

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Strasbourg, 18 November 2014

**DH-BIO/ abr RAP 6**

**COMMITTEE ON BIOETHICS**

**(DH-BIO)**

**6<sup>th</sup> MEETING**

**Strasbourg, 12-14 November 2014**

**ABRIDGED REPORT**

### **Adoption of the agenda**

1. The Committee on Bioethics (DH-BIO) held its 6<sup>th</sup> meeting in Strasbourg from 12 to 14 November 2014. The agenda of the meeting and the list of participants appear in Appendix I and Appendix II to this abridged report.

### **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**

2. The DH-BIO was informed that on 31 July 2014, Bosnia and Herzegovina signed the Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings (CETS no. 168, 1998).

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

3. 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**

4. The DH-BIO held an exchange of views on the revised draft Recommendation on the processing for insurance purposes of personal health-related data, in particular data resulting from genetic tests. The DH-BIO welcomed the revised version of this text prepared by Mrs Doris Wolfslehner (Austria), Rapporteur, with the assistance of the Secretariat, in the light of the comments made by delegations.
5. Comments, in particular of an editorial nature, were raised by delegations. **The delegations were invited to submit in written form the comments made orally as well as possible complementary comments, accompanied where possible by proposals, on the revised version of the draft Recommendation by 15 December 2014, taking also into account the elements for the Explanatory Memorandum prepared by Mrs Doris Wolfslehner.**
6. So as to leave more time to delegations to consult and send written comments, the DH-BIO agreed to postpone, the **consultation meeting** with interested delegations, initially foreseen on 15 December 2014. The Bureau proposed holding a specific session on the draft Recommendation revised in the light of the comments made by delegations during its next meeting to be held on 17-19 March 2015 in Paris (date to be confirmed). Delegations interested would be invited to participate in this session.
7. In accordance with the terms of reference of the DH-BIO, the finalisation of the draft Recommendation is foreseen for the 8<sup>th</sup> plenary meeting in November 2015. The draft Recommendation, as finalised by the DH-BIO, will then be sent to the CDDH for approval with a view to its presentation at the Committee of Ministers for adoption.

### **Dissemination and translation in non-official languages of adopted documents**

8. The DH-BIO was informed that the information document on genetic testing had been translated into 28 non-official languages. It was also informed that the Guide on the Decision-Making Process regarding Medical Treatment in End-of-Life Situations had so far been translated into 6 non-official languages and translations into 5 other languages of the Guide were underway. These documents 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**

9. Following the end of the public consultation concerning the Working document on research on biological materials of human origin (March-August 2014), the Drafting Group on biobanks will analyse the numerous comments received and prepare a revised version of the draft Recommendation for examination by the DH-BIO at its meeting in May 2015.
10. In accordance with the terms of reference of the DH-BIO, the finalisation of the revision of the Recommendation is foreseen for the 8<sup>th</sup> plenary meeting in November 2015 with a view to its approval and subsequent presentation to the Committee of Ministers for adoption.

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

11. The DH-BIO held an exchange of views on the revised version of the draft Additional Protocol, prepared by the Drafting Group in the light of the comments made by delegations. The DH-BIO acknowledged the valuable work of the Drafting Group in making progress on this important instrument.
12. When examining the provisions of the draft Additional Protocol, clarifications were suggested by delegations on several provisions. Numerous comments, both of substance and of an editorial nature, were raised in this context. Delegations were invited to submit the comments they had made orally also in writing.
13. Lack of time prevented the DH-BIO to go through the preamble or to discuss the scope of the Protocol with regard to minors. Delegations were invited to include comments on these matters in their written submissions (delegations in favour of including minors, are invited to make wording proposal(s) on the way this could be done; delegations not in favour of covering minors, are invited to indicate the provisions which would raise problems in their possible application to minors).
14. **Delegations were invited to send their written comments, where possible accompanied by drafting proposals, by 15 December 2014.**

