COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Strasbourg, 30 September 2022 CDBIO/BU RAP (2022) 2

BUREAU OF THE STEERING COMMITTEE FOR HUMAN RIGHTS IN THE FIELDS OF BIOMEDICINE AND HEALTH (CDBIO/BU)

MEETING REPORT
20-21 September 2022 (Paris)

I. Opening

1. Ritva Halila (SF), Chair of the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) opened the meeting. The list of participants appears in Appendix I to this report.

2. Aurélie Pasquier who has recently joint the Human Rights and Biomedicine Division introduced herself to the Bureau. She will take over the responsibility of the dossiers previously ensured by Natalia Zaytseva.

II. Adoption of the draft agenda

3. The agenda was adopted as it appears in Appendix II to this report.

III. Recommendation promoting the use of voluntary measures in mental health care services

4. The Secretariat introduced the two documents prepared by Elaine Gadd (UK), Consultant. The first document identifies the key principles that could be derived from the Compendium of good practices promoting voluntary measures. The second document based on the first one present a draft outline for the new recommendation to be developed by the CDBIO.

5. It was pointed out that the need for appropriate resources refer to in paragraph 9 of the document presenting key principles would need to be properly underlined in the draft recommendation.

6. It was agreed to include a paragraph clarifying that the text, as this was the case with the compendium, focuses on adults. However, mental health issues relevant to adolescents and children may also need to be addressed independently. It was recalled in the context that the new Strategy for the rights of the child has already identified this topic as a priority for possible action in cooperation with the CDBIO.

7. Subject to this addition, the Bureau agreed for the two documents to be presented to the CDBIO as its proposals.

IV. Preliminary draft agenda and order of business of the 2nd plenary meeting (2-4 November 2022)

8. The Bureau finalised the draft agenda/order of business for the meeting which will be held in presential.

9. With regard to the draft recommendation on equitable access to medicinal products and medical treatment in shortage situation, it was pointed out that the recommendation did not prevent member states to go further. It was hoped that the revision made in the draft during the consultation held on 20 September will make it possible to finalise the work and approve the text at the plenary meeting as planned.

10. The Secretariat referred to new activities to be initiated in accordance with the SAP for which groups need to be set up:

- Equitable access to innovative therapy
- Preparation of the mid term report

- Preparation of the Youth Forum: thanks to a voluntary contribution of Ireland, a pilot version of the Youth Forum will be organised in Spring 2023 with young people from Ireland.

11. Delegations will be invited to express their interest in joining those groups. Mark Bale expressed interest in joining the group for the preparation of the Youth Forum. Together with Pierre Mallia, he also volunteered to work in the group which will be in charge of the preparation of the midterm report to be drafted in 2023.

12. The Bureau agreed on the draft agenda and order of business to be sent to delegations.

V. Mid-term report

13. The Strategic Action Plan on Human Rights and Technologies (2020-2025) provides for "the preparation of a midterm report …to be communicated to the Committee of Ministers. The midterm report will contain a review of progress in respect of the objectives and actions in the SAP, and an assessment of their ongoing relevance. "

14. The Bureau agreed to entrust a small group of its members with the preparation of a concept note presenting the objectives and methodology for the development of the midterm report due by the end of 20213 in accordance with the timeline agreed for the SAP.

15. This group will be composed of the Chair and Vice Chair, Mark Bale and Pierre Mallia and will prepare a document to be discussed at the 2nd CDBIO plenary meeting.

VI. Overview of national legislation on the protection of patients' rights

16. The Secretariat recalled that the CDBIO terms of reference, as adopted by the Committee of Ministers, provided for the finalisation, by the end of 2023, of an overview of the national legislation on the protection and promotion of patients' rights.

17. The Bureau agreed for this work to result in a document which would not only be descriptive but could also help identifying possible avenues for future action(s) to improve the protection of human rights in the healthcare field.

18. In this context, reference was made to the evolution in the approach to healthcare over the last decades, with the promotion of a "patients' rights approach". It was recognised though that prevention was an increasing component of healthcare and healthcare systems, explaining a progressive change from a "patients' rights approach" to a "human rights-based approach" where the subject is not anymore a "patient" but a "user of healthcare services".

19. The suggestion was made that, rather than considering a specific list of rights/principles (such as consent, protection of private life, equitable access to health care) and examine how they were reflected in the legislation, consideration could be given to an analysis on how relevant legislation where reflecting and contributing to a "human rights-based approach" in healthcare.

20. With regard to a human rights-based approach, it was underlined that people using health and social care services were entitled to expect that their human rights will be promoted and protected when they require care and support from services. Human rights were about people being treated with fairness, respect, equality and dignity, having a say over their lives and participating as fully as possible in decisions relating to their own healthcare. A human rights-based approach involved empowering people to know and claim their rights to care and

to support, and sought to ensure that the human rights of people using health and social care services were protected, promoted and supported in practice.

