

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Strasbourg, 24 June 2019

DH-BIO/abr RAP 15

**COMMITTEE ON BIOETHICS  
(DH-BIO)**

**15<sup>th</sup> meeting**

**4-7 June 2019**

**Strasbourg**

**Abridged report**

## **I. Adoption of the agenda**

1. The Committee on Bioethics (DH-BIO) held its 15th meeting in Strasbourg from 5-7 June 2019. The agenda of the meeting and the list of participants appear in Appendix I and Appendix II to this report.
2. The Chair, Tesi Aschan (Sweden), welcomed the new members of the DH-BIO.

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

3. The DH-BIO took note of the developments in the field of bioethics, in particular developments at the European Court of Human Rights.

## **III. 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 (to be dealt with in writing)**

4. The DH-BIO took note that the Additional Protocol on genetic testing for health purposes (ECTS n°203) was ratified by the Czech Republic on 16 May 2019.

## **IV. Public debate**

*High level Seminar on public debate as a tool for the governance of new technologies – 4 June, organised under the auspices of the French Presidency of the Committee of Ministers*

5. The DH-BIO congratulated the French Presidency, the speakers, the Secretariat and everyone else who contributed to the success of the high-level seminar. The Committee praised the quality of the event and underlined a number of issues arising from it.

*Draft guide on public debate*

6. The Chair introduced the draft guide on public debate in the biomedical field, in particular summarising the replies to the targeted questionnaire on it. As a result of the discussions held, the drafting group was invited to: (i) Make the overall document as concise and as practical as possible, (ii) clarify certain wording (e.g. “excluded voices”) in order to make the document as positive and as neutral as possible, (iii) develop the pedagogical value of the guide, in particular to promote education and training on public debate as well as the linkages between the public and those with responsibilities and expertise, (iv) increase the number of geographically diverse examples of public debates and to highlight the lessons learned from them, including those from outside of Europe to be kindly provided by UNESCO.
7. **DH-BIO delegations were invited to send to the Secretariat additional examples of public debate at the latest by 23 August 2019.**

## **V. Genome editing**

8. The DH-BIO took note of the replies to the questionnaire, summarised by the Rapporteur, Ingo Härtel (Germany), and decided to await the findings of the studies by two experts respectively on ethical issues raised by genome editing technologies and

the overview of the technological advances, and to continue observing relevant work undertaken namely by the World Health Organisation (WHO).

## **VI. Gender equality**

9. The gender rapporteur, Prof. Constantinos Phellas, gave a presentation on gender mainstreaming and the work of the DH-BIO. He recalled the Bureau's decision to invite delegations to inform the Secretariat whether they have data on the number of men and the number of women subject to involuntary measures. He also stressed the need for gender to form an integral part of the strategic action plan on human rights and technologies 2020-2025.

## **VII. Draft study on good practices in mental healthcare - How to promote voluntary measures**

10. The DH-BIO examined the concept note prepared by the Secretariat and agreed on the importance of the work proposed. Delegations expressed their support for it and agreed on the need to further define the scope and methodological approach of the study.
11. **Delegations and the Conference of INGOs, as well as the other relevant bodies of the Council of Europe, would be invited to send their suggestions on how to approach the scope and methodology of the study by 23 August 2019** with a view to refining the concept note.
12. The DH-BIO also agreed to designate a Rapporteur for the study on good practices in mental health care and to entrust, subject to confirmation, the representative of Finland with this task.
13. The DH-BIO entrusted the Secretariat, in co-operation with the Rapporteur, to organise a Round Table meeting with relevant actors in the field (including representatives from the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), the Council of Europe Commissioner for Human Rights, PACE, European Network of National Human Rights Institutions (ENNHRI), relevant INGOs and professional organisations) with a view to further refining the scope and methodology of the study and taking into account relevant work already undertaken in the field.
14. **Delegations were invited to explore possibilities to make voluntary contributions towards the financing of this project.**

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

15. The DH-BIO took note of the replies, received from professional organisations, to the questionnaire on the draft Additional Protocol prepared by the Bureau. Following an exchange on the way forward, the DH-BIO **agreed to invite Delegations to submit, by 23 August 2019, concrete drafting proposals** in view of the comments received, keeping in mind the decision taken at its 14<sup>th</sup> plenary meeting to carefully review the draft, and having particular regard to strengthening the aspect of alternative and preventive measures.
16. The DH-BIO further agreed to hold an extended Bureau meeting on 14 October 2019, in Paris, with the participation of delegations having submitted drafting proposals, with a view to presenting a revised draft Protocol at the 16th plenary meeting.

