COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Strasbourg, 13 December 2012 **DH-BIO/ abr RAP 2**

COMMITTEE ON BIOETHICS

(DH-BIO)

2nd MEETING
Strasbourg, 4-6 December 2012

ABRIDGED REPORT

Adoption of the agenda

1. The Committee on Bioethics (DH-BIO) held its 2nd meeting in Strasbourg from 4 to 6 December 2012. 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. Several delegations provided information about the state of progress towards signature or ratification of the Convention and its Protocols.

The decision-making process regarding medical treatment in end-of-life situations

3. The DH-BIO examined the draft Guide and took note of the recent improvements to the text. Several delegations made supplementary remarks.

4. The Committee entrusted the Drafting Group with revising the text taking into account the comments made by delegations.

5. It agreed that the revised text be then made public for consultation as a working document and under the responsibility of the Drafting Group.

6. With the aim of launching the consultation during the month of February 2013, delegations were invited to send to the Secretariat, by 11 January 2013 at the latest, their suggestions concerning associations/institutions/experts representing in particular the professionals concerned, carers/support providers, patients and family which should be invited to make comments on the working document. The consultation process would finish at the end of April 2013.

Predictivity, genetic testing and insurance

7. The Committee took note of the synthesis made by the Secretariat of the responses received during the consultation process which ended on 27 April 2012. Several delegations made comments about the next step which was to draft a document containing recommendations on the issue.

8. The Committee noted that the Bureau had entrusted the Secretariat with the following task:

   In consultation with the experts having participated in the previous Working Party, and taking into account the comments from delegations during the discussion at the 2nd plenary meeting (4-6 December 2012), the Secretariat will make proposals and, where appropriate, alternative proposals on the content of a preliminary outline of a possible non-binding legal instrument on predictivity, genetic testing and insurance. These proposals will be submitted to the DH-BIO at its 3rd plenary meeting (May 2013).

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

9. The Committee noted with satisfaction that the information document would be translated into numerous non-official languages thanks to the help and support of the European Society of Human Genetics and EuroGentest.

10. Delegations were invited to:

    - send their suggestions for a wider dissemination of the leaflet at national and, where appropriate, international level;
    - communicate measures taken at national level to disseminate information about the leaflet and to make it available to the general public.

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

11. The DH-BIO examined the conclusions prepared by the Drafting Group following the symposium organised in June 2012. Several delegations made comments on this issue.

12. The Committee agreed to entrust the Drafting Group with preparing proposals for the re-examination of Rec(2006)4 on the basis of the conclusions drafted by the Group following the symposium, and taking into account the comments made by the delegations. These proposals would be submitted to the DH-BIO at its 3rd plenary meeting (May 2013).

13. Following her election as Chair of the Committee (see below), Dr Anne Forus (Norway), who had been the coordinator on biobanks, was replaced in this role by Dr Javier Arias (Spain).

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

14. The DH-BIO agreed to set up a Drafting Group entrusted with the task of preparing a preliminary draft Additional Protocol on the protection of the dignity and fundamental rights of persons with mental disorders with regard to involuntary treatment and placement.

15. This Group would be chaired by Dr Beatrice Ioan (Romania), member of the Bureau of DH-BIO.

16. It would be composed of:

    - a core group (two or three members of the DH-BIO);
    - experts designated by the CDDH and the CPT; and
    - where appropriate, other experts to be proposed by the delegations.

17. A first meeting of the Drafting Group was foreseen for the last week of March 2013.

18. Delegations were invited to send to the Secretariat:

    - by 31 January 2013 at the latest, proposed names of experts with clinical expertise/experience in psychiatry and/or experience in policy development in this field ; each proposal should be accompanied by a CV;
    - by 1 March 2013 at the latest, their general/specific comments on the provisions contained in the outline prepared by the Secretariat in 2011 (document CDBI(2011)11).