21. The Bureau saw value in adopting this broader approach to the question of patient rights. In addition to establishing what protections are in place in existing legislation, standards and guidance, this analysis potentially lays the groundwork for future initiatives. For example, the literature showed that there exists a gap in the knowledge of health and social care staff of how to incorporate a human right based approach into day-to-day practice and there is difficulty in practically applying the legislation as part of everyday care and support. Illustrating good practice in this area can help ingrain human rights into healthcare organisational culture.

22. To that end, a consultant could be entrusted with the preparation of an introductory document identifying the main themes and provisions/measures to be included in legislation to promote/facilitate the implementation of a "human rights-based approach" in health care.

23. This document could then provide a basis for a short questionnaire addressed to delegations of member states for them to indicate the relevant provisions in their national legislation that correspond to the themes/measures identified in the study.

24. This work could also cover the implementation of a human right-based approach in specific crisis situations, such as the one caused by the Covid-19 pandemic.

25. Subject to the approval of the proposal by the CDBIO, the timeline for this work could be as follows:

- Consultant document to be finalised in March 2023
- Short questionnaire presented to the CDBIO in June 2023
- Responses to the questionnaire compiled and presented to the CDBIO and Committee of Ministers by the end of 2023, together with a short analysis identifying possible avenue(s) for action

VII. PACE Recommendation 2233 (2022) – "Addiction to prescribed medicines"

26. On the basis of a draft prepared by the Secretariat, the Bureau finalised the comments on PACE Recommendation 2233 (2022) taking into account the comments received from delegations. The text of comments appears in appendix III to this report.

VIII. Date of the next meeting

27. The Bureau agreed on the date of 18 (14h00) - 20 (13h00) April 2023, in Paris, for its next meeting.

IX. Other business

a. Discussion on the relevance of a possible declaration on health-related issues and migrants and refugees

28. The Bureau noted that the CDBIO, in the priorities revised in the light of the pandemic and the socio and demographic changes, including those linked to conflict situations, has already pay specific attention to the situation of migrants and refugees as illustrated by the close cooperation developed with the Office of the Special Representative of the Secretary General or migration and refugees in the actions under the Equity pilar of the SAP. It would seem more relevant to keep these topics throughout the actions undertaken. Here relevant a more targeted action could be considered in the next SAP.

b. Genome editing: communication strategy for the publication of conclusion of the re-examination of Article 13 (doc. CDBIO(2022)7 Final clarification ER Art.13 e)

29. The Bureau was informed that the clarifications adopted in June by the CDBIO will be presented to the Committee of Ministers on 27 September. They will then be published online with an interview of Anne Forus, Chair of the Drafting Group on Genome Editing and Pete Mills, member of the Drafting Group on Genome Editing, who will present their background and content.

c. Neurotechnologies: preparation of the publication of the rapporteur's report of the round table

30. The Bureau was informed that the communication strategy for the publication and possible follow up to the round table will be discussed with the OECD. The outcome of the discussion will be presented to the CDBIO at its 2nd plenary meeting.

d. Request from the CD-P-TO on the issue of "reasonable remuneration"

31. Dr Beatriz Dominguez Gil, member of the CD-P-TO presented and provided clarifications on the request made in a letter from the CD-P-TO Chair and Vice Chair addressed to the Chair of the CDBIO on "*the possibility of analysing and elaborating guidance for the interpretation of what may constitute reasonable remuneration for services rendered in the provision of organs, tissues and cells for transplantation/human application or preparation of other therapies involving human organs, tissues and cells as starting material*."

32. Following the presentation, the Bureau acknowledged that the question put raised many very complex issues and not necessarily relevant to the question of "reasonable remuneration", including transparency but also eventually the issue of equitable access to those therapies. Reference was made in the context to the work to be undertaken by the CDBIO in the context of its SAP on equitable access to innovative treatment and technologies in healthcare. The Representative of the CDBIO in the CD-P-TO, Assunta Morresi (I), will present this work at the 28th CD-P-TO meeting to be held in Warsaw on 6 and 7 October 2022.

33. The suggestion was made for the CD-P-TO to participate in this work, including where considered appropriate in designating an expert for the drafting group to be set up by the end of the year.

e. Rapporteur's report on the seminar on early intervention on intersex children

34. The Bureau was informed that the report of the seminar should be finalised by the rapporteur for the next plenary meeting.

Appendix I
List of participants

Bureau members / Membres du Bureau

Czech Republic/République Tchèque

Doc. JUDr. Tomáš DOLEŽAL
Head of the Department of Private Law and Head of the Research Unit for Medical Law and Bioethics
Czech Academy of Science
Institute of State and Law

Finland / Finlande

Prof. Ritva HALILA — Chair
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Prof. Siobhan O'SULLIVAN — Apologised
Royal College of Surgeons
Dublin

Italy / Italie

Prof. Assunta MORRESI
Dipartimento di Chimica, Biologia e Biotecnologie
Università degli Studi di Perugia
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Malta / Malte

Prof. Pierre MALLIA
Professor of Family Medicine, Bioethics & Patients' Rights
Chairperson, National Health Ethics Committee, Dept. of Health
Chairperson, Bioethics Consultative Committee, Ministry of Health, Coordinator
Bioethics Research Programme, Univ. of Malta, President, Malta College of Family Doctors

