIO examined for the first time the preliminary draft Additional Protocol prepared by the Drafting Group in the light of comments made by delegations and also taking into account remarks by INGOs which had participated at a hearing organised on 11 March 2014. It discussed in particular the questions raised by the Drafting Group concerning the wording of the scope, the question of whether to include or exclude minors in the scope of the Protocol and the person of trust.

#### Scope

14. The delegations examined the 3 drafting proposals presented by the Drafting Group. They agreed on Alternative C (Article 2.1 : *"The provisions of this Protocol apply to involuntary placement and involuntary treatment of persons to address risk arising from a mental disorder"*) as a working basis for the Drafting Group which would be entrusted with revising the wording in the light of comments already made and those to be sent by delegations.

#### Minors

15. A majority of delegations was in favour of excluding minors from the scope of the Protocol. Nevertheless, it was agreed to come back to this point in the light of the written comments to be submitted, in particular on the approach proposed by the delegations in favour of including minors in the scope of the Protocol.

#### Person of trust

16. Delegations agreed on the importance of the concept of the "person of trust". With regard to the role of this person of trust, it was agreed that it needed to be clarified particularly in relation to that of the other possible actors in the procedure (representative, lawyer, where appropriate the attorney, etc.). Delegations were invited to send their comments on this issue and on the relevant provisions of the preliminary draft Protocol (Chapter III).
17. **Delegations were invited to send their written comments, where possible accompanied by drafting proposals, by 20 June 2014 at the latest.**
18. These comments would then be examined by the Drafting Group, as well as comments to be sent by CDDH delegations on this preliminary draft Protocol, with a view to preparing a revised version to be presented to the DH-BIO at its 6<sup>th</sup> plenary meeting.
19. Delegations which had not done so at the time of the adoption of the Declaration on the UN Convention on the Rights of Persons with Disabilities (adopted by the CDBI at its 41<sup>st</sup> meeting (2-4 November 2011)), were invited to send information on possible relevant discussions having

taken place at national level (in particular for those States having signed/ratified this Convention) on the interpretation of the provisions of the UN Convention on the Rights of Persons with Disabilities, and in particular Article 14.

20. Finally, the possibility of asking for an opinion from the Committee of Experts on the rights of people with disabilities (CS-RPD) of the Council of Europe on the draft Protocol might also be envisaged.

### **Prenatal sex selection**

21. The DH-BIO examined the proposals from the Bureau that had been prepared taking into account the proposals from delegations, in response to the decision of the Committee of Ministers and the subsequent mandate of the CDDH regarding prenatal sex selection.

22. The DH-BIO agreed with the conclusions of the Bureau:

- It acknowledged the importance of the concerns raised for the protection of human rights by prenatal sex selection and recalled, in this respect, the prohibition established in Article 14 of the Oviedo Convention, to allow the use of techniques of medically-assisted procreation for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.
- However, it considered, as underlined in particular by WHO and UNFPA at the 13th meeting of the UN Interagency Committee on Bioethics (25–26 March 2014), that the root cause of this problem was not related to the biomedical field but to the issue of gender equality. Therefore, it considered that any initiative it might take in the biomedical field would have limited added value to properly address this problem.
- Consequently, it did not consider it appropriate to take the initiative of starting a specific activity on this topic. Nevertheless, it wished to contribute, in its field of competence, to any activity that might be undertaken by another body/committee of the Council of Europe on this issue, or at the request of a member State.
- Furthermore, it was foreseen, in the continuity of its work on genetic testing, to further examine the issue of tests offered directly to consumers, namely those which made it possible, by means of a simple sampling of the mother's blood, to determine the sex of the foetus at a very early stage of pregnancy. In this perspective, an information document would be prepared on this new type of so-called « non invasive » tests. The possibility of a statement on this subject might be considered.

23. These conclusions would be communicated to the CDDH at its next meeting (24-27 June 2014).

### **Cooperation programme (DEBRA)**

24. The Representative of the Slovak Republic presented the draft programme of the International Conference on genetic testing for health purposes that will take place in Bratislava on 29-30 May 2014.
25. He invited interested delegations to participate in this event which aims to promote and facilitate the implementation of the principles laid down in the Oviedo Convention and its Additional Protocol, and to encourage the ratification of the latter by member States.

### **Election of a Bureau member**

26. By acclamation and for a term of office of two years, the DH-BIO elected to the Bureau Ms Doris Wolfslehner (Austria).

## **Future activities and working methods of the DH-BIO**

### **Reorganisation within the Secretariat**

27. Mr Christos Giakoumopoulos, Director – Directorate of Human Rights, and Mr Mikhail Lobov, Head of Human Rights Policy and Development, informed the DH-BIO about the recent changes within the Department and referred to current projects and discussions.

### **Ethical issues raised by emerging technologies and their convergence**

28. The DH-BIO took note of the timetable of work for the preparation of the second study by the Centre for the study of sciences and humanities of the University of Bergen (Norway) on ethical issues raised by emerging technologies. As was the case for the first study, an extended Bureau meeting was foreseen to which experts already proposed by delegations for the drafting of this study would be invited. Interested delegations would be able to participate in this meeting to be held in Paris on 1 October 2014. A draft study would be presented at the 6<sup>th</sup> plenary meeting for an exchange of views with the delegations. Comments made by delegations would be taken into account for its finalisation foreseen at the latest by 15 December 2014.