    The DH-BIO noted that the Secretariat also envisaged inviting a consultant expert to participate in the work of the Drafting Group in preparing the preliminary draft Protocol.

Cooperation programme (DEBRA)

19. The Secretariat informed the DH-BIO that no requests had been submitted for organising cooperation activities in 2013. It was recalled that any request from a member State should be submitted to the Secretariat at the latest by 10 November of the year preceding the one during which the activity was envisaged. It was also pointed out that these activities were not necessarily limited to ethics in biomedical research, but might also cover other topics such as transplantation or genetic testing so as to raise awareness of the principles adopted in these fields and facilitate their implementation.

Election of the Chair, Vice-Chair and Bureau members

20. The DH-BIO elected by acclamation Dr Anne Forus (Norway), Chair of the DH-BIO, and Mr Mark Bale (United Kingdom), Vice-Chair, for a term of office of one year.

21. The DH-BIO elected to the Bureau, by a majority of two thirds of the votes cast, the following members for a term of office of two years: Prof. Elmar Doppelfeld (Germany), Dr Beatrice Ioan (Romania), Dr. Siobhan O'Sullivan (Ireland) and Prof. Zvonko Magic (Serbia).

Future activities and working methods of the DH-BIO

22. Mr Philippe Boillat, Director General, Directorate General of Human Rights and Rule of Law, and Mr Rafael Benítez, Director of Programme, Finance and Linguistic Services, made presentations to the DH-BIO highlighting the context of preparing the programme of activities for the 2014-2015 biennium.

23. The DH-BIO agreed on the topics as identified and ranked in Appendix III to this abridged report, which would be presented to the CDDH.

24. It was also agreed, for its proposals, to follow the approach proposed in this appendix.

25. The working method to be adopted for each activity would however be further specified and proposals could be made by the Bureau for that purpose.

Trafficking in human organs

Examination of the preliminary draft Convention elaborated by the PC-TO

26. The Committee took note of the latest developments which had taken place during the meeting of the European Committee on Crime Problems (CDPC) held this same week, which had approved a draft Convention containing, for some points, alternative solutions.

27. The draft Convention would be submitted to the GR-J, the Rapporteur Group of the Committee of Ministers responsible for legal issues. The DH-BIO delegations could forward their comments to their counterparts in the relevant ministries.

Dates of the next meetings

28. The DH-BIO agreed to hold its third plenary meeting in Strasbourg from 28 to 30 May 2013. The dates of the fourth plenary meeting, foreseen for the month of November in Strasbourg, would be proposed by the Bureau.

29. The Bureau had agreed to meet on 18 and 19 April 2013 in Paris.

30. The Drafting Group on biobanks would meet on 17 April 2013 in order to finalise proposals for the re-examination of Rec(2006)4, which it would subsequently present to the DH-BIO.

Gender equality

31. Dr Beatrice Ioan (Romania), gender equality Rapporteur within the DH-BIO, informed the Committee of the discussions held during the exchange of views between the Gender Equality Commission (GEC) and the gender equality rapporteurs, organised on 16 November 2012.

Draft Recommendation on the promotion of the human rights of older persons

32. The DH-BIO took note of the draft Recommendation prepared by the Drafting Group on the human rights of older persons (CDDH-AGE). Several delegations made comments on some of its provisions, in particular paragraph 33 and the following ones.

33. Delegations were invited to send to the Secretariat, by 15 February 2013 at the latest, comments together with wording proposals, where appropriate, on the draft Recommendation on the promotion of the human rights of older persons, in particular on paragraph 33 and the following ones, but also on the provisions of the chapters concerning palliative care and care in institutions.

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)

Modernisation of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data

34. The DH-BIO noted that the T-PD had finalised its proposals for the modernisation of the Convention for the protection of individuals with regard to automatic processing of personal data. These proposals would be submitted to the Committee of Ministers, which might entrust an ad hoc Committee to carry out a modification of the current Convention.