## **Emerging Technologies**

15. The draft of the study on ethical issues raised by emerging sciences and technologies and their convergence was presented to the DH-BIO by Professor Roger Strand of the Centre for the Study of the Sciences and Humanities of the University of Bergen (Norway), which had been entrusted with its preparation.
16. Delegations made a number of general comments on this draft study as well as more specific ones relating, in particular, to its draft recommendations for the future work of the DH-BIO as well as more generally for the Council of Europe on the subject. Professor Roger Strand and Professor Matthias Kaiser, drafters of the study, were invited to take account of these comments in the finalisation of the study foreseen by 15 December 2014.
17. The DH-BIO was informed that the date of the Conference on the human rights challenges raised by emerging technologies had been brought forward to 4-5 May 2015 so as to be within the duration of the Belgian chairmanship of the Committee of Ministers – the Belgian authorities having expressed interest in giving support to this event in the framework of their Chairmanship.
18. The DH-BIO examined the draft programme of the Conference, as prepared at its second meeting (1 October 2014) by the Preparatory Group responsible for the Conference. In so doing, a number of suggestions were put forward regarding the structure of the draft programme in order to clarify the general approach, the expected content and complementarity of the presentations foreseen.

19. Finally, **delegations were invited to send suggestions for speakers to the Secretariat by 10 December 2014**. The DH-BIO agreed to entrust the Preparatory Group with the task of selecting the speakers from amongst the proposed names, bearing in mind the need to respect diversity of expertise as well as a geographical and gender balance.

#### **Prenatal sex selection**

20. The DH-BIO took note of the mandate given by the Committee of Ministers to the CDDH concerning prenatal sex selection, which it instructed, with the support of the DH-BIO, and in co-operation with the Gender Equality Commission (GEC), to consider and make proposals for concrete action to be undertaken by the Council of Europe in this field.

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

21. The DH-BIO was informed of a request received from the competent authorities of Serbia for the organisation of a Regional Conference on New Technologies and Genetics, towards the end of 2015.

#### **Election of a Chair and Vice-Chair and Bureau members**

22. The DH-BIO elected by acclamation Mr Mark Bale (United Kingdom), Chair of the DH-BIO, and Dr Beatrice Ioan (Romania), Vice-Chair, for a term of office of one year starting on 1 January 2015.
23. The DH-BIO elected, by acclamation, to the Bureau the following members for a term of office of two years: Ms Tesi Aschan (Sweden), Dr Givi Javashvili (Georgia) and Ms María Concepción Martín Arribas (Spain).
24. Prof. Zvonko Magic (Serbia) was re-elected by acclamation for a second term of office of two years.

#### **Working methods and future activities of the DH-BIO**

25. Mr Philippe Boillat, Director General, Directorate General of Human Rights and Rule of Law, made a presentation to the DH-BIO with a view to the preparation of the proposals of activities for the next biennium. He highlighted in this context, the priority areas for the Council of Europe identified in particular in the report by the Secretary General on the state of democracy, human rights and rule of law in Europe, and the strategies defined to address them.
26. With a few editorial changes, the DH-BIO approved the proposals made by the Bureau for its activities in 2016-2017, as presented in Appendix III to this abridged report.
27. In agreement with the Bureau, the DH-BIO supported the project of developing a specific course on the principles laid down in the Oviedo Convention in the framework of the European Programme for Human Rights Education for Legal Professionals (HELP).

#### **Dates of the next meetings**

28. The DH-BIO agreed on the following dates for its next meetings:
- 7<sup>th</sup> meeting of the DH-BIO: 4-7 May 2015 (the Conference on the human rights challenges raised by emerging technologies would take place on 4-5 May).
  - 8<sup>th</sup> meeting of the DH-BIO: 17-20 November 2015.
29. The DH-BIO took note that the Bureau would hold its next meeting on 17-19 March 2015. A specific session on the draft Recommendation on the processing, for insurance purposes, of personal health-related data, in particular data resulting from genetic tests, would be held to which interested delegations would be invited. A joint session would also be organised with the Drafting Group on biobanks to discuss the draft Recommendation on research on biological

materials of human origin revised in the light of the comments received during the public consultation, which took place in March-August 2014.

## **Other business**

### **Cooperation with other committees**

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

30. The Committee welcomed the joint meeting between the Bureaux of the T-PD and DH-BIO on 30 September 2014, which provided a very positive basis for future cooperation projects.

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


31. The representative of the DH-BIO to the CD-P-TO informed the Committee of the results of the CD-P-TO meeting which had taken place in Rome on 9-10 October 2014.