29. The DH-BIO supported the proposal of the Bureau for the preparation of the Conference foreseen for spring 2015. In particular, it agreed with the setting up of a group entrusted with the preparation of this conference. This group would be composed of:

- two members of the Bureau;
- two experts selected from those proposed by delegations for the drafting of the second study;
- one or two other members of the DH-BIO.

30. It was foreseen that the group would hold its first meeting before the summer so as to begin work on the approach and the preliminary draft programme of the conference for the purpose of facilitating the identification of speakers on the basis of proposals to be submitted by delegations.

## **Trafficking in human organs**

31. The Committee was informed that the draft Convention against Trafficking in Human Organs was being examined by the Committee of Ministers' Rapporteur Group on Legal Co-operation (GR-J) which will meet again on 22 May 2014.

## **Dates of the next meetings**

32. The DH-BIO agreed to hold:

- its 6<sup>th</sup> plenary meeting on 12 to 14 November 2014 in Strasbourg;
- its 7<sup>th</sup> plenary meeting on 2-5 June 2015 in Strasbourg. The Conference on emerging technologies would be organised on the occasion of this plenary meeting.

## **Other business**

### **Cooperation with National Ethics Committees**

33. The DH-BIO recognised the importance of maintaining relations with National Ethics Committees. In this context, it agreed with the proposals made by the Bureau to this effect.

34. The Secretariat was entrusted with sending a message to all the National Ethics Committees drawing their attention to the information documents available on the web site after each meeting which enable them to follow the work of the DH-BIO. These concern in particular the public abridged reports, but also, where appropriate, documents such as the Rathenau Instituut (NL) study or statements like the one adopted by the DH-BIO on the prohibition of any form of commercialisation of human organs (see points 42 to 44 below).

35. It was also agreed that the National Ethics Committees would be invited to conferences and symposia organised by the DH-BIO.

36. Finally, the delegations were encouraged to regularly inform the Committee of work carried out by the National Ethics Committee in their respective countries.

### Co-operation with other committees

#### Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)

37. The Secretary of the T-PD informed the DH-BIO that, with a view to the re-examination of Recommendation (97) 5 on the protection of medical data, a draft questionnaire had been prepared which would be sent to the Secretariat of the DH-BIO for possible comments before its finalisation. The re-examination of this Recommendation could be discussed in more detail at the joint meeting of the Bureaux of the committees foreseen on 30 September 2014.
38. It was recalled that the DH-BIO's work on emerging technologies might interest members of the T-PD due to the issues relating to data protection in this field. The T-PD might wish to designate an expert to participate in the extended Bureau meeting to be held in Paris on 1 October during which a preliminary draft study on ethical issues raised by emerging technologies would be examined.

#### European Committee on Organ Transplantation (CD-P-TO)

39. The Secretary of the CD-P-TO informed the DH-BIO about different projects on which the latter was invited in particular to cooperate: Guide to the quality and safety of tissues and cells for human application, work on vascularised composite tissue and a draft resolution and exchange of views on "organ donation and end of life".
40. The importance of cooperation with the CD-P-TO was underlined, as well as the willingness to promote efficient cooperation by nominating, for example, rapporteurs/experts on certain topics. With regard to the project on organ donation and end of life, the DH-BIO was therefore intending to designate an expert who could participate in the preparation and in the exchange of views foreseen by the CD-P-TO on this issue.
41. Finally, in response to the request by the Secretariat of the CD-P-TO concerning a project for collaboration with the Ukrainian authorities on organ donation and transplantation, the DH-BIO agreed, in principle, to cooperate with the CD-P-TO in the framework of this project. The participation of the DH-BIO, within its field of competence, would aim in particular to contribute to the respect of the standards established in the relevant instruments of the Council of Europe, namely the Oviedo Convention and its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin.

#### **Statement on the prohibition of any form of commercialisation of human organs**

42. The DH-BIO unanimously adopted a statement on the prohibition of any form of commercialisation of human organs.
43. The DH-BIO agreed to invite the CD-P-TO to join it in this statement, hoping that it could agree with the wording of the text which met the agreement of all the DH-BIO delegations (the statement appears in Appendix IV to this abridged report)<sup>1</sup>.
44. It also agreed to transmit this statement to the Committee of Ministers, as well as to the Parliamentary Assembly of the Council of Europe, inviting them to recall its terms in a declaration at their level.

---

<sup>1</sup> On 15 May 2014, the CD-P-TO replied positively to the invitation of the DH-BIO.

## APPENDIX I

### Agenda

Items for information, without decision required by the DH-BIO, are indicated by the following symbol:



#### 1. Adoption of the agenda



#### 2. Chart of signatures and ratifications of the Convention on Human Rights and Biomedicine, the Protocol on the Prohibition of Cloning Human Beings, the Protocol concerning Transplantation of Organs and Tissues of Human Origin, the Protocol concerning Biomedical Research and the Protocol concerning Genetic Testing for Health Purposes

Delegations, including observers, are invited to send information **in writing**.

- a. Developments in the field of bioethics in member states and other states
- b. Developments in the field of bioethics in international organisations
- c. Developments in the field of bioethics in other Council of Europe bodies

#### 4. Predictivity, genetic testing and insurance

**Examination of the draft Recommendation** on the use for insurance purposes of personal health-related information, in particular information of a genetic and predictive nature, **in the light of the comments submitted by delegations**.



