Strasbourg, 25 June 2024 CDBIO/RAP5

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

5th meeting

11-13 June 2024

Report

I. Adoption of the agenda

1. Siobhan O'Sullivan (Ireland), CDBIO Chair, opened the meeting and welcomed the new members of the Committee. The list of participants appears in Appendix I to this report.

2. The agenda was adopted. It appears in Appendix II of this report.

3. The delegations, invited to express views on the change of format of the meeting (start at 14h of the first day and finished at 16h in the last), agreed to go back to the usual time schedule at the next plenary.

II. Equitable and timely access to appropriate innovative treatments and technologies in healthcare

4. The Chair invited Tomáš Doležal (Czech Republic), Chair of the Drafting Group, to introduce the outline of the draft white paper having regard to the motivation behind this work, differentiating it from past challenges, and referring both to the previous discussion paper and to Recommendation CM/Rec(2023)1 on "Equitable access to medicinal products and medical equipment in a situation of shortage".

5. It was recalled that the CDBIO had decided not to prepare a recommendation, considering that the approach and form of a white paper would be more appropriate having regard to how the general and procedural principles of Recommendation CM/Rec(2023)1 "Equitable access to medicinal products and medical equipment in a situation of shortage" might apply to the decision-making processes for ensuring equitable access to innovative treatments and technologies.

6. The Chair of the Drafting Group presented the considerations supporting the outline. This included the need to address a wide range of health conditions beyond those considered to be life-threatening involving resources in situations of shortage as long as the safety and efficacy of the innovative (novel, non-conventional) treatments and technologies concerned are supported by scientific evidence. Reference to ECHR jurisprudence on experimental treatments and a new chapter on possible tensions between individual rights and public health needs were also to be included.

7. Prof. Kristof Van Assche (B), consultant, presented in detail the outline, notably the definition and characteristics of innovative treatments and technologies, their potential benefits, various challenges related to equity (affordability, accessibility, complexity in decision making), balancing individual rights and public health needs, and assessing the need for additional principles.

8. Exchanges with delegations highlighted the need for clarification as to the criteria to be applied in determining access to innovative treatments and technologies, the coverage of areas already highly regulated (e.g. organ transplantation), the terminology and meaning of medical devices, and the reference to ethical committees.

9. As regards the section on definition and characteristics of innovative treatments and technologies in healthcare, discussions focused on the definition of "treatments" and the distinction between "treatments" and "technologies", especially whether technologies should be considered separate to or are an integral (assistive) part of treatments. Further, the scope of treatments and technologies (having a therapeutic purpose) to be covered was considered, especially whether this includes treatments as measures of prevention and technologies used in prevention (e.g. mHealth). There was also discussion on the characteristics of treatments as they relate to technology and as they relate to other features, such as the personalisation of

treatments and the irreversibility of certain treatments (e.g. gene therapy), potentially impacting on equitable access to healthcare.

10. As regards the section on challenges related to equity, accessibility, availability and affordability were discussed and distinguished having regard inter alia to different practices, their financial implications, the inequities at national and international levels, and the sustainability of treatments supported by technologies.

11. As regards the section on complexity of decision making, there was emphasis on addressing who decides what is "reasonable" when granting access to treatments and technologies, also noting the roles played by ethics committees.

12. As regards the section on balancing individual rights and public health needs, a range of issues were raised, including the type of (individualistic approach vs communitarian approach) public health system, the level of public health to be attained (highest attainable level of public health and/or equitable access to healthcare of appropriate quality), the affordability of healthcare as a determinant of equitable access to it, differentiation between individual advantages and collective benefits. It was noted that there is a need to reflect on what access to healthcare is available and which are the challenges, with a view to making some suggestions; and, possibly, leading to a revision of the section heading to reflect diversity in approaches taken by member states.

13. CDBIO delegations were invited to send any written comments on the outline to the Secretariat at the latest by 28 June 2024.

III. Other business

a. Follow up to the Guide to children's participation in decisions about their health

14. The Secretariat recalled that the Guide to children's participation in decisions about their health available was available online in two versions (web and PDF). It renewed its call to disseminate the Guide widely. It thanked those delegations which had already taken steps to translate the Guide in their national language and invited others to do so.

15. The Secretariat also updated delegations on the steps taken to develop child friendly materials based on the guide.

16. It also informed that the Guide will be launched in April 2025 during a conference organized by CDENF for the mid-term review of the Strategy for the rights of the child (2022-2027).

17. Delegations were encouraged to keep an eye open for any event in their country that could provide an opportunity to promote this work and to liaise with the Secretariat. In this respect the CDBIO was informed that the Guide will be presented at the Conference of the European Society of Health Law which will take place in September 2024 in Warsaw.

b. Armenia Action Plan

18. The Secretariat informed about the results of and activities planned in the cooperation project "Human rights in biomedicine II", in Armenia (See power point presentation in appendix IV to this report). The project is focused namely in aligning national legislation in biomedicine and healthcare with the principles laid down in the Oviedo Convention, strengthening the skills of legal and health care professionals and promoting public dialogue. Among the achievements, the signature on 16 May 2024 of the Oviedo Convention and substantial progress achieved towards the ratification, including aligning the Armenian legislation with the Oviedo Convention when it comes to the prohibition of sex selection, were underlined.

19. The success of the activities carried out and engagement of all stakeholders in this cooperation project have been a source of inspiration and strengthened the interest regarding cooperation programs in this field, namely under the action plans in Georgia, Ukraine and Moldova.

20. Two new pillars were added in the programme in response to the refugee crisis linked to the conflict in the Nagorno-Karabakh region: reintegration of health care professionals from Nagorno-Karabakh in the general health care system and the mental health support needed to cope with post-traumatic situation.