## **Follow up to the Declaration on the Prohibition of any form of commercialisation of human organs**


32. The Committee took note that a “horizon scanning meeting” had been proposed by the Bureau as a follow up to the Declaration adopted in May 2014 by the DH-BIO and CD-P-TO on the prohibition of any form of commercialisation of human organs, and taken over by the Committee of Ministers as well as the Committee on social affairs, health and sustainable development of the parliamentary Assembly of the Council of Europe. The meeting, to which CD-P-TO and CD-P-TS would be invited, would take place on 16 December 2014 in Paris. A few experts would be asked to give an overview of possible challenges to the principle of Article 21 (prohibition of financial gain) in the different fields concerned (blood, tissues and cells, organs). The information and documents provided at the meeting will also be sent to delegations. The meeting mainly aimed at benefiting from information facilitating the identification of issues for possible actions in the future.

## **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**

Preliminary exchange on the revised draft Recommendation on the processing for insurance purposes of personal health-related data, in particular data resulting from genetic tests, prepared by Mrs Doris Wolfslehner (Austria), Rapporteur.

#### **5. Dissemination and translation in non-official languages of adopted documents**

- a. Genetic testing for health purposes:** information document on genetic testing in particular their nature and possible implications of their results
- b. Guide on the Decision-Making Process regarding Medical Treatment in End-of-Life Situations**

#### **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 the provisions of the preliminary draft Additional Protocol revised by the Drafting Group in the light of the comments made by delegations.

## 8. Emerging Technologies

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

- Presentation of the 2<sup>nd</sup> study by the Centre for the Study of the Sciences and the Humanities of the University of Bergen (Norway) on Ethical issues raised by emerging technologies and their convergences
- Preparation of the Conference foreseen on 4-5 May 2015: discussion on the proposals made by the drafting group for the draft programme of the Conference with a view to its approval

## 9. Prenatal Sex Selection

## 10. Cooperation programme (DEBRA)

- Information on the International Bioethics Conference on genetic testing for health purposes in Central and Eastern Europe held 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.

## 11. Election of a Chair and Vice-Chair and Bureau members

The DH-BIO is invited to elect its new Chair and Vice-Chair, whose terms of office will start on 1 January 2015.

The DH-BIO is also invited to elect, subject to the result of the Chair and Vice-Chair election, 4 Bureau members, taking into account that the terms of office of the following 4 Bureau members will also end in December 2014:

Elmar Doppelfeld (not renewable)

Beatrice Ioan (not renewable)

Siobhan O'Sullivan (renewable)

Zvonko Magic (renewable)

**Deadline for submission of nominations: Thursday 13 November, 14.00**

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

Preparation of the 2016-2017 biennium

- Examination of the proposals made by the Bureau for future activities with a view to the approval of the proposed activities for 2016-2017 to be submitted to the CDDH

## 13. Relations with other international bodies

## 14. Dates of the next meetings

Dates proposed:

7<sup>th</sup> meeting of the DH-BIO: 4-7 May 2015

8<sup>th</sup> meeting of the DH-BIO: 17-20 November 2015

## **15. Other business**

### **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)  
- Follow up to the Declaration on the Prohibition of any form of commercialisation of human organs
- iv) European Committee on Blood Transfusion (CD-P-TS)

## **16. Decisions taken by the DH-BIO at its 6<sup>th</sup> meeting**

**Approval of the list of decisions.**



## **APPENDIX II**

### **List of participants**

<b>MEMBER STATES / ETATS MEMBRES</b>
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**Albania/Albanie** -

**apologised/excusé**

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

**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, Radetzkystasse 2, A-1030 WIEN

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

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**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

**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

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

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**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

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

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**Iceland/Islande** – Asa Thorhildur THORDARDOTTIR, Legal Advisor, Ministry of Welfare, Hafnarhúsinu við Tryggvagötu, 101 Reykjavík

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

Dr. Siobhán O'SULLIVAN, Chief Bioethics Officer, Dept. of Health, Hawkins House, 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**

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**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

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

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

**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

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Dr. phil. Matthias KAISER, Professor / Director, Centre for the study of the sciences and the humanities, University of Bergen, Po Box 7800, 5020 Bergen, Norway **apologised/excused**

#### PARTICIPANTS

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

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## **APPENDIX III**

### **Proposals for DH-BIO activities in the 2016-2017 Biennium**

1. Since 2012, the programme of activities for the Council of Europe is defined by periods of two years.
2. For the 2016-2017 Biennium, proposals for the programme of activities will have to be finalised by spring 2015 with a view to their presentation to the Committee of Ministers. To that end, the DH-BIO had foreseen the approval of its proposals for activities in the field of bioethics at its 6<sup>th</sup> plenary meeting with a view to their presentation to the CDDH.
3. This issue was discussed by the Bureau of the DH-BIO, at its last meeting (29-30 September 2014) with a view to presenting proposals to the delegations for discussion at the 6<sup>th</sup> plenary meeting (12-14 November 2014).