35. The DH-BIO might be invited to be represented on this ad hoc Committee.

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

36. The DH-BIO delegations had recently received a draft Resolution prepared by the European Committee on Organ Transplantation (CD-P-TO) on utilisation of kidneys from living donors for transplantation. They were invited to send to the Secretariat, by 15 January 2013 at the latest, in the light of the relevant provisions of the Oviedo Convention and its Additional Protocol concerning the transplantation of organs and tissues of human origin, comments on this draft Resolution.

European Committee on Blood Transfusion (CD-P-TS)

37. The Secretary of the CD-P-TS informed the DH-BIO about a project initiated by the European Blood Alliance (EBA), and supported by the CD-P-TS. He recalled the principle in Article 21 of the Convention on human rights and biomedicine, reiterated in the Charter of Fundamental Rights, which prohibits that the human body and its parts, as such, give rise to financial gain. The EBA project aims to promote voluntary non-remunerated blood donation and responds to a number of interventions by the commercial sector in favour of remunerating donors. The CD-P-TS intends to examine initiatives which might be taken in the field of blood transfusion in order to strengthen the enforcement of the principle established in Article 21 of the Oviedo Convention. It will then inform the DH-BIO of its proposals with a view to possible cooperation.

APPENDIX I

Agenda

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

1. Adoption of the agenda

ℹ **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**

ℹ **3. Developments in the field of bioethics**

a. Developments in the field of bioethics in member states and other states

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

b. Developments in the field of bioethics in international organisations

c. Developments in the field of bioethics in other Council of Europe bodies

4. Decision-making process regarding medical treatment in end-of-life situations

Examination of the draft "Guide" prepared by the drafting group on decision-making process regarding medical treatment in end-of-life situations.

5. Predictivity, genetic testing and insurance

Early exchange on the replies to the consultation and the possible follow up

ℹ **6. Genetic testing for health purposes: information document on genetic testing in particular their nature and possible implications of their results**

Discussion concerning the dissemination of the leaflet

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

Discussion on the synthesis and proposals for the follow up to the symposium

8. Cooperation programme (DEBRA)

Delegations wishing to organise DEBRA activities in 2013 are invited to send their written request by 10 November 2012 at the latest.

9. Election of the Chair, 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 2013.
The DH-BIO is also invited to elect bureau members taking into account that the term of office of the following three Bureau members will also end in December 2012:
Pavel Martacek (non re-eligible),
Elmar Doppelfeld (re-eligible)
Beatrice Ioan (re-eligible)
Deadline for submission of nominations: Wednesday 5 December, 2pm

10. Future activities and working methods of the DH-BIO

a. Discussion on possible future activities based on the proposals sent by delegations

- Presentation on Electronic medical filing system in Denmark
  by **Ms Birgitte Drewes**, National Board of eHealth, Denmark
- Presentation on the work carried out by the European Commission in the field of eHealth, in particular in relation to Electronic medical file
  by **Dr Peteris Zilgalvis**, Head of Governance and Ethics Unit at the European Commission.

b. Preparation of the 2014-2015 programme of activities

Discussion on possible activities to be included in the 2014-2015 programme on the basis of the proposals presented by delegations.

11. Trafficking in Human Organs

Examination of the Convention against trafficking in human organs as revised by the Committee of experts on trafficking in Human Organs, Tissues and cells (PC-TO) at its last meeting on 15-19 October 2012

- Presentation by Mr Emmanuel Jauffret (France), representative of the DH-BIO at the PC-TO

12. Relations with other international bodies

13. Dates of the next meeting

Dates proposed:

3rd meeting of the DH-BIO: 27-30 May [alternative 3-6 June 2013]
4th meeting of the DH-BIO: November 2013

14. Other business

a. Gender Equality

- Report on the meeting of gender equality rapporteurs by Dr. Beatrice Ioan (Romania), Gender Equality Rapporteur