21. A third cooperation project in Armenia was being prepared with follow up activities based on the results of the current project, in particular in relation to mental health using as a basis the HELP course on human rights and mental healthcare being currently finalized.

c. Gender equality

22. Cécile Gréboval, Administrator in the Gender Equality Division of the Council of Europe, presented the Gender Equality Strategy 2024-2029 which includes reference to gender stereotypes, violence against women, equal access to justice, and gender mainstreaming. The Strategy also seeks to address gender-based discrimination in AI systems and to review the Committee of Ministers Recommendation on gender differences in health policy. The Strategy also foresees cooperation with the CDBIO, where appropriate.

23. Iuliia Davydova (Ukraine), gender equality rapporteur to the CDBIO, presented gender-related concerns in biomedicine, especially noting the considerable amount of time that women spend in poor health due to difficulties in receiving correct diagnoses by (male) doctors. She stated that this relates to a lack of biomedical research on female subjects and the unequal amount of references made to female authors in research.

24. The CDBIO took note of the proposals made by its gender equality rapporteur with a view to integrating this theme in its strategic action plan 2026-2030.

d. PACE Recommendation 2275(2024) – “Ending the detention of “socially maladjusted” persons”

25. Pierre-Alain Fridez (CH), member of the Parliamentary Assembly, presented the PACE Recommendation on “Ending the detention of “socially maladjusted” persons”. He referred to the discussion held on the language of Article 5 of the European Convention on Human Rights. An evolution of the terms used was considered appropriate namely with regard to the persons with mental health problems, to make a distinction between crisis situations that may occur and the mere existence of a mental health problem.

26. One delegation raised a point on the lack of consultation of other committees of the PACE, namely the Committee on Legal Affairs and Human Rights and on the process adopted. The Secretariat clarified that the invitation to make comments on the recommendation was on content and that the procedure followed for the adoption of the recommendation by PACE was relevant to the latter’s internal procedure.

27. As the Steering Committee for Human Rights (CDDH) had also been invited to make comments on the PACE recommendation, Delegations may wish to liaise with their national delegation in this steering committee to exchange views on the PACE recommendation in the light of the complementary expertise of the committees.

28. The Chair thanked the presence and presentation of the PACE.

29. **Delegations were invited to send their comments on the PACE Rec 2275(2024) by 28 June 2024.** The Bureau was entrusted with the task of preparing the CDBIO comments to be sent to the Committee of Ministers, on the basis of the delegations' comments and the relevant work of the CDBIO.

e. Neurotechnology

30. The Chair informed about the draft report on the analysis of the existing human rights framework with regard to the human rights issues raised by neurotechnologies and their applications prepared by Prof. Roberto Andorno (CH), consultant. This report will soon be finalized and sent to all delegations. She underlined the importance of this work for deciding the next steps to take.

31. The Committee entrusted the Bureau with the task of proposing a way forward on the work on neurotechnologies and human rights based on the report prepared by Prof. Roberto Andorno.

32. The Secretariat informed the CDBIO about a Report on the Privacy and Data Protection Implication of the use of Neurotechnology and Neural Data from the Perspective of Convention 108 prepared by Prof. Marcelo Ienca (CH) and Dr Eduardo Bertoni (USA) for the T-PD and presented on 5th June at the Committee's plenary session. The report will be shared with all CDBIO delegations. On the basis of this report the T-PD agreed to develop guidelines on neurodata.

33. The Secretariat informed on the consultation that UNESCO initiated as part of the process to develop a draft Recommendation on the Ethics of Neurotechnology. The consultation is opened until 12th July 2024. The experts' group in charge of this work will then revise the draft in the light of the comments received. The revised draft will then be discussed at intergovernmental level.

34. It was agreed for the CDBIO not to send comments to UNESCO on the draft at that stage but to wait for the discussion at intergovernmental level (2025). However, in this prospect, it would be useful if delegations wishing to participate already in the current consultation could send copy of their comments to the Secretariat.

35. One delegation asked for more details on the dates and phases of discussion of UNESCO's Recommendation on the Ethics of Neurotechnology with the concern of avoiding possible clash with other meetings. The question will be addressed to UNESCO but some information was already provided in the document on developments in other intergovernmental organisations.

f. Xenotransplantation

36. The Chair informed about the invitation to CDBIO sent by CD-P-TO to take part in the project to develop a State of the art on xenotransplantation. The first meeting of the working group entrusted with this task will take place between the 24th and 26th of June 2024.

37. **Delegations were invited to express their possible interest in joining the Group set up by the CD-P-TO by Tuesday 18 June 2024.**

IV. Dates of the next meetings

38. The CDBIO agreed to hold its next meetings on:

- 6th meeting of the CDBIO: 26-29 November 2024, in Strasbourg
- 7th meeting of the CDBIO: 3-6 June 2025, in Strasbourg

39. It was mentioned the possible need to alter the date of the 7th plenary meeting according to the European Parliamentary Sessions Calendar, still to be approved.

V. Draft Recommendation on respect for autonomy in mental healthcare

40. The Chair invited Elaine Gadd (UK), consultant, to present the main changes which had been brought to the draft Recommendation since the last CDBIO meeting. The amendments reflected the comments received during the targeted consultation exercise conducted between December 2023 and February 2024, as well as the conclusions of the discussions held by the members of the Bureau when they met in April 2024. The consultant highlighted that the comments and changes made were mostly on clarity, simplification, and terminology.

41. The Chair recalled that the objective for the discussion was to finalize the text of the draft Recommendation, in view of its approval in November 2024. It was stressed that the explanatory memorandum (EM) did not require formal approval; yet its content should adequately reflect the views of the drafters.

42. Members of the INGOs present voiced a general satisfaction with the process of consultation and progress made on the text, although they highlighted that the revised text did not reflect all of the comments they had sent. In particular, they noted that there could still be a greater degree of alignment with the UN Convention on the Rights of Persons with Disability (UNCRPD) and that the text could provide more details in respect to monitoring and compliance mechanisms.