#### 5. Genetic testing for health purposes: information document on genetic testing in particular their nature and possible implications of their results

Information on progress made in the translation of the leaflet into non-official languages and in the dissemination of the leaflet in member states.



#### 6. Re-examination of Recommendation (2006) 4 on research on biological materials of human origin

Information on the public consultation on the revised draft Recommendation as a working document.

#### 7. Additional Protocol on the protection of the human rights and dignity of persons with mental disorders with regard to involuntary placement and involuntary treatment

**Examination of a preliminary draft Additional Protocol** prepared by the Drafting Group.

#### 8. Prenatal Sex Selection

**Examination of proposals** by the Bureau on possible actions that could be undertaken by the DH-BIO in the light of the proposal presented by the Secretariat on the basis of the suggestions sent by delegations, **with a view to a decision on (a) possible activity(ies)**.



#### 9. Cooperation programme (DEBRA)

- Information on the International Bioethics Conference on genetic testing for health purposes in Central and Eastern Europe, to be organised in Bratislava on 29-30 May 2014 in cooperation with the Slovak authorities.
- Delegations wishing to organise DEBRA activities in 2015 are invited to send their written request by 10 November 2014 at the latest.

## 10. Election of a Bureau member

The DH-BIO is invited to elect one Bureau member taking into account that the term of office of Dr Javier Arias (Spain) comes to an end in June 2014 and is not renewable.

*Deadline for submission of nominations: Tuesday 6 May, 2pm*

## 11. Working methods and future activities of the DH-BIO



### a. Re-organisation within the Secretariat

### b. Ethical issues raised by emerging technologies and their convergences

- Timetable of work for completion of the 2<sup>nd</sup> study
- Proposal from the Bureau for the organisation of the conference in Spring 2015, **for discussion**



## 12. Trafficking in Human Organs



## 13. Relations with other international bodies

## 14. Dates of the next meetings

Dates proposed:

6<sup>th</sup> meeting of the DH-BIO: 12-14 November 2014

7<sup>th</sup> meeting of the DH-BIO: 2-5 June 2015 (alternative 26-29 May 2015)

## 15. Other business

### a. Cooperation with National Ethics Committees

**Examination of (a) possible proposal(s)** made by the Bureau on possibilities for closer cooperation with National Ethics Committees in the light of suggestions made by delegations

### b. Cooperation with other Committees

- i) Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)
- ii) Ad hoc Committee on Data Protection (CAHDATA)
- iii) European Committee on Organ Transplantation (CD-P-TO)
- iv) European Committee on Blood Transfusion (CD-P-TS)

## 16. Decisions taken by the DH-BIO at its 5<sup>th</sup> meeting

**Approval of the list of decisions.**

## **APPENDIX II**

### List of participants

MEMBER STATES / ETATS MEMBRES
-------------------------------

**Albania/Albanie** -

**apologised/excusé**

**Andorra/Andorre** – Mr Pere PASTOR VILANOVA, Juge, Cour Suprême de Justice, Avda de Tarragona, AD 500 Andorra la Vella, Andorra

**Armenia/Arménie** – Mr Igor MADOYAN, Phd, President of National Center of Bioethics, n.24, ave Sayat-Nova, apt. 14, entrance 1, 0001 YEREVAN

**Austria/Autriche** – Dr. Doris WOLFSLEHNER, Head of the division “Bioethics” at the Federal Chancellery of the Republic of Austria, Ballhausplatz 2, 1014 Wien

Dr Renate FALLY-KAUSEK, Medical Officer, Federal Ministry of Health, Department III/8– Health of children and young people, gender aspects, nutrition, Radetzkystrasse 2, A-1030 WIEN

Dr. Peter BARTH, Oberstaatsanwalt, Abteilungsleiter-Stellvertreter in der Zivilrechtssektion, Museumstraße 7,1070 Wien, **apologised/excusé**

**Azerbaijan/Azerbaïdjan** –

**apologised/excusé**

**Belgium/Belgique** – Mme Régine WILMOTTE, Juriste au sein de la direction générale des Etablissements de Soins du Service public fédéral « Santé publique », Place Victor Horta 40, boîte 10, 1060 Bruxelles, Belgique

**Bosnia and Herzegovina/Bosnie-Herzégovine** – Dr. Serifa GODINJAK, Head of Department for European Integration and International Cooperation, Sector for Health, Ministry of Civil Affairs, Trg BiH 1, 71000 Sarajevo, Bosnia and Herzegovina

**Bulgaria/Bulgarie** – Ms Sylvia TOMOVA, Ministry of Health, Legal Directorate, Chief Legal Advisor, Place St Nedelia 5, Sofia 1000

**Croatia/Croatie** - Dr. Vanja NIKOLAC, Head of Service, Service for blood, tissues and cells inspection, Ministry of Health, Ksaver 200a, 10 000 Zagreb, Croatia

**Cyprus/Chypre** – Mrs Rena PETRIDOU-VRAHIMI, Attorney of the Republic of Cyprus, Office of the Attorney General of the Republic of Cyprus, Appeli Street n° 1, 1403 NICOSIA **apologised/excusée**