## **IX. Cooperation with other committees**

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

17. . The DH-BIO was informed of the adoption by the Committee of Ministers of Recommendation CM/Rec (2019)2 on the protection of health-related data. The DH-BIO also took note of the work to be undertaken by the T-PD during the next biennium 2020-2021
18. The Chair underlined the importance of future cooperation between the DH-BIO and the T-PD in the framework of the 2020-2025 Strategic Action Plan on human rights and new technologies.

## **X. Strategic Action Plan**

19. The Chair of the drafting group, Dr Siobhan O’Sullivan (Ireland), introduced the draft Strategic Action Plan as further developed by the drafting group to include action proposals under the pillars and specific objectives already agreed at the last plenary meeting. She underlined that the proposals for specific action were based on ‘SMART’ criteria. This was followed by presentations by members of the drafting group on the actions proposed under each pillar, namely governance, equity, integrity, and cooperation.
20. The Committee considered the action proposals, and had wide ranging discussions on priorities. Children’s participation in decision making processes, older person’s access to innovative treatments, public debate, and the challenges of neurotechnology were all highlighted in conjunction with possibilities for cooperation, capacity building and exchanges with the OECD, WHO, and UNESCO.
21. Noting that, at that stage, there was no clear consensus on the choice of action proposals, **the delegations were invited to send comments and/or indicate their priorities among the actions proposed to the Secretariat, at the latest by 26 July 2019.**

## **XI. Priorities for the 2020-2021 biennium**

22. The Committee took note of the proposals for priorities prepared by the Bureau, also taking into account the proposed activities referred to in the draft Strategic Action Plan. Following extensive discussions, the Committee decided on the following priority actions for the next biennium:
  - Finalisation of the draft Additional Protocol for the protection of human rights and dignity of persons with mental disorders with regard to involuntary placement and involuntary treatment.
  - Carrying out and publication of the study on good practices in mental health care - How to promote voluntary measures (subject to funding).
  - Launching of the Strategic Action Plan with particular focus on the human rights challenges raised by new technologies, such as neurotechnologies.
  - Examination of ethical and legal issues raised by developments in genome editing technologies, in relation to Article 13 of the Oviedo Convention.
  - Mapping legislation and best practices with a view to developing a guide for health care professionals on children’s participation in the decision making process.

- Launching of the Guide on Public Debate.
- Further translation and dissemination of the HELP course, keeping in mind the double target audience: legal but also health professionals.

## **XII. Cooperation activities**

23. The DH-BIO was informed about a new Action Plan for Belarus which focuses on inter alia new technologies including health and medical privacy. The DH-BIO was also informed about a new Action Plan for Armenia which, subject to secured financing, includes activities in the field of bioethics.

## **XIII. Bureau election**

24. The DH-BIO elected by acclamation, Ms Ritva Halila (Finland), as its new Vice-Chair for a six month term, renewable once for one year.
25. The DH-BIO elected by acclamation Mr Mark Bale (United Kingdom), as member of the DH-BIO Bureau for a term of two years, renewable once.

## **XIV. Dates of the next meetings**

26. The DH-BIO agreed on the following dates for its next meetings to be held in Strasbourg:
- 16th meeting of the DH-BIO: 19-21 November 2019
  - 17th meeting of the DH-BIO: 2-5 June 2020

## **XV. Decisions taken by the DH-BIO at its 15th meeting**

27. The DH-BIO adopted its decisions on 7 June 2019.

## **XVI. Other business**

*a. Committee of Ministers request for comments on PACE Recommendation Rec 2156 (2019) on anonymous donation of sperm and oocytes: balancing the rights of parents, donors and children*

28. The DH-BIO held an exchange on the issues raised in PACE Rec 2156 (2019) and examined the draft comments prepared by the Secretariat in the light of the written comments sent by delegations. The DH-BIO considered that the wording of paragraph 8 of the draft comments, relating to information on the conception and information about the identity of the donor, should be reworded to reflect the opinions expressed, and agreed on the wording and content of the other paragraphs.
29. The DH-BIO entrusted the Secretariat to re-word paragraph 8 of the draft comments to reflect the opinions expressed and to send the draft to Delegations **for possible comments on the revised paragraph 8 by 14 June 2019**..
30. In the absence of remarks by delegations, the comments as revised by the Secretariat were considered adopted on 17 June 2019 and sent to the Committee of Ministers.