United Kingdom / Royaume-Uni

Dr Mark BALE
Advisor to the Science Research and Evidence Directorate
Department of Health and Social Care

CD-P-TO (via Bluejeans)

Dr Beatriz DOMINGUEZ-GIL
Spain

SECRETARIAT

Department of Biological Standardisation - OMCL Network & HealthCare (DBO) EDQM - European Committee on Organ Transplantation

Ms Marta LOPEZ-FRAGA, Secretary of the CD-P-TO (via Bluejeans)

Directorate General I – Directorate of Human Rights – Human Rights and Biomedicine Division

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Appendix II
Agenda

I. Opening

II. Adoption of the agenda

III. Recommendation promoting the use of voluntary measures in mental health care services

- Examination two documents prepared by Dr Elaine Gadd, consultant
  - a document presenting key principles for the development of the draft recommendation
  - a draft outline for a recommendation promoting the use of voluntary measures in mental health care services

with a view to the presentation of a preliminary draft Recommendation to be presented to the CDBIO at its 2nd plenary meeting.

IV. Preliminary draft agenda and order of business of the 2nd plenary meeting (2-4 November 2022)

- Agreement on the draft agenda/order of business

V. Midterm report

- Discussion on proposals for the preparation of the midterm report (and possible new priorities) to be submitted to the CDBIO

VI. Overview of the national legislation on the protection of patient's rights

- Discussion on the best approach and the scope of a possible questionnaire to collect relevant information with a view to a decision at the 2nd plenary meeting

VII. PACE Recommendation 2233 (2022) – "Addiction to prescribed medicines"

- Finalisation of the comments to be sent to the Committee of Ministers

VIII. Date of the next meeting

IX. Other business

a. Discussion on the relevance of a possible declaration on health-related issues and migrants and refugees
b. Genome editing: communication strategy for the publication of conclusion of the re-examination of Article 13 (doc. CDBIO(2022)7 Final clarification ER Art.13 e)
c. Neurotechnologies: preparation of the publication of the rapporteur's report of the round table
d. Guidance request from the CD-P-TO on the issue of "reasonable remuneration"
   Doc. Letter from the Chair and Vice Chair of the CD-P-TO
   The former chair of the CD-P-TO will present the request made to the CDBIO on "*the possibility of analysing and elaborating guidance for the interpretation of what may constitute reasonable remuneration for services rendered in the provision of organs, tissues and cells for transplantation/human application or preparation of other therapies involving human organs, tissues and cells as starting material*."


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e. Rapporteur's report on the seminar on early intervention on intersex children

Appendix III

Comments of the CDBIO on PACE Rec 2233(2022) - Addiction to prescribed medicine
finalised by the CDBIO Bureau in the light of the remarks
received from delegations, at its meeting on 21 September 2022

1. At its 1437th meeting at Deputies level (15 June 2022), the Committee of Ministers agreed to communicate PACE Recommendation 2233 (2022) – "Addiction to prescribed medicines" to the Council of Europe International Cooperation Group on Drugs and Addictions (Pompidou Group), to the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO), to the Governmental Committee of the European Social Charter and European Code of Social Security (GC), to the European Committee of Social Rights (ECSR) and to the European Committee for Social Cohesion (CCS), for information and possible comments.

2. The CDBIO examined PACE Recommendation 2233 (2022) – Addiction to prescribed medicine, and agreed to entrust its Bureau with the task of finalising its comments using as a basis of the remarks sent by delegations.

3. The CDBIO underlines that PACE Res 2441 (2022) covers aspects which are outside its field of competence which focuses on human rights protection in the fields of biomedicine and health. It is within this framework, that it agreed on the following comments.

4. It notes that the main concern of the PACE is the addiction to prescribed medicines as reflected in the title of the Recommendation. However, paragraph 2.1 refers to different points, which in themselves would justify specific attention i.e., patients' rights, effective access, essential medicines and dependency.

5. The CDBIO agrees with the importance of respect of patient rights as laid down in the Convention on Human Rights and Biomedicine, which include the right to equitable access to healthcare of appropriate quality, laid down in Article 3 of the Oviedo Convention. Medicinal products are essential component of health care. It wishes to underline in this context, the work currently carried out in the framework of its Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020 – 2025), in particular in relation to equitable access to healthcare, with the development of a recommendation on equitable access to medicinal products and medical equipment in situation of shortage.

6. In its Recommendation, the PACE refers to "essential" medicines". The CBDIO wishes to raise the question as to whether limiting the scope of a possible recommendation to such category of drugs would be appropriate with the regard to the issue of dependency, as well as access to healthcare of appropriate quality i.e., meeting the needs of the persons concerned to ensure protection of his or her health.

7. The CDBIO agrees with the overall concerns supporting the Recommendation of the PACE. Should the Committee of Minister decide to follow the recommendation of the PACE, the CDBIO would be ready to contribute to this work in accordance with its terms of reference. However, it considers that the exact terms and scope of a possible legal instrument to address the issues raised by the PACE would need to be clarified.