**Czech Republic/République Tchèque** – Pr. Pavel MARTASEK, Professor of Medicine, Expert on Genetics, Dept. of Pediatrics, Center for Applied Genomics, 1st School of Medicine, Charles University, Ke Karlovu 2, Building D /2nd floor, 128 08 PRAGUE 2

**Denmark/Danemark** - Anna Skat NIELSEN, Special Advisor, Center for Hospital Policy, The Ministry of the Interior and Health, 10-12 Slotsholmsgade, DK-1216 Copenhagen K, Denmark **apologised/excusée**

**Estonia/Estonie** – Prof Hele EVERAUS, Head of the Clinic, Haematology and Oncology Clinic, Tartu University, Tartu University Hospital, Puusepa 8, 51014 Tartu, Estonia

**Finland/Finlande** – Ritva HALILA, M.D., Ph.D., Senior Medical Officer, National Advisory Board on Social Affairs and Health Care (ETENE), Ministry of Social Affairs and Health, P.O. Box 33, FI-00230 Government

Jaakko HALTTUNEN, Counsellor, Ministry for Foreign Affairs, Legal Service, Unit for Human Rights Courts and Conventions, PO Box 441, FI-00023 Government, Finland

Ms. TÖRRÖNEN Anneli, Ministry of Social Affairs and Health, P.O. Box 33, FI- 00023 Government, Finland

**France** - Mme Isabelle ERNY, Attachée principale d'administration centrale, Ministère de la Santé, Direction Générale de la Santé, Secrétariat Général, Division droit, éthique et appui juridique, 14 avenue Duquesne, 75350 PARIS 07 SP

M. Rodolphe FERAL, Sous-direction des droits de l'homme, Direction des affaires juridiques, Ministère des affaires étrangères et européennes, 57, bd des Invalides, 75700 Paris

Dr Jacques MONTAGUT, Directeur de l'IFREARES, 20 route de Revel, 31400 TOULOUSE

Mme Marie LAMBLING, Ministère de la Justice, Direction des Affaires Civiles et du Sceau, 13, Place Vendôme, F-75001 PARIS

Céline ROUX Ministère de la Justice, Direction des Affaires Civiles et du Sceau, 13, Place Vendôme, F-75001 PARIS

Mme Sandrine BOURDIN, Magistrate au sein du bureau du droit des personnes et de la famille à la direction des affaires civiles et du Sceau **apologised/excusée**

Mme Caroline AZAR, Ministère de la Justice, Direction des Affaires Civiles et du Sceau, 13, Place Vendôme, F-75001 PARIS **apologised/excusée**

**Georgia/Géorgie** – Dr Givi JAVASHVILI, Head of Family Medicine Department, State Medical Academy of Georgia, Chairman of the National Council on Bioethics, 29 I. Chachavadze Avenue, 0179 TBILISI

**Germany/Allemagne** – Mrs Andrea MITTELSTÄDT, Federal Ministry of Justice and Consumer Protection, Division III B 2, Mohrenstraße 37, D-10117 Berlin

Prof. Elmar DOPPELFELD, Honorary Chair of the Permanent Working Party of Research Ethics Committees in Germany Inc., Lenaustraße 15, D-50858 Köln

Prof. Thomas HEINEMANN, Philosophical-Theological University of Vallendar (PTHV), Pallottistraße 3, 56179 Vallendar

Dr. Ingo HÄRTEL, Federal Ministry of Health, Division 313, Friedrichstraße 108, D-10117 Berlin

Dr. Daniela von BUBNOFF, Federal Ministry of Education and Research, Division 612, Friedrichstraße 130 B, D-10117 Berlin

**Greece/Grèce** – Dr Stamatia GARANIS-PAPADATOS, Lecturer, National School of Public Health, 196 Alexandras Avenue, 11521 Athens

**Hungary/Hongrie** - Ms Eszter MAROSI, Head of Secretariat, Medical Research Council, H-1051 Budapest, Arany János utca 6-8. 3/334

**Iceland/Islande** – Mrs Laufey Helga GUDMUNSDOTTIR, Specialist, Department of Protection of Rights, Ministry of Welfare **apologised/excusée**

Gudridur THORSTEINSDOTTIR, Head of Department, Department of Protection of Rights, Ministry of Welfare, Hafnarhusinu vid Tryggvagotu, IS-150 Iceland **apologised/excusée**

**Ireland/Irlande** – Ms Angela O'FLOINN, Dept of Health, Hawking House, Dublin 2, Ireland **apologised/excusée**

Dr. Siobhán O'SULLIVAN, Chief Bioethics Officer, Dept. of Health, Hawkins House, Dublin 2, Ireland **apologised/excusée**

Mrs Emily DE GRAE, The Irish Council for Bioethics, Academy House, 19 Dawson Street, DUBLIN 2

**Italy/Italie** - Prof. Francesco d'AGOSTINO, Honorary President of the National Committee for Bioethics, Comitato Nazionale per la Bioetica, Via della Mercede 96, 00187, Roma  
**apologised/excusé**

Laura PALAZZANI, Lumsa, Facoltà di giurisprudenza, via Pompeo Magno 22, 00192 Roma

**Latvia/Lettonie** – Dr.Vents SĪLIS, Assistant Professor at Riga Stradins University, Department of Humanities, Dzirciema street 16, Riga, LV- 1007

