



Strasbourg, 28 November 2024

CDBIO/RAP6

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

6th meeting

26-28 November 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. Gianluca Esposito, new Director General for Human Rights and Rule of Law, made an opening address to the CDBIO. He praised the Committee for its work and achievements as well as its constant concern for added value and complementarity within the COE and with international partners. Referring to the priorities stated in the Declaration of Reykjavik, he namely underlined “the pioneering global role of the CoE in developing standards in emerging and new policy areas and its determination to address current and future challenges” which includes technology related challenges. In the Reykjavik spirit, he acknowledged the pioneering work of the CDBIO in including a youth perspective in its work and its continuous engagement with civil society. He specifically referred to the protection of persons with mental health issues acknowledging the particular sensitivity of the issues at stake and the demanding task for the CDBIO to address them. But he considered essential “to continue making all possible efforts to protect human rights, dignity and equality, especially to the benefit of persons in vulnerable situations, as a person with health concern may be, and ensured the CDBIO of the continued support of the Secretariat. Finally, he informed the CDBIO of the moving of the Division on Human Rights and Biomedicine in the Directorate on Social Rights, Health and Environment. He underlined however that this will have no real impact for the CDBIO in terms of staff and budget.

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

4. The Chair of the Drafting Group updated the Committee on changes to the structure and terminology of the draft white paper. This was followed by a comprehensive presentation of the entire document by Kristof Van Assche, Consultant.
5. Delegations generally welcomed the document, considering it to be comprehensive and timely. The scope of the document and the issues covered were also welcomed with some reflection on how it might be perceived by certain groups, such as patients and industry actors. Suggestions were made on the need for criteria to differentiate traditional and innovative treatments and technologies for their rigorous assessment. The need to foreground challenges posed by access to certain among them (surveillance capacity of wearables, discrimination, unknown risks, etc) was also highlighted.
6. The section on affordability in chapter 4 was discussed extensively in conjunction with the scope and purpose of the white paper. There was an important discussion about the wider implications and involvement of non-state actors in pricing determinations and reimbursement policies of the state. This included striking the right balance of interests, the need for clarity in understanding when a treatment is considered experimental, and the need to educate the public and health professionals on expectations about innovative treatments and technologies. Support was expressed for developing list of principles to be used when making determinations about the funding of equitable access to innovative treatments and technologies.
7. Chapter 5 on balancing individual rights and public health needs was welcomed and delegations underlined its importance for policy making (i.e. the human rights principles that need to be taken into account by policy makers). A range of comments and proposals were made to strengthen this chapter, including the need for independent bodies to balance individual rights and public health needs, and the need to review the reference to the method ‘Quality Adjusted Life Years’ (QALYS) as a way to measure and compare different health benefits in the knowledge that certain groups in society (older person, persons with disabilities etc) may be more vulnerable and susceptible to discrimination.

8. A number of practical suggestions were made to develop and strengthen the document, most notably the following:
 - Ensuring consistency between the title (quality and superiority) and the content of chapter 3 (safety, quality and superiority).
 - Using examples to illustrate and balance the interests and issues at stake, including regard to the use of different innovative technologies.
 - Maintaining reference to social determinants of health taking into consideration the comments of delegations (e.g. determinants of health are co-determinants and could be the topic of a future piece of work ; importance of social determinants in the development of new technologies in healthcare) to be either : (i) placed in a shorter section in the document on social determinants of health, clarifying their relation with main subject matter of the white paper, or (ii) appended to the document with a reference to them in the preface in order to connect and explain their relevance to the white paper.
 - The need for a concluding chapter which succinctly sets out considerations for policy makers.
9. **Delegations were invited to make any written comments to the document by 20 December 2024** with a view to its revision and finalisation at its next plenary, in June 2025. The CDBIO took note that this will include technical comments provided by an independent expert identified by the Chair.