43. Firstly, there were a couple of points made on the form. One delegation questioned the use of the term “Guidelines” as a heading for the second part of the Recommendation. The Secretariat provided clarification stressing that this was a common form for CM recommendations (see e.g. Rec (2016)6 on research on biological materials of human origin).

44. Secondly, there was a discussion about the suggested reference, in the preamble, to the draft Additional Protocol on the protection of human rights and dignity of persons with regard to involuntary placement and treatment within mental healthcare services (Draft AP). Several delegations expressed uncertainty about the adoption of a text that referred to another instrument that was not yet adopted.

45. It was recalled that the Committee of Ministers had entrusted CDBIO with the preparation of a package of deliverables (recommendation, draft Additional Protocol, report on caselaw of the European Court of Human Rights, compendium of good practices, declaration), with a view to improving the protection and the autonomy of persons in mental health care services. Even if the Committee of Ministers were to examine both texts at the same time, the process and timeline for their adoptions differed (the CM being required to consult the Parliamentary Assembly on any draft legally binding instrument).

46. Several delegations agreed that not referring at all to the draft additional protocol would not be an acceptable alternative. Several options were discussed, including referring to the “preparatory work of the Committee on the Draft AP” (rather than to the instrument itself), or referring to the draft additional protocol in a footnote. Delegations indicated a preference for the latter solution. The Secretariat planned to consult the Legal Advice Division on this point.

47. Regarding the substance of the draft, a couple of points of a general nature were made. Firstly, one delegation expressed concern over the fact that the recommendation focused “only” on the aspect of “autonomy” in mental healthcare, which in its view, may be perceived as being too narrow. However, the Committee confirmed that this was precisely the object of the text, and that autonomy had a wide range of application.

48. Regarding the general objective of the recommendation stated in Article 1, it is stated in the explanatory memorandum (EM) that the long-term objective is to “eliminate” the resort to coercion. One delegation questioned whether this goal was realistic and/or even desirable. It

was recalled that the recommendation left room for exceptions to the general rule (article 3.2). Another delegation pointed to the fact that both the terms “ultimate” and “eventually” were used in the EM and called for a harmonization. The Committee considered that the terms were synonyms in English and that the word “*ultimate*” brought more clarity.

49. Regarding Article 4, one delegation suggested an addition by replacing “mental healthcare” with “healthcare responsive to their needs”. The majority of delegations found this to be unnecessary.

50. Regarding Article 7 dealing with information on rights, some delegations expressed the view that the term “rights” was too vague and should be characterized. It was agreed to rephrase by specifying that “(*P)ersons should be individually informed of their rights in respect of mental healthcare*’.

51. On Article 8 dealing with advance care planning, it was suggested to bring clarification as whom should ensure that the wills and preferences of persons concerned are documented. It was felt that with the current wording, the onus was on the person concerned. To better reflect the responsibility of the healthcare professionals in that respect, the wording was revised, stating that “Persons concerned should be encouraged to express their will and preferences for their future care *and these should be documented*”. Discussions underlined the need for the EM to define “care” which was not to be understood as being limited to healthcare here.

52. On Article 11, there was a discussion on the term “social network” and its possible translation in other languages. After discussing how broadly should the person’s circle of relations be considered, the expression was retained considering that it represented the right group of people to be considered for the purpose of the article. In English, the expression does not have the connotation it has in French (“*réseaux sociaux*” tend to refer the internet / online networks).

53. An editorial amendment was made to Article 12.2, removing ‘*of the persons concerned’*.

54. Regarding Article 13, there were doubts expressed in respect of the term “recovery” and the phrase “autonomy as a human rights principle” but this did not lead to changes in the text.

55. Regarding Article 19 dealing with monitoring, some voices called for a more detailed provision. A majority of delegations agreed however that text should not prescribe any specific mechanism and that it was up to Member States to decide how to best ensure their monitoring obligations. As to the involvement of persons with lived experience in monitoring activities, it was recalled that Article 6 already included an explicit reference to this.

56. **Delegations were invited to send written comments on the draft Explanatory memorandum by 28 June 2024.**

VI. Youth Forum

57. Stéphanie Burel, Administrator in the Youth Policy Division, presented the Council of Europe’s commitment to the early integration of a youth perspective (aged between 18-30 years) in its work, as referred to in the Reykjavik Declaration adopted by the Heads of States and Governments in May 2023. Policy options, methodological guidelines, and an action plan are being developed, as part of a mandated Council of Europe wide reference framework, to assist committees and structures in this integration.

58. The importance of meaningful youth participation in intergovernmental work was underlined by Jessý Jónsdóttir, member of the Council of Europe Advisory Council of Youth (CCJ), who expressed interest in supporting the CDBIO’s efforts, which includes the creation of networks of sustainable and honest dialogues with young people.

59. Mark Bale (UK), Chair of the Drafting Group on Youth, echoed the importance of youth dialogues and capacity building and highlighted the opportunity to address national ethics committees in order to collect good practice on youth engagement.

60. The CDBIO agreed to step-up its focus on the integration of youth perspectives, in particular by designating Mark Bale (UK) as rapporteur on youth and by inviting the CCJ to participate in its work to develop a new strategic action plan 2026-2030. The Committee also agreed to carry out a survey on national practices and experiences on youth engagement on ethical and bioethical topics, as a follow-up the Secretariat's participation in the 14th Global Summit of National Ethics Committees (NECs), held in San Marino on 17-19 April 2024.

VII. Artificial intelligence and biomedicine

61. Joni Komulainen (FI), Chair of the Drafting Group, presented the updated report on the impact of AI on the 'patient-doctor' relationship, highlighting main changes to it as a result of comments and suggestions by CDBIO delegations and by respondents to the targeted consultation.