**Liechtenstein** **apologised/excusé**

**Lithuania/Lituanie** – Dr Eugenijus GEFENAS, Chairman of Lithuanian Bioethics Committee, Associate Professor at Vilnius University, Lithuanian Bioethics Committee, Vilnius str.33, LT-2001 VILNIUS

Ms Jurate SEREPKAITE, Chief specialist, Lithuanian Bioethics Committee, Vilnius str. 33, LT-2001, Vilnius  
**apologised/excusée**

**Luxembourg** – Mr Jean-Paul HARPES, membre du Comité National d'Ethique de la Recherche, 119, Val des Bons Malades, L-2121 Luxembourg  
**apologised/excusé**

Mr Mike SCHWEBAG, Attaché de Gouvernement 1er en rang, Ministère de la Santé, Allée Marconi - Villa Louvigny, 2423 Luxembourg  
**apologised/excusé**

**Malta/Malte** - Mme Mary Anne CIAPPARA, B. Pharm., M. Phil. Pharmacist, Hon. Secretary, Bioethics Consultative Committee, Palazzo Castellania, 15 Merchant Street, VALLETTA **apologised/excusée**

**Republic of Moldova/République de Moldova** – Lucia TURCAN, Assistant Professor, PhD., The State University of Medicines and Pharmacy "Nicolae Testemitanu", Clinical Pharmacology Department, Chisinau, Republic of Moldova

**Monaco** - **apologised/excusé**

**Montenegro/Monténégro** – Ms Olivera MILJANOVIC, Prim. doc., Director of the Centre for Medical Genetics and Immunology, Medical Centre of Montenegro, Krusevac bb, 81000 Podgorica

**Netherlands/Pays-Bas** – Ms. Joyce BROUWERS-VERSTAPPEN, (Senior) Beleidsmedewerker, Afdeling Ethiek, directie Publieke Gezondheid, Ministerie van Volksgezondheid, Welzijn en Sport  
**apologised/excusée**

Ms. Judith VAN DEN BERG, Ministry of Health, Welfare and Sports, Rijnstraat 50, 2515 XP The Hague

**Norway/Norvège** – Mrs Anne FORUS, Senior Adviser, ph.d, Biotechnology and health legislation department, Division of specialised health care services, Norwegian Directorate of Health, P.O.Box 7000, St Olavs plass, N-0130 Oslo

Camilla Closs WALMANN, Senior Adviser, Department for Biotechnology and Health Law, Norwegian Directorate of Health, P.O.Box 7000 St Olavs plass, N-0130 Oslo, Norway

Ms Vårin Kathrin HELLEVIK, Senior Adviser, Department for Mental Health Care Services, Division of Specialist Health Care Services, Norwegian Directorate of Health, P.O. Box 7000 St Olavs Plass, N-0130 Oslo, Norway

**Poland/Pologne** – Dr Jerzy UMIASTOWSKI, Chairman of the Medical Ethics Committee of the Polish Medical Board, Local Medical Board, Ul. Sniadeckich 33, 80-204 GDANSK

**Portugal** - Prof. Miguel OLIVEIRA DA SILVA, Conselho Nacional de Ética para as Ciências da Vida Av. D. Carlos I, nº 146, 2º Esq, 1200-651, Lisboa, Portugal  
**apologised/excusé**

**Romania/Roumanie** – Mr. Gheorghe BORCEAN, Vice-President of the Romanian College of Physicians, Spitalul Municipal Caransebes, str. Gradinilor nr. 36<sup>a</sup>, CARANSEBES, jud. CARAS-SEVERIN 325400

Prof. Dr. Vasile ASTARASTOAE, Institutul de Medicina Legala, Buna Vestire nr. 4, 700455 IASI, Romania  
**apologised/excusé**

Mrs Beatrice Gabriela IOAN, Associate Professor, President of the Bioethics Commission of the Romanian College of Physicians, Institutul de Medicina Legala, str. Bunavestire nr. 4, IASI

**Russia/Russie** – Mr Boris YUDIN, Director, Institute of Human Studies, Russian Academy of Sciences, Volkhonka 14, MOSCOW 119992

**San Marino/Saint-Marin** - Dr. Luisa BORGIA, Vice-President of the National Ethics Committee, Contrada Le Grazie, n.3, 62029 Tolentino (MC), Italia

**Serbia/Serbie** - Prof. Dr Zvonko MAGIC, Head of the Institute for Medical Research in the MMA (Military Medical Academy), professor of the human genetics at the Medical Faculty and Cochairmen of the National Committee for bioethics of UNESCO Commission of Serbia, Serbian Academy of Sciences and Arts, 11000 Belgrade, Serbia

**Slovakia/Slovaquie** – Assoc. Prof. Jozef GLASA, MD, PhD, PhD; Institute of Pharmacology and Clinical Pharmacology, Slovak Medical University; National Reference Centre for Management of Chronic Hepatitis; Institute of Medical Ethics and Bioethics n.f.\*; Ethics Committee, Ministry of Health SR; Limbová 12, 83303 Bratislava, Slovak Republic

**Slovenia/Slovénie** – Dr. Božidar VOLJČ, Institute for Transfusion Medicine, Slajmerjeva 6, Ljubljana 1000

Urh GROSELJ, MD,MA, University Children's Hospital, University Medical Center Ljubljana, Bohoriceva 20, 1000 Ljubljana, Slovenia