III. Draft Recommendation on respect for autonomy in mental healthcare

10. The CDBIO approved by unanimity the draft Recommendation on respect of autonomy in mental healthcare and agreed to send it to the Committee of Ministers with a view to its adoption; it noted that this was the last deliverable the Committee had been requested to complete by the Committee of Ministers on the protection of human rights in mental healthcare.
11. Subject to the insertion of references to the Guide on children participation in decision relevant to their health and the Guide on public debate, the CDBIO agreed on the Explanatory Memorandum to the draft Recommendation and to send it to the Committee of Ministers for it to take note.
12. The Chair made closing remarks as this session presumably marked the end of CDBIO's work on this set of deliverables. She underlined the vital and very deeply human purpose of the work achieved to ensure the dignity and autonomy of persons with mental health problems and to make sure their voice is heard. This work, firmly rooted in the ECHR, was marked by thoughtful deliberations and compromise, steadfast commitment and spirit of respectful dialogue. She thanked the representatives of the INGOs for their insight and contribution, acknowledging moments of disagreement but highlighting the shared objective of affirming the dignity of the persons with mental health issues. She also thanked Elaine Gadd, Consultant, for her work.
13. Representatives of INGOs also expressed final remarks. They warmly welcomed the recommendation, seeing it as the result of shared efforts, sustained over many years. They underlined that the approved text had a huge potential for transforming mental healthcare and mental health legislation across Europe. With that, however, they renewed a firm opposition to the draft additional protocol, which they viewed as "bringing no hope for the future", adding that professionals and persons with mental health problems could find new ways, that were fully compliant with human rights, to solve problems, without resorting to coercion, and stressing that "coercion is not care".

14. One delegation welcoming the approval of the draft recommendation stressed that, in substance and objectives, the aspirations of the INGOs were fully shared. However, she stressed the importance of ensuring the legal protection of vulnerable persons; the objective remaining to prevent the use of coercion against these persons.
15. The Secretariat provided information of the next steps with view to the adoption, by the Committee of Ministers (CM), of the legal instruments drafted by the CDBIO, taking into account the decision taken by the CM in May 2022 (See doc. CDBIO(2022)14).

IV. Preparation of a new Strategic Action Plan (SAP(2026-2030))

16. The CDBIO Chair presented preliminary elements for a new Strategic Action Plan (2026-2030) prepared by the Drafting Group (her presentation appears in Appendix III to this report). She then invited delegations to make comments on the missions specified for the CDBIO and the strategic goals proposed for the new SAP.
17. The representative of WHO agreed with the critical component of complementarity in the work carried out by different intergovernmental organisations. She noted that WHO was already engaged in many areas of work and collaboration could be promoted as this had already been the case on AI or genome editing for example. She also underlined the benefit of collaboration to increase the impact of the work. She had concrete suggestions to continue on that basis on AI and health literacy which will be forwarded to the Secretariat.
18. The representative of UNESCO echoed the importance of complementarity of the work. She expressed interest in collaborating with the CoE as well as WHO and discuss further the areas where such collaboration could materialise.
19. The representative of the Conference of INGOs also noted the interest of namely health care professionals to work with CDBIO on issue such as climate and health, mental health and training of healthcare professionals.
20. Several delegations proposed specific topics to be addressed:
 - Patients' rights as an umbrella topic covering also autonomy, end of life, safety, migrants health – Considered as important also as no other intergovernmental organisation is addressing the topics
 - Prenatal diagnostics
 - Intergenerational justice and gender equality: to have a broader view e.g. Rights of the elderly
 - Autonomy together with responsibility
 - Synthetic biology and the applicability of the Oviedo Convention on its developments e.g. embryo model
 - AI as a technology with the biggest impact in the field of medicine and health – need to identify guiding ethical principles and address possible gaps.
21. One delegation welcomed the remarks from WHO and UNESCO about complementarity, but pointed out that the CDBIO was not a bioethics committee and that its focus was on human rights in biomedicine. He also stressed the need to have a look at existing instruments and to reflect on the way to promote and disseminate the results of the work achieved. He suggested for the CDBIO to be realistic and only initiated work on few topics.
22. The need to improve visibility and dissemination was also acknowledged by another delegation. The latter pointed out importantly that people tend to look at ethics in biomedicine as an obstacle, whereas it should be presented as an enabler.
23. In response to a delegation pointed out that the notion of “future generation” was more and more discussed in international fora, the Chair pointed out that there were issues on which

other were working which the CDBIO could join and issues that only the CDBIO could address in the light of its unique mandate.

24. **Delegations were invited to send comments by 15 January 2025, namely on the CDBIO missions and the strategic objectives for the new SAP.**

Gender equality

25. Iuliia Davydova, gender equality rapporteur, was invited to present proposals for clear and measurable action to be included in the new strategic action plan 2026-2030.
26. The rapporteur explained how a lack of research and clinical evidence concerning women can lead to delays in their treatment and care. She referred to disorders left under-diagnosed in (i.e. heart attack, endometriosis). She also referred to the “hidden curriculum” in which trainee health professionals inadvertently carry forward into their careers a lack of perception about symptoms and conditions, particular to women.
27. On this basis, the rapporteur proposed that strategic