62. Upon careful examination, the CDBIO decided to delete reference to "health systems" (in para 12) and the sentence "They [health professionals] cannot be held liable for AI system errors" (in para 44).

63. On this basis, the CDBIO approved the report and thereafter to publish it, **subject to any possible editorial comments to be sent to the Secretariat by 8 July 2024.**

64. The representative of WHO welcome this work which is cutting edge. He congratulated working team and also informed about the work of WHO on ethics of AI including clinical ethics.

65. The CDBIO also welcomed the proposal of the Ministry of Social Affairs and Health of Finland to organise a conference on the report, to launch and further discuss its implications.

66. The Committee exchanged with Kristian Bartholin, Secretary to the Committee on Artificial Intelligence, who presented the new Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law" adopted by the Committee of Ministers on 17 May 2024. Exchanges with delegations discussed the framework nature of the instrument and how sector-specific committees, such as the CDBIO, can use it as a legal basis on which to develop its own further work regarding AI systems.

VIII. Preparation of a new strategic action plan (SAP(2026-2030))

67. Dr Federica Lucivero (UK), consultant, presented the Report of the Horizon scanning exercise (questionnaire and event held on 3 April 2024). Her presentation appears in Appendix to this report. Four technological areas were identified by combining the findings: AI, Robotics and the impact of digital developments on data; gene editing and advanced genetic therapies; stem cells research; and neurotechnology.

68. When it comes to healthcare and social trends, challenges were highlighted on equitable access to healthcare, on more systemic way of thinking health, digital transition, vulnerable groups, as well as those at the core of ongoing debates such as, assisted reproduction, end of life, but also centralization of research ethics governance and climate change and degradation of the environment.

69. Some gaps were identified in current ethical tools and guidelines to address emerging issues in research ethics and professional standards, consent and right to information, crises preparedness, human rights in cases of infections; and tissues/cells donations in assisted

reproduction. Different ways of addressing those gaps include, in addition to developments of legislation or guidelines, anticipatory governance, engagement civil society as well as education and capacity building. Some considerations for the CDBIO include to have a critical look to technologies trends, meaningful engagement with stakeholders (including in the private sector), to take into account the diversity in healthcare systems; and to broadening bioethics maintaining the focus. But also to have a close perspective to the role of human rights and bioethics to be presented as enablers for innovation but also as a way to provide critical perspective and ensure responsible approach.

70. Following the presentation, the suggestion was made to have an executive summary presenting the big themes.

71. One delegation pointed out that quite a number of responses to the questionnaire mentioned assisted reproduction which could be more underlined in the report.

72. The representative of WHO pointed out the difficulties for international organization to prioritise. He invited the CDBIO consider what is the comparative advantage for the committee to work on a particular topic. When it comes to AI and research ethics, he considered the Oviedo Convention was one of the most important instruments and it would be interesting to consider how AI will change research (potentially no more bench work) and research ethics. It would be interesting to explore this intersection.

73. Inquired by the Chair about climate change and relevant work done by WHO, he referred to the guidelines that are being prepared in the Ethics of Climate Change. Guidance was expected to be finalized next year. Relevant documents and information will be shared with CDBIO.

74. Another delegation referred to safety issues raised by technologies but also health care in general and asked about possible work done by WHO. It was pointed out that patient rights may be one of the pilar/main trend in the new SAP.

75. The Chair pointed out that many topics mentioned were familiar but that the discussion around the topics was changing with more and more convergence between fields. She thanked Dr Lucivero for her work and on this occasion also all those having contributed to the horizon scanning exercise.

76. **Delegations were invited to send possible additional comments on the report prepared by Dr Lucivero <u>by 28 June 2024</u>.**

77. It was agreed to set up a drafting group in charge of developing a new draft strategic action plan on human rights in biomedicine and health (2026-2030). The Group will have to look at the different topics identified and do a prioritisation exercise in the light of the mandate of the CDBIO, the added value of the possible outcome of the work that could be undertaken and its feasibility. It should therefore be composed of members of the CDBIO (around 8 to 9 members respecting a geographical balance). However, this would not prevent, at one point in the SAP development process, calling upon some specific expertise outside the group, including among the experts having participated in the horizon scanning event. The group will use as a basis the outcome of the horizon scanning exercise organized to that end.

78. **Delegations were invited to express interest in joining the Drafting Group <u>by 28 June 2024</u>.**

79. The first meeting of the Drafting Group will take place in Paris on 24-25 September 2024, back to back with the Bureau meeting.

IX. <u>Adoption of decisions taken by the CDBIO at its 5th meeting</u>

80. In the absence of opposition, the abridged report resented to delegations at the end of the meeting, was adopted on Tuesday 18 June 2024.

Appendix I
List of participants

MEMBERS / *MEMBRES*

ALBANIA / *ALBANIE*	Awaiting nomination / *Nomination en attente*
ANDORRA / *ANDORRE*	Awaiting nomination / *Nomination en attente*
ARMENIA / *ARMENIE*	**Izabel ABGARYAN** Chair of the Medical Ethics Committee
AUSTRIA / *AUTRICHE*	**Benjamin BACHL** Head of Competence Center Federal Ministry of Social Affairs, Health Care and Consumer Protection Section VI - Human Medical Law Department VI/A/2 – Competence Center for Genetic Engineering **Sabine FASCHING** **Apologised/Excusée** Federal Chancellery Secretariat of the Bioethics Commission **Lilo MARTINI** Legal Officer Federal Ministry of Social Affairs, Health, Care and Consumer Protection Directorate General VI – Human medicine law and health telematics A/4 – Department of legal affairs concerning medical products, medical devices, pharmacies, hospitals and communicable diseases **Ulrich PESENDORFER** **Apologised/Excusé** Ministry of Justice and jurisdiction **Andreas VALENTIN** **Apologised/Excusé** Member of the Bioethics Commission
AZERBAIJAN / *AZERBAÏDJAN*	**Ismayil S ZULFUGAROV** **Apologised/Excusé** Head of Proteomics Lab Institute of Molecular Biology and Biotechnologies of the Azerbaijan National Academy of Sciences
BELGIUM / *BELGIQUE*	Awaiting nomination / *Nomination en attente*
BOSNIA AND HERZEGOVINA / *BOSNIE-HERZÉGOVINE*	**Dalibor PEJOVIĆ** Head of Unit for Statistics and Analytical Affairs and Reporting in Health Department for Health **Dunja PEJOVIC** **Apologised/Excusée** Coordinator of the Regional Health Development Center for Mental Health in SEE Ministry of Civil Affairs
BULGARIA / *BULGARIE*	**Vihra MILANOVA** **Apologised/Excusée** Head of Psychiatric Clinic