**Spain/Espagne** – Carlos ALONSO BEDATE, [Centro de Biología Molecular](#), Member of the National Committee for Bioethics, C/ Alberto Aguilera, 21. 28015 Madrid, Spain

Prof. Carlos M. ROMEO – CASABONA, Professor of Penal Law, Head, Inter-University Chair in Law and the Human Genome, Avda. de las Universidades 24; 48007 BILBAO, Spain

Javier ARIAS-DIAZ, Associate Professor of Surgery, Subdirección de Terapia Celular y Medicina Regenerativa, Instituto de Salud Carlos III, Sinesio Delgado 4, 28029 Madrid

Asier URRUELA MORA, Facultad de Derecho, Universidad de Zaragoza, C/ Pedro Cerbuna, 12, 50009, Zaragoza  
**apologised/excusé**

M<sup>a</sup> Concepción MARTIN ARRIBAS, Subdirección General de Investigación en Terapia Celular y Medicina Regenerativa – Instituto de Salud Carlos III – ISCIII, Avda. Monforte de Lemos 5, 28029 Madrid

**Sweden/Suède** – Mrs Tesi ASCHAN, Legal Adviser, The National Board of Health and Welfare, Socialstyrelsen, 106 30 Stockholm

Ms. Ellen RINGQVIST, Legal Advisor, The National Board of Health and Welfare, Department of Regulations and Authorisations, Legal Unit, Health Care, SE - 106 30 Stockholm  
**apologised/excusée**

**Switzerland/Suisse** – Dr Martin GÖTZ, Office fédérale de la santé publique, Division Biomédecine, collaborateur scientifique, Seilerstrasse 8, 3003 Bern  
**apologised/excusé**

Mme Nadine KELLER, Collaboratrice scientifique, Département fédéral de l'intérieur – DFI, Office fédéral de la santé publique – OFSP, Section Sécurité biologique et génétique humaine, Seilerstrasse 8, 3003 Berne

Rahel MÜLLER, avocate, Collaboratrice scientifique, Département fédéral de justice et police DFJP, Office fédéral de la justice OFJ, Domaine de direction de Droit privé, Gestion, état-major, Bundesrain 20, 3003 Berne

**"The Former Yugoslav Republic of Macedonia"/"l'ex-République yougoslave de Macédoine"** –  
**apologised/excusé**

**Turkey/Turquie** – Prof. Ergun ÖZSUNAY, Professor of Civil, Comparative Law and EU Private law, Istanbul Culture University, Faculty of Law, İstiklal cad. 233/1, Tunca Apt. Daire 7, 34430 ISTANBUL

**Ukraine** - Prof Zoreslava SHKIRYAK-NYZHNYK, Vice-president of Bioethics Committee of National Academy of Medical Sciences, Chief of the Department of Family Health Problems, Academy of Postgraduate Education, Institute of Paediatrics, Obstetrics and Gynaecology, Mayborody str., 8, 04050 KYIV

**United Kingdom/Royaume-Uni** - Dr Mark BALE, Deputy Director, Health Science & Bioethics Division, Department of Health, Richmond House, Whitehall, London SW1A 2NS

#### INVITED EXPERTS / EXPERTS INVITES

Prof. Elaine GADD, Honorary Professor, School of Law, Queen Mary University of London, Fox Court, 14 Gray's Inn Road, London, WC1X 8HN

#### PARTICIPANTS

**CDCJ** - Mrs Xeni SKORINI, Professeur associé, Faculté de Droit d'Athènes, 6 rue Essopou, GR-14563 ATHENES-Kifissia, GRECE  
**apologised/excusée**

Ms. Marion NAPIERALA, Secretariat of CDCJ, DGI, Directorate General Human Rights and Rule of Law, Legal Co-operation

**CDDH** – Mme Brigitte KONZ, Juge de Paix directrice, Cité judiciaire, Plateau du St Esprit, Bâtiment JP - L-1475 Luxembourg  
**apologised/excusée**

**CD-P-TS** – Dr. Guy RAUTMANN, Secretary of the European Committee on Blood Transfusion (CD-P-TS), European Directorate for the Quality of Medicines and HealthCare, Department of Biological Standardisation and OMCL Network  
**apologised/excusé**

**CD-P-TO** – Ms Marta LOPEZ FRAGA, Secretary of the CD-P-TO

**T-PD** – Mme Sophie KWASNY, Secretary of the T-PD

**PARLIAMENTARY ASSEMBLY/ASSEMBLÉE PARLEMENTAIRE** – Mr Valeriu GHILETCHI, Chairperson, Committee on Social Affairs, Health and Sustainable Development

Ayşegül ELVERİŞ, Co-Secretary to the Committee on Social Affairs, Health and Sustainable Development, Parliamentary Assembly of the Council of Europe, F-67075 Strasbourg Cedex

#### OTHER PARTICIPANTS / AUTRES PARTICIPANTS

**EUROPEAN COMMISSION/COMMISSION EUROPEENNE** – Mr Lino PAULA, European Research Area, Ethics and Gender Unit, Directorate-General for Research and Innovation, Office SDME 3/14, B-1049 Brussels, Belgium  
**apologised/excusé**

Dr Maurizio SALVI, Senior scientist, Ethics of science and new technologies, Joint Research Centre (JRC), B-1049 Brussels/Belgium, rue du Champ de Mars 21 - CDMA 6/112 **apologised/excusé**