*b. Proposal to prepare a request to the ECtHR under Article 29 of the Oviedo Convention*

*(participation restricted to the Representatives of the Parties of the Oviedo Convention)*

31. Following an exchange of views, the representatives of the States Party to the Oviedo Convention agreed to entrust the Bureau, assisted by the Secretariat, with drafting a proposal for a request for an advisory opinion on legal questions concerning the interpretation of the Oviedo Convention that they will examine at the 16th DH-BIO plenary meeting. **The representatives of the States Parties to the Oviedo Convention were invited to send their proposals for possible questions to the Secretariat by 23 August 2019.**

*c. Council of Europe Recommendation Rec(2016)8 on the processing of health-related data for insurance purposes, including data resulting from genetic testing: questionnaire on impact at national level. Deadline 29th June 2019*

32. The Chair reminded DH-BIO members of the need to **reply, by the deadline of 29 June 2019, to the questionnaire on impact at the national level of Council of Europe Recommendation Rec(2016)8 on the processing of health-related data for insurance purposes, including data resulting from genetic testing.**

## Appendix I List of participants

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

**apologised/excusé**

**Andorra/Andorre** – Mme Imma RODRIGUEZ, BATLLIA D'ANDORRA, Av. Tarragona, Ed. Les Columnes 62, Andorra, la Vella, AD 500 PRINCIPAUTÉ D'ANDORRE

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**Austria/Autriche** – Mag. Martina ERLEBACH, juge, référendaire de la section civile, droit national de la famille, département I 1, 1070 Vienne, Museumstraße 7, Autriche

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**apologised/excusée**

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

**apologised/excusée**

Mr Peter KIMPIAN, Administrator

**CPT** – Michael NEURAUTER, Head of Division of the Secretariat of CPT

**CAHENF** – Ms Livia STOICA, Administrator

**apologised/excusée**

Ms Maria-Andriani KOSTOPOULOU, Chair of the Ad Hoc Committee for the Rights of the Child (CAHENF)

**apologised/excusée**

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

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#### **DIRECTORATE GENERAL HUMAN RIGHTS AND RULE OF LAW**

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**INTERPRETERS / INTERPRETES**

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**Appendix II**  
**Agenda/order of business**

**Tuesday 4 June 2019 (9.15-17.30) – Room 1**

**High Level Seminar on Public Debate as a Tool for the Governance of New Technologies**  
Under the auspices of the French Presidency of the Committee of Ministers

**Wednesday 5 June 2019 (9.00 – 13.00) - Room 2**

**1. Adoption of the draft agenda**



To be dealt with in writing

**2. Developments in the field of bioethics**

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

- a. Developments in member states and other states
- b. Developments in the field of bioethics in international organisations
- c. Relations with other international organisations: list of meetings
- d. Developments in other Council of Europe bodies
- e. Developments at the European Court of Human Rights



To be dealt with in writing

**3. 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 Purpose**

**4. Public debate**

- Brief exchange of view on the outcome of the high level seminar
- Presentation of the draft Guide and addendum prepared by the Drafting Group
- Short presentation of the results of the targeted consultation on the draft Guide
- Discussion to provide guidance for the Drafting Group with a view to the finalisation of the draft and its adoption at the 16<sup>th</sup> plenary meeting

**Wednesday 5 June 2019 (14.30-18.00) - Room 2**


**4. Public debate (to continue, where necessary)**

**5. Genome editing**

- Presentation and discussion on the basis of the updated replies to questionnaire in relation to Article 13 of the Oviedo Convention
- Presentation of the possible forms that could be taken by the outcome of the examination