	Alexandrovska University Hospital
CROATIA / *CROATIE*	**Vanja NIKOLAC** **Apologised/Excusée** Head of Service, Service for blood, tissues and cells inspection Ministry of Health
CYPRUS / *CHYPRE*	**Zoe KYRIAKIDOU** **Apologised/Excusée** Member of the Cyprus National Bioethics Committee **Constantinos N. PHELLAS** **Apologised/Excusé** Chair of the Cyprus National Bioethics Committee University of Nicosia
CZECHIA / *TCHEQUIE*	**Tomáš DOLEŽAL** Ph.D., LL.M., 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 **Hana KONEČNÁ** Ph.D., University of South Bohemia in České Budějovice
DENMARK / *DANEMARK*	**Berit Dea HVOLBY** **Apologised/Excusée** Head of Section, Personalized Medicine, Research and Privacy Ministry of Health
ESTONIA / *ESTONIE*	**Aime KEIS** **Apologised/Excusée** ViceChair of the National Committee on Bioethics and Human Research University of Tartu
FINLAND / *FINLANDE*	**Maija MIETTINEN** Ministerial Advisor Ministry of Social Affairs and Health General Secretary, National Advisory Board on Social Welfare and Health Care Ethics (ETENE) **Katja PASANEN** Legal Officer Unit for Human Rights Courts and Conventions Legal Service Ministry for Foreign Affairs
FRANCE	**Kamyar ASSARI** Consultant juridique Sous-direction des droits de l'Homme Direction des affaires juridiques Ministère de l'Europe et des Affaires étrangères **Lucie BOZEC** Chargée de mission greffe Bureau bioéthique, éléments et produits du corps humain (PP4) Direction générale de la Santé (DGS) Ministère de la Santé et de la Prévention **Estelle FAUCHARD** **Apologised/Excusée** Rédactrice Bureau du droit des personnes et de la famille Sous-direction du droit civil Direction des affaires civiles et du sceau (DACS)

	Ministère de la Justice **Jacques MONTAGUT** Ancien membre du CCNE **Diane RICHARD** Bureau du droit des personnes et de la famille Sous-direction du droit civil Direction des affaires civiles et du sceau (DACS) Ministère de la Justice
GEORGIA / *GÉORGIE*	**Givi JAVASHVILI** Head of Family Medicine Department Tbilisi State Medical University Chairman of the National Council on Bioethics
GERMANY / *ALLEMAGNE*	**Elmar DOPPELFELD** Honorary Chair of the "Permanent Working Party of Research Ethics Committees in Germany Inc." **Carlo GRIMM** Division 611 Federal Ministry of Education and Research **Ingo HÄRTEL** Division 316 Federal Ministry of Health **Thomas HEINEMANN** Philosophical-Theological University of Vallendar (PTHV) **Judith MENTGEN** Head of Division III A 6 – Insurance law; IOPC-Funds; UNCITRAL; bioethics; genetic diagnostics Federal Ministry of Justice **Vincent WÄCHTER** **Apologised/Excusé** III A 6 – Insurance law; IOPC-Funds; UNCITRAL; bioethics; genetic diagnostics Federal Ministry of Justice
GREECE / *GRECE*	**Alexandra TSAROUCHA** Professor of Experimental Surgery School of Medicine Democritus University of Thrace
HUNGARY / *HONGRIE*	**Tamás KARDON** Associate professor, Secretary of the Scientific and Research Ethics Committee of Medical Research Council
ICELAND / *ISLANDE*	**Kristín Ninja GUDMUNDSDÓTTIR** **Apologised/Excusée** Legal Advisor Ministry of Health
IRELAND / *IRLANDE*	**Siobhán O'SULLIVAN** Royal College of Surgeons

ITALY / *ITALIE*	**Assunta MORRESI** Prof. Associato di Chimica Fisica, Dipartimento di Chimica, Biologia e Biotecnologi Università degli Studi di Perugia **Laura PALAZZANI** **Apologised/Excusée** Lumsa, Facoltà di giurisprudenza Roma
LATVIA / *LETTONIE*	**Signe MEŽINSKA** Associate Professor, Faculty of Medicine Senior Researcher, Institute of Clinical and Preventive Medicine University of Latvia
LIECHTENSTEIN	Awaiting nomination / *Nomination en attente*
LITHUANIA / *LITUANIE*	**Asta ČEKANAUSKAITĖ** Director of Lithuanian Bioethics Committee
LUXEMBOURG	Awaiting nomination / *Nomination en attente*
MALTA / *MALTE*	**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
REPUBLIC OF MOLDOVA / *RÉPUBLIQUE DE MOLDOVA*	**Vadim AFTENE** Head General Department of Policies in the Field of Integrated Medical Services Ministry of Health
MONACO	**Thomas ALTHAUS** **Apologised/Excusé** Médecin de Santé Publique Direction de l'Action Sanitaire
MONTENEGRO / *MONTÉNÉGRO*	**Olivera MILJANOVIC** MD, PhD, Head of Centre for Medical Genetics and Immunology – Clinical Centre of Montenegro, Chief lecturer of biomedicine, bioethics, clinical genetics and pediatrics at the Faculty of Medicine University of Montenegro
NETHERLANDS / *PAYS-BAS*	**Harrie STORMS** Ministry of Health, Welfare and Sports **Sanne VAN WEEZEL** **Apologised/Excusée** Ministry of Health, Welfare and Sports
NORTH MACEDONIA / *MACÉDOINE DU NORD*	**Jovan GRPOVSKI** State Counsellor Ministry of Health
NORWAY / *NORVEGE*	**Anne FORUS** Senior Adviser, ph.d, Biotechnology and health legislation department Division of specialised health care services