Dr Jim DRATWA, Head of Ethics and Head of the EGE Secretariat, Member of the Bureau of European Policy Advisers (BEPA), European Commission, Rue de la Loi 200 Wetsraat, BERL 8/358, B-1049 Brussel **apologised/excusé**

**Canada** – Mr. Michael HALUCHA, Policy Analyst, Bioethics, Department of Health Canada, Science Policy Directorate, Strategic Policy Branch, Health Canada, Brooke Claxton Building, 70 promenade Colombine Driveway, Tunney's Pasture, Ottawa, Ontario K1A 0K9 , Postal Locator: 0909C **apologised/excusé**

Dr. Peter MONETTE, Manager of Bioethics, Department of Health Canada, Science Policy Directorate, Strategic Policy Branch, Health Canada, Brooke Claxton Building, 70 promenade Colombine Driveway, Tunney's Pasture, Ottawa, Ontario K1A 0K9 , Postal Locator: 0909C **apologised/excusé**

**Holy See/Saint-Siège** – Mgr. Jacques SUAUDEAU, Cure Saint Bruno, 5 Place Saint Bruno, 38500 Voiron, France

**Japan/Japon** – **apologised/excusé**

**Mexico/Mexique** – Dr. Manuel H Ruiz de CHÁVEZ, President of the National Academy of Medicine of Mexico, President of The Council of the National Commission of Bioethics, Carretera Picacho-Ajusco No. 154, piso 6°, Col. Jardines de la Montaña. C.P. 14210, Del. Tlalpan, Mexico, D. F, Mexico **apologised/excusé**

**USA/Etats-Unis d'Amérique** – **apologised/excusé**

**UNESCO** – Mrs. Dafna FEINHOLZ KLIP, Section de la bioéthique, Division de l'éthique des sciences et des technologies, UNESCO, 1 rue Miollis, 75732 PARIS CEDEX 15

**OECD/OCDE** – Dr Jacqueline E M Allan, Senior Policy Analyst (Biotechnology and Nanotechnology) Directorate for Science, Technology and Industry, OECD, 2 rue André-Pascal, 75775 Paris Cedex 16 France **apologised/excusée**

**World Health Organisation/Organisation Mondiale de la Santé (WHO/OMS)** – Dr Abha SAXENA (MD), Coordinator, Global Health Ethics, Secretary, Research Ethics Review Committee (ERC), HIS/ESD, Cluster of Health Systems and Innovation, World Health Organization, 20, Avenue Appia, CH- 1211, Geneva 27, Switzerland **apologised/excusée**

Dr Andreas REIS, Technical Officer, Department of Ethics, Equity, Trade and Human Rights, WHO, 20 Avenue Appia, CH-1211 GENEVA 27, Switzerland **apologised/excusé**

**Permanent representation of Turkey/Représentation permanente de la Turquie** – Ms Ayşen EMÜLER, Legal expert/Experte Juridique, Permanent Representation of Turkey to the CoE

#### **OBSERVERS / OBSERVATEURS**

**Australia** - Samantha ROBERTSON, Executive Director, Research Translation, National Health and Medical Research Council (NHMRC), Postal Address: **National Health and Medical Research Council, GPO Box 1421, Canberra ACT 2601, Australia** **apologised/excusée**

**Israel/Israël** – Dr Ilana SCHMIDT-HOPFELD, Department of Science Teaching, Weizmann Institute of Science, 200 Herzl St., REHOVOT 76100, Israel **apologised/excusée**

Professeur Michel REVEL, Weizmann Institute, Department of Molecular Genetics, Brasil House, 5 REHOVOT 76100, Israel **apologised/excusé**

**European Science Foundation/Fondation Européenne de la Science (ESF)** – Dr Maria Manuela NOGUEIRA, Senior Science Officer, European Science Foundation, 1 quai Lezay-Marnésia, BP 90015, 67080 Strasbourg cedex, France **apologised/excusée**

Prof. Isabel VARELA-NIETO, Instituto Investigaciones Biomédicas "Alberto Sols", Neurobiology of Hearing Group, Arturo Duperier 4, 28029 Madrid, Spain **apologised/excusée**

**KEK – Church and Society Commission of the Conference of European Churches/Commission Eglise et Société de la Conférence des Eglises Européennes** – Pasteur Richard FISCHER, Secrétaire Exécutif de la Commission Eglise et Société de la Conférence des Eglises européennes, 8, rue du Fossé des Treize, 67000 Strasbourg

## **SECRETARIAT**

**Directorate General Human Rights and Rule of Law**

**Human Rights Policy and Development Department  
Bioethics Unit**

/

**Direction Générale Droits de l'Homme et Etat de Droit  
Service des politiques et du développement des droits de l'Homme  
Unité de la Bioéthique**

Mrs Laurence LWOFF, Secretary of the DH-BIO / Secrétaire du DH-BIO, Tel: +33 (0) 388 41 22 68, Email: [laurence.lwoff@coe.int](mailto:laurence.lwoff@coe.int)

Mrs Lindsay YOUNGS, Administrator / Administratrice, Tel: +33 (0) 388 41 21 63, email: [lindsay.youngs@coe.int](mailto:lindsay.youngs@coe.int)