#### **Considerations made by the Bureau when preparing the proposals for activities**

4. The Bureau had first examined the current activities which would most likely be carried over to 2016 and those which have already been considered for the next biennium:

- Additional Protocol concerning the Protection of the Human Rights and Dignity of Persons with Mental Disorder with regard to Involuntary Placement and Involuntary Treatment:

The terms of reference of the DH-BIO provide for the finalisation of the preparation of a draft Protocol in 2015. However, time will be needed for consultation of other committees/bodies on the draft before its final approval and presentation to the Committee of Ministers, which would be considered at the end of 2016.

- Emerging technologies: When proposing the organisation of a conference on emerging technologies and their convergence in 2015, the DH-BIO had already considered the drafting of a White Paper on the basis of its conclusions. The White Paper could be finalised by the end of 2017.

5. Furthermore, in agreement with the decision taken at the 1<sup>st</sup> plenary meeting of the DH-BIO (19-22 June 2012), the re-examination process of the Additional Protocol concerning Biomedical Research should be considered in September 2015, for possible work in 2016.

6. As agreed at the joint meeting of the Bureaux of the Consultative Committee for the Protection of Individuals with regard to automatic Processing of Personal Data (T-PD) and DH-BIO held on 30 September 2014, cooperation between the two committees is foreseen, starting in 2016 in relation to health related data, in particular for the purpose of the re-examination process of Recommendation (97) 5 on the protection of medical data.

7. As this has been the case during the current Biennium, the Bureau underlined also the possibility that the Committee could be requested to examine, in 2016-2017, a topical subject (for example, at the request of the Committee of Ministers, following a recommendation by the Parliamentary Assembly as was the case with prenatal sex selection, or at the request of a delegation).

8. Finally, the Bureau noted that 2017 will mark the 20<sup>th</sup> anniversary of the opening for signature of the Oviedo Convention. It agreed to propose organising an international conference on this occasion, which would aim at examining the relevance of its principles and possible challenges raised by the developments in the fields concerned.

#### **Approval by the DH-BIO**

9. **In discussing the proposals made by its Bureau, the DH-BIO kept in mind the priorities for the Council of Europe, as highlighted in particular in the report of the Secretary general on the State of Democracy, Human Rights and the Rule of Law in Europe, referred to by Mr Philippe Boillat, Director General, DGI, in his address to the DH-BIO on 12 November 2014. It**



**also took into account the criteria of feasibility of carrying out the activities and achieving the results foreseen, considering their number, the workload for the Committee as well as for the Secretariat and the budgetary resources.**

**10. The DH-BIO made few editorial modifications and approved the proposals presented by the Bureau, as they appear in the table below.**

				Reinforcing Human Rights legal corpus	Emerging challenges – Oviedo Convention and its Additional Protocols				
	End-of-life	Revision Rec(2006)4 on research on biological materials	Predictivity genetics and insurance <sup>1</sup>	Protection of human rights and dignity of persons with mental disorders – Involuntary measures	Re-examination of Biomedical Research Additional Protocol	Health-related data (cooperation with T-PD)	Direct to consumer genetic testing	Emerging technologies <sup>1</sup>	20 <sup>th</sup> anniversary of the Oviedo Convention
2014	Launching of the Guide	Public Consultation	Preparation of a draft Recommendation	Preparation of a draft Additional Protocol				Studies on : - Scientific aspects - Ethical aspects	
2015		Finalisation	Finalisation	↓			International Round table (professionals, intergov. organisations)	International Conference on human rights and emerging technologies	
2016				Finalisation of the draft Additional Protocol and presentation to the Committee of Ministers	Re-examination of Biomedical Research Protocol, and where appropriate, revision	Contribution to the re-examination of Rec(97)5 on protection of medical data	[where appropriate, follow up to the round table, in particular concerning non-invasive genetic testing]	Preparation of a White Paper on the basis of the outcome of the Conference (precise scope to be defined)	Survey on the Oviedo Convention (impact, relevance, challenges)  ↓  International Conference for the 20 <sup>th</sup> anniversary of the Oviedo Convention: “Relevance and challenges”
2017									

<sup>1</sup> Work carried out under the supervision of the CDDH