	Norwegian Directorate of Health
POLAND / *POLOGNE*	**Mariola GROCHULSKA** Département des droits de l'homme Ministère de la Justice
PORTUGAL	**Maria do Céu PATRÃO NEVES** **Apologised/Excusée** Full Professor Universidade dos Açores
ROMANIA / *ROUMANIE*	**Gheorghe BORCEAN** Président de l'Ordre des Médecins et Prof. Ass. à l'Université de Médecine et Pharmacie " Victor Babes" de Timisoara Vice-President of the Romanian College of Physicians Spitalul Municipal Caransebes **Beatrice Gabriela IOAN** Associate Professor President of the Bioethics Commission of the Romanian College of Physicians Institutul de Medicina Legala
SAN MARINO / *SAINT-MARIN*	**Luisa BORGIA** Professor of Bioethics, Polytechnic University of Marche President of National Bioethics Committee
SERBIA / *SERBIE*	**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
SLOVAK REPUBLIC / *REPUBLIQUE DE SLOVAQUIE*	**Jozef GLASA** Institute of Pharmacology and Clinical Pharmacology, Institute of Health Care Ethics, Slovak Medical University in Bratislava; Institute of Medical Ethics and Bioethics n.f.; Ethics Committee (NEC) Ministry of Health
SLOVENIA / *SLOVÉNIE*	**Marjeta TERČELJ ZORMAN** Vice President of the National Ethics Commission
SPAIN / *ESPAGNE*	**Carlos M. ROMEO-CASABONA** Professor of Penal Law, Head Inter-University Chair in Law and the Human Genome
SWEDEN / *SUÈDE*	**Tesi ASCHAN** Legal Adviser The National Board of Health and Welfare, Socialstyrelsen
SWITZERLAND / *SUISSE*	**Damaris CARNAL** Deputy Head of Section International Affairs Division
TÜRKIYE / *TÜRKIYE*	**Tuna İLBARS** **Apologised/Excusée** Unit Coordinator Department of Blood and Blood Products **Directorate General of Health Services** Ministry of Health

UKRAINE	**Iuliia DAVYDOVA** Professor, Head of High-Risk Pregnancy Department Institute of Pediatrics, Obstetrics and Gynecology, member of Local Bioethics Committee
UNITED KINGDOM / *ROYAUME-UNI*	**Mark BALE** Advisor to the Science Research and Evidence Directorate Department of Health and Social Care **Ana HALLGARTEN LA CASTA** **Apologised/Excusée** Emerging Technologies Team Lead Department of Health and Social Care

PARTICIPANTS / *PARTICIPANTS*

CDCJ	**Rodrigo RODRIGUEZ** **Apologised/Excusé** Département fédéral de justice et police DF Office fédéral de la Justice OFJ Domaine de direction Droit privé
UNITED NATIONS OFFICE OF THE HIGH COMMISSIONER FOR HUMAN RIGHTS / *HAUT-COMMISSARIAT DES NATIONS UNIES AUX DROITS DE L'HOMME*	Awaiting nomination / *Nomination en attente*

OTHER PARTICIPANTS / *AUTRES PARTICIPANTS*

EUROPEAN UNION / *UNION EUROPEENNE*	**Jim DRATWA** **Apologised/Excusé** Head of Ethics and Head of the EGE Secretariat Member of the Bureau of European Policy Advisers (BEPA) European Commission
CONFERENCE OF INGOS / *CONFERENCE DES OINGS*	**Frank Ulrich MONTGOMERY** **Apologised/Excusé** Standing Committee of European Doctors (CPME) **Ruth ALLEN** **Apologised/Excusée** International Federation of Social Workers (IFSW)
CANADA	**Peter MONETTE** **Apologised/Excusé** Health Canada
HOLY SEE / *SAINT-SIEGE*	**Leonardo NEPI** Official - Dicastery for Laity, Family and Life
JAPAN / *JAPON*	**Tetsushi HIRANO** **Apologised/Excusé** Chargé de mission
MEXICO / *MEXIQUE*	**Patricio J. SANTILLAN DOHERTY** **Apologised/Excusé** National Commissioner of Bioethics **Gustavo Fernando OLAIZ BARRAGAN** **Apologised/Excusé** Deputy Director on Public Policy and Bioethics National Commission of Bioethics

USA / *ETATS-UNIS D'AMERIQUE*	Awaiting nomination / *Nomination en attente*
UNESCO	**Dafna FEINHOLZ** **Apologised/Excusée** Chief of the Bioethics Section
OECD / *OCDE*	**David WINICKOFF** **Apologised/Excusé** STI/STP
WHO / *OMS*	**Andreas REIS** (12-13/06) Co-Unit Head, Health Ethics & Governance Research for Health Department Science Division

OBSERVERS / *OBSERVATEURS*

CONFERENCE OF EUROPEAN CHURCHES (CEC) / *CONFERENCE DES EGLISES EUROPEENNES (CEC)*	**Elizabeta KITANOVIC** **Apologised/Excusée** Membre du Groupe de travail

INGOS / *OINGS* (12/06)

REHABILITATION INTERNATIONAL (RI)	**Regina ERNST** **Apologised/Excusée** RI National Secretary for Germany **Gustav WIRTZ**
EUROPEAN ASSOCIATION OF SERVICE PROVIDERS FOR PERSONS WITH DISABILITIES (EASPD)	**Ferran BLANCO ROS** Responsable de l'Àrea de Projectes i Desenvolupament
EUROPEAN DISABILITY FORUM (EDF)	**John Patrick CLARKE,** Vice-President, European Disability Forum **Markaya HENDERSON**, European Disability Forum **Camille ROUX**, Mental Health Europe **Olga KALINA**, Chair of the European Network of (Ex)Users and Survivors of Psychiatry (ENUSP) **Stephanie WOOLEY,** ENUSP

CONSULTANTS / *CONSULTANTES*

UNITED KINGDOM / *ROYAUME-UNI*	**Elaine GADD** (12/06 online) Consultant for the Draft Recommendation for the promotion of voluntary measures
	Federica LUCIVERO (13/06 online) Consultant for Horizon scanning
BELGIUM / *BELGIQUE*	**Kristof VAN ASSCHE** (11/06) Consultant for the Equitable and timely access to appropriate innovative treatments and technologies in healthcare

INVITED GUESTS / *INVITES*

FINLAND / *FINLANDE*	**Joni KOMULAINEN** (13/06) Chair of the Drafting Group on AI in healthcare

SECRETARIAT / *SECRETARIAT*

PARLIAMENTARY ASSEMBLY / *ASSEMBLÉE PARLEMENTAIRE*	**Liliana TANGUY** **Apologised/Excusée** Committee on Social Affairs, Health and Sustainable Development **Aiste RAMANAUSKAITE** Committee on Social Affairs, Health and Sustainable Development +1
OFFICE OF THE COMMISSIONER FOR HUMAN RIGHTS / *BUREAU DU COMMISSAIRE AUX DROITS DE L'HOMME*	**Patricia OTVOS** Adviser
OFFICE OF THE SPECIAL REPRESENTATIVE OF THE SECRETARY GENERAL ON MIGRATION AND REFUGEES / *BUREAU DE LA REPRESENTANTE SPECIALE AUPRES DE LA SECRETAIRE GENERALE SUR LES MIGRATIONS ET LES REFUGIES*	**Anne KAYSER** **Apologised/Excusée** Administrator
COMMITTEE ON ARTIFICIAL INTELLIGENCE / *COMITE SUR L'INTELLIGENCE ARTIFICIELLE* **(CAI)**	**Kristian BARTHOLIN** Secretary
STEERING COMMITTEE ON ANTI DISCRIMINATION, DIVERSITY AND INCLUSION / *COMITE DIRECTEUR SUR L'ANTI-DISCRIMINATION, LA DIVERSITE ET L'INCLUSION* **(CDADI)**	**Wolfram BECHTEL** **Apologised/Excusé** Secretary
SEXUAL ORIENTATION AND GENDER IDENTITY UNIT / *UNITE ORIENTATION SEXUELLE ET IDENTITE DE GENRE* **(SOGI)**	**Eleni TSETSEKOU** **Apologised/Excusée** Head of Unit

GENDER EQUALITY COMMISSION / *COMMISSION POUR L'EGALITE DE GENRE* **(GEC)**	**Cécile GREBOVAL**	
EUROPEAN COMMITTEE FOR THE PREVENTION OF TORTURE AND INHUMAN OR DEGRADING TREATMENT OR PUNISHMENT : COMITE EUROPEEN POUR LA PREVENTION DE LA TORTURE ET DES PEINES OU TRAITEMENTS INHUMAINS OU DEGRADANTS **(CPT)**	**Hugh CHETWYND** Head of Division	**Apologised/Excusé**
COMMITTEE OF THE CONVENTION FOR THE PROTECTION OF INDIVIDUALS WITH REGARD TO AUTOMATIC PROCESSING OF PERSONAL DATA / *COMITÉ CONSULTATIF DE LA CONVENTION POUR LA PROTECTION DES PERSONNES À L'ÉGARD DU TRAITEMENT AUTOMATISÉ DES DONNÉES A CARACTÈRE PERSONNEL* **(T-PD)**	**Albina OVCEARENCO** **Peter KIMPIAN** Secretary	**Apologised/Excusée** **Apologised/Excusé**
STEERING COMMITTEE FOR THE RIGHTS OF THE CHILD / *COMITE DIRECTEUR POUR LES DROITS DE L'ENFANT* **(CDENF)**	**Katrin UERPMANN** Secretary	**Apologised/Excusée**
EUROPEAN COMMITTEE ON BLOOD TRANSFUSION / *COMITE EUROPEEN (ACCORD PARTIEL) SUR LA TRANSFUSION SANGUINE* **(CD-P-TS)**	**Richard FORDE** Secretary	**Apologised/Excusé**
EUROPEAN COMMITTEE ON ORGAN TRANSPLANTATION / *COMITE EUROPEEN SUR LA TRANSPLANTATION D'ORGANES* **(CD-P-TO)**	**Marta LOPEZ-FRAGA** Secretary	**Apologised/Excusée**

DIRECTORATE GENERAL OF DEMOCRACY AND HUMAN DIGNITY - YOUTH POLICY DIVISION / *DIRECTION GENERALE POUR LA DEMOCRATIE ET LA DIGNITE HUMAINE – DIVISION DE LA POLITIQUE POUR LA JEUNESSE*	**Stéphanie BUREL** Youth Policy Division **Jessý JÓNSDÓTTIR** (online 12/06) LUF – National Youth Council of Iceland
HUMAN RIGHTS, JUSTICE AND LEGAL COOPERATION, STANDARD SETTING ACTIVITIES DEPARTMENT - HUMAN RIGHTS AND BIOMEDICINE DIVISION / *SERVICE DES ACTIVITES NORMATIVES EN MATIERE DE DROITS DE L'HOMME, JUSTICE ET COOPERATION JURIDIQUE - DIVISION DES DROITS DE L'HOMME ET DE LA BIOMEDECINE* **(CDBIO)**	**Laurence LWOFF** Secretary of the CDBIO / *Secrétaire du CDBIO* Tel: +33 (0) 388 41 22 68, Email: laurence.lwoff@coe.int **Lee HIBBARD** Administrator / *Administrateur* Tel: +33 (0) 388 41 31 04, Email: lee.hibbard@coe.int **Aurélie PASQUIER** Administrator / *Administratrice* Tel: +33 (0) 390 21 52 75, Email: aurelie.pasquier@coe.int **Catherine FORNE** Assistant / *Assistante* Tel: +33 (0) 388 41 22 20, Email: catherine.forne@coe.int **Laura HENNINGER** Assistant / *Assistante* Tel: +33 (0) 388 41 30 05, Email: laura.henninger@coe.int **Tatiana WINTER** Assistant / *Assistante* Tel: +33 (0) 388 41 33 67, Email: tatiana.winter@coe.int **Marta DIOGO** Trainee / *Stagiaire* (Portugal) **Jana BÄRLOCHER** Trainee / *Stagiaire* (Switzerland/*Suisse*)
INTERPRETING, TRAVEL, EVENTS AND MULTIMEDIA DEPARTMENT / *SERVICE DE L'INTERPRETATION, DES VOYAGES, DES EVENEMENTS ET DU MULTIMEDIA* **(ITEM)**	**Amanda LARIVIERE** **Lucie DEBURLET-SUTER** **Gillian WAKENHUT (12/06)** **Chloé CHENETIER (13/06)**

Appendix II
Agenda

Tuesday 11 June 2024 (14.00-17.30)	
	1. Adoption of the draft agenda ○ New CDBIO members invited to introduce themselves ○ Reminder about the main decisions to be taken during the meeting
	2. Equitable and timely access to appropriate innovative treatments and technologies in healthcare *Objective: Examination of the outline of a draft white paper with a view to give guidance to the Drafting Group for it to present a full text at the 6th plenary (November 2024) to be submitted for adoption at the 7th plenary meeting (June 2025)* - Examination of the outline of the draft white paper prepared by the Drafting Group
	3. Other business a. Follow up to the Guide to children's participation in decisions about their health b. Armenia Action Plan II *Objective: Information on the cooperation project Human Rights and Biomedicine II* c. Gender equality *Objective: brief presentation of proposals by the CDBIO Gender Equality rapporteur* *d. PACE Recommendation 2275(2024) – "Ending the detention of "socially maladjusted" persons"* *e. Neurotechnologies* *f. Xenotransplantation*
	4. Dates of the next meetings ○ *6th meeting of the CDBIO: 26-29 November 2024, Strasbourg* ○ *7th meeting of the CDBIO: 3-6 June 2025, Strasbourg*

Wednesday 12 June 2024 (09.30-13.00 / 14.30-18.00)	
	5. Draft Recommendation on respect for autonomy in mental healthcare *Objective: Examination of the revised draft Recommendation with a view to its approval at the 6th CDBIO meeting (November 2024)* ○ Examination of the draft Recommendation revised by the Bureau in the light of the comments received during the targeted consultation ○ Examination of the draft Explanatory Memorandum prepared by Elaine Gadd, Consultant, based on previous inputs from CDBIO delegations, observers and participants and respondents of the targeted consultation exercise
	6. Youth Forum *Objective: Examination of the draft paper prepared by the Drafting Group on how best to integrate the youth perspective in the work of the CBDIO and give guidance towards the finalization of the paper for 6th plenary (November 2024).* - Presentation of the draft paper on the integration of the youth perspective
Thursday 13 June 2024 (09.30-12.30 / 14.00-16.00)	
	8. Preparation of a new strategic action plan (SAP(2026-2030)) *Objective: Definition of the next step in the preparation of a new SAP (2026-2030)* - Presentation of the report of the replies to the Horizon scanning questionnaire and event held on 3 April 2024 - Guidance to the Drafting Group entrusted with the development of the new SAP (2026-2030)
	7. Artificial intelligence and biomedicine *Objectives: Finalisation of the draft report on AI on the application of AI in healthcare and its impact on the patient-doctor relationship and publication. To consider follow up steps.* - Examination of the draft report revised in the light of the comments received during the targeted consultation with a view to its finalisation and publication
	9. Adoption of decisions taken by the CDBIO at its 5th meeting *Objective: Approval of the abridged meeting report*

POINTS TO BE DEALT WITH IN WRITING

10. 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. Developments in other Council of Europe bodies
d. Developments at the European Court of Human Rights

11. 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

12. Cooperation with other committees

a. Steering Committee for Human rights (CDDH)
b. European Committee on Organ Transplantation (CD-P-TO)
c. European Committee on Blood Transfusion (CD-P-TS)
d. Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)
e. Steering Committee for the Rights of the Child (CDENF)
f. Steering Committee for Legal Cooperation (CDCJ)

Appendix III

Presentation by Kristof Van Assche, Consultant for the equitable access to appropriate innovative treatments and technologies in healthcare

Presentation outline white paper

Appendix IV

Presentation by Iuliia Davydova, Gender Equality Rapporteur

Main issues in gender problems in

Appendix V

Presentation by Federica Lucivero, Consultant for the Horizon scanning

What's on the horizon for CDBIO.p

Appendix VI

Presentation by Joni Komulainen, Chair of the Drafting Group on AI in healthcare

AI report_ Joni_Komulainen_CI