	<p>of the ethical and legal issues raised by genome editing technologies in the health field</p> <ul style="list-style-type: none"> <li>- Proposal for the organisation of the work on ethical and legal issues with a view to an agreement</li> </ul>
	<p><b>16. Other business</b></p> <p>a. Committee of Ministers (CM) invitation to comment on PACE Recommendation Rec 2156 (2019) on anonymous donation of sperm and oocytes: balancing the rights of parents, donors and children</p> <ul style="list-style-type: none"> <li>- Examination of a draft prepared by the Secretariat in the light of the comments sent by delegations with a view to its adoption and presentation to the CM.</li> </ul>
	<p><b>6. Gender equality</b></p> <ul style="list-style-type: none"> <li>- Presentation of proposals by the Gender Equality Rapporteur</li> </ul>
<p><b>Thursday 6 June 2019 (9.00-13.00) - Room 2</b></p>	
	<p><b>7. Draft study on good practices in mental healthcare - How to promote voluntary measures</b></p> <ul style="list-style-type: none"> <li>- Examination of a concept note prepared by the Secretariat with a view to its approval and, where appropriate, agreement on the modalities of its further development, including the designation of a rapporteur.</li> </ul>
	<p><b>8. Additional Protocol on the protection of the human rights and dignity of persons with mental disorders with regard to involuntary placement and involuntary treatment</b></p> <ul style="list-style-type: none"> <li>- In the light of the comments received from delegations and professional organisations, discussion on the organisation of the work with a view to a decision</li> </ul>
	<p><b>16. Other business</b></p> <p><b>b. Proposal to prepare a request to the ECtHR under Article 29 of the Oviedo Convention (participation restricted to the Representatives of the Parties to the Oviedo Convention)</b></p> <p>The Parties to the Convention are invited to exchange on the principle of a possible request to the ECtHR under Article 29 of the Oviedo Convention, with a view to agree to entrust the Bureau, with the assistance of the Secretariat, to draft such request to be examined by the Parties to the Oviedo Convention during the 16<sup>th</sup> DH-BIO for formal decision.</p> <ul style="list-style-type: none"> <li>- The possible request for advisory opinion could evolve around the question whether Article 7, seen in conjunction with Article 26 of the Oviedo Convention, rules out that a person with a mental disorder of a serious nature be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder, provided that that person's mental health condition represents a significant risk of serious harm to others. It could further require specifications about the protective conditions foreseen in Article 7 of the Oviedo Convention.</li> </ul>
	<p><b>9. Cooperation with other committees</b></p> <p>a. European Committee on Organ Transplantation (CD-P-TO)</p> <p>b. European Committee on Blood Transfusion (CD-P-TS)</p>



	<p>c. Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)</p> <p>d. Ad Hoc Committee For the Rights of the Child (CAHENF)</p>
<b>Thursday 6 June 2019 (14.30-18.00) - Room 2</b>	
	<p><b>10. Strategic Action Plan</b></p> <ul style="list-style-type: none"> <li>- Presentation of the draft prepared by the Drafting Group</li> <li>- Discussion on the action proposals with a view to identify those which are supported and, where appropriate suggesting new ones, taking into account of the criteria set for their inclusion in the Strategic Action Plan (Specific, Measurable, Achievable, Relevant, Timely/Timed)</li> <li>- Discussion to provide guidance for the Drafting Group with a view to the finalisation of the document and its approval at the 16<sup>th</sup> plenary meeting</li> </ul>
	<p><b>11. Priorities for the 2020-2021 biennium</b>  <u>2020 – 2021 biennium</u></p> <ul style="list-style-type: none"> <li>- Examination of the proposals prepared by the Bureau taking into account the activities considered in the draft Strategic Action Plan</li> <li>- Decision on priority activities for the next biennium with a view to their presentation to the CDDH for approval and presentation to the Committee of Ministers.</li> </ul>
<b>Friday 7 June 2019 (9.00- 13.00) - Room 2</b>	
	<p><b><u>10. Strategic Action Plan</u></b>  <b><u>11. Priorities for the 2020-2021 biennium</u></b>  <i>(to continue where necessary)</i></p>
	<p><b>12. Cooperation activities</b></p> <ul style="list-style-type: none"> <li>- Belarus Action Plan</li> <li>- Armenia Action Plan</li> </ul>
	<p><b>13. Bureau election</b></p> <p>Delegations are invited to proceed to:</p> <ul style="list-style-type: none"> <li>- the election of the Vice-Chair for a 6 months term, renewable once for a one year term.</li> <li>- subject to the result of the election to the Vice-Chair and following the departure of Prof. Miguel Oliveira da Silva, the election of a new Bureau member for a two year terms renewable once.</li> </ul> <p><b><u>Submission for nominations should be sent in writing to the Secretariat by 14.00 on Wednesday 6 June 2019.</u></b></p>
	<p><b>14. Dates of the next meetings</b></p> <p>Dates proposed:</p> <ul style="list-style-type: none"> <li>- 16<sup>th</sup> meeting of the DH-BIO: 19 -21 November 2019</li> <li>- 17<sup>th</sup> meeting of the DH-BIO: 2– 5 June 2020 / 9 – 12 June 2020</li> </ul>

	<b>15. Decisions taken by the DH-BIO at its 15<sup>th</sup> meeting</b> - Approval of the list of decisions
	<b>33. Other business</b> - Rec(2016)8 on the processing of health-related data for insurance purposes, including data resulting from genetic testing: questionnaire on impact at national level. Deadline <u>29<sup>th</sup> June 2019</u>