Mr Sébastien SERVE, Administrator / Administrateur, Tel: +33 (0) 388 41 24 38, email: [sebastien.serve@coe.int](mailto:sebastien.serve@coe.int)

Ms. Catherine FORNÉ, Assistant / Assistante, Tel: +33 (0) 388 41 22 20, Email: [catherine.forne@coe.int](mailto:catherine.forne@coe.int)

Ms. Joanna KILLY, Assistant / Assistante, Tel: +33 (0) 388 41 30 84, Email: [joanna.killy@coe.int](mailto:joanna.killy@coe.int)

Mr Vlad TITERLEA, Trainee / Stagiaire

## **INTERPRETERS / INTERPRETES**

Amanda BEDDOWS  
Luke TILDEN  
Shéhérazade HOYER  
Christine TRAPP

### **APPENDIX III**

#### **Launching Conference of the Guide on the decision-making process regarding medical treatment in end-of-life situations**

Strasbourg, 5 May 2014

#### **Programme**

13.30 - 14.00

#### **Registration**

14.00 - 14.30

#### **Opening**

- . **Mr Christos Giakoumopoulos**, Director, Directorate of Human Rights, Council of Europe
- . **Mr Wolfgang-Lukas Strohmayer**, Deputy Permanent Representative of Austria to the Council of Europe
- . **Dr Anne Forus**, Chair of the Committee on Bioethics (DH-BIO), (Norway)
- . **Dr Christiane Druml**, Chair of the Austrian Bioethics Commission (Austria)
- . **Mr Valeriu Ghiletschi**, Committee on Social Affairs, Health and Sustainable Development, Parliamentary Assembly of the Council of Europe (Moldova)

14.30 - 15.15

#### **Session 1 - Presentation of the Guide**

Chair:

**Dr Béatrice Ioan**, Member of the Drafting group on the end of life (Romania)

- . **Ms Isabelle Erny**, Principal Attaché in Central Administration, Law, Ethics and Legal Support Division, Ministry of Health, Paris  
Co-ordinator on the end of life, DH-BIO (France)
- . **Prof. Andréas Valentin**, Medical director, General and Medical Intensive Care Unit, Rudolfstiftung Hospital, Vienna  
Member of the DH-BIO Drafting group on the end of life (Austria)

15.15 - 15.45

*Break*

15.45 - 17.15

#### **Session 2 - The points of view of the users**

Moderators:

**Dr Mark Bale**, Vice-Chair of the DH-BIO (United Kingdom)

**Prof. Dr. Elmar Doppelfeld**, member of the Bureau of the DH-BIO (Germany)

- . **Prof. Dr. med. Peter M. Suter**, Honorary Professor, University of Geneva; former president, Swiss Academy of Medical Sciences, Geneva (Switzerland)
- . **Dr Juan Manuel Núñez Olarte**, Internal Medicine, Head of Palliative Care Unit, Hospital Gregorio Marañón, Madrid (Spain)
- . **Prof. Bridget Johnston**, Professor of Palliative and Supportive Care  
Sue Ryder Care Centre for the Study of Supportive, Palliative and End of Life Care,  
School of Health Sciences, University of Nottingham (United Kingdom)
- . **Dr Iva Holmerova**, Vice-Chairperson of Alzheimer Europe, Chair of the Czech Alzheimer Society, Gerontology Centre, Prague (Czech Republic)

Discussion open to all participants

17.15 - 17.45

**Conclusions**

Chair:

**Dr Anne Forus**, Chair of the Committee on Bioethics (DH-BIO)

- . **Prof. Günter Virt**, Institute of Moral Theology, University of Vienna (Austria)
- . **Prof. Didier Sicard**, Honorary President of the National Consultative Ethics Committee (France)

17.45 - 18.00

**Closing**

18.00

**Cocktail offered by the Austrian Chairmanship of the Committee of Ministers**

## **APPENDIX IV**

### Statement

#### on the prohibition of any form of commercialisation of human organs

The Committee on Bioethics (DH-BIO) and the European Committee on Organ Transplantation (CD-P-TO) of the Council of Europe are concerned by some views, including in international fora, suggesting some forms of commercialisation of organs in response to shortage of organs for transplantation.

In this context, the DH-BIO and the CD-P-TO emphasise in particular the need to respect the fundamental legal principle that the human body and its parts shall not, as such, give rise to financial gain. Enshrined in the Convention on Human Rights and Biomedicine (CETS No 164) opened for signature in 1997 (Article 21), this principle was reaffirmed in 2002 in its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (CETS No 186) and later by Article 3 of the EU Charter of Fundamental Rights. It was also included by the World Health Organisation in its Guiding Principles on Human Cell, Tissue and Organ Transplantation.

Human organs must not, therefore, be bought or sold or give rise to financial gain or comparable advantages for the person from whom they have been removed or for third party.

The DH-BIO and the CD-P-TO reiterate the fundamental importance of that established principle for the protection of human dignity, which must be strictly respected in any regulation and procedures concerning the transplantation of human organs. They strongly support any measure for reinforcement and better implementation of the principle at both national and international levels with a view to contribute to the setting up and functioning of appropriate transplantation systems, respecting the fundamental principles for the protection of human rights.

The DH-BIO and the CD-P-TO wish therefore to reaffirm their support to initiatives currently being taken in the Council of Europe and by other international, as well as professional organisations with a view to reinforcing the international legal framework on organ transplantation.