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

iii) European Committee on Blood Transfusion (CD-P-TS)

c. Prenatal sex selection

ANNEXE II

Liste des participants

MEMBER STATES / ETATS MEMBRES

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

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Ms Tanja KLEINSORGE, Head of Secretariat, Committee on Social Affairs, Health and Sustainable Development

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EUROPEAN UNION TO THE COUNCIL OF EUROPE/UNION EUROPEENNE AUPRES DU CONSEIL DE L'EUROPE - Mme Marion LAMBERT, 18, Boulevard de l'Orangerie, 67000 Strasbourg,

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APPENDIX III

Proposed new activities for 2014-2015

I. Priority topics as supported by the DH-BIO delegations during the discussion:

- Emerging technologies
- Neuroscience/neuromodulation

- Clinical ethics committees
- Medical files

- Direct to consumer testing

II. Decisions

The DH-BIO agreed with the approaches proposed below. The working method to be adopted for each activity would however be specified at a later stage and proposals could be made by the Bureau for that purpose.

1. Emerging technologies/neuroscience

- **EXPERT STUDY(IES)** on emerging technologies in the biomedical field , in particular genetics, neuromodulation and nanotechnologies (scope to be possibly refined)

  Objective: identifying major challenges for human rights of emerging technologies

  Timetable: to be launched in 2013

  Assessment by the DH-BIO: end of 2014

- **WHITE PAPER** on targeted subject(s)

  Timetable: 2015

2. Clinical ethics committees (CEC)

- **QUESTIONNAIRE**

  Objective: General overview of nature, composition, role and issues addressed by CEC

  Timetable: 2014

- **IMPACT STUDY** on a selected type of CEC (e.g. CEC in hospital) on the protection of patients' rights

  Means: expert consultant (subject to availability of budgetary allocation)

  Timetable: 2015

3. Medical files

- **QUESTIONNAIRE** on current situation (on regulation and practices) in member states (where appropriate complementing already collected data, in particular by European Commission, focusing then on new practices in the medical field and access to medical files by third parties)

  Timetable: 2013

- **ANALYSIS OF THE MAIN ETHICAL CONCERNS** raised by new developments, such as the use of electronic medical files and transborder flow of personal medical data

  Means: expert consultant

  Timetable: 2014

- where appropriate, **CONTRIBUTION TO THE RE-EXAMINATION OF REC(97)5 ON THE PROTECTION OF MEDICAL DATA (T-PD)** and other relevant work possibly undertaken by other intergovernmental organisations

  Timetable: subject to T-PD calendar

4. Direct to consumer testing

- **ROUND TABLE** with**:**

  - patient organisations
  - consumer organisations
  - geneticists
  - where appropriate, other stakeholders

Provisional calendar of activities in progress and proposed new activities

Activities begun in the 2012-2013 biennium					New activities proposed for the 2014-2015 biennium			
Activity	**Biobanks Re-examination of Rec(2006)4**	**Decision-making process in the field of medical treatment in end-of-life situations**	**Draft Protocol on the protection of human rights and dignity of persons with mental disorders**	**Prenatal sex selection**	**Emerging tech/neuromod.**	**CEC**	**Medical files**	**Direct to consumer testing**
1st part 2014	Finalisation	Finalisation/ Launching of a "Guide"	⇩	(Preparation of draft guidelines)	Expert study *(to be launched in 2013)* Assessment by the Committee	Questionnaire	Questionnaire (*to be launched in 2013*) Analysis of main ethical concerns	Round table
2nd part 2014			⇩	(Preparation of draft guidelines)	Drafting of a white paper			
1st part 2015			Finalisation of draft Protocol	(Preparation of draft guidelines)	⇩	Impact study on selected type of CEC	Where appropriate, contribution to T-PD work or other work	
2nd part 2015				(Finalisation of draft guidelines)	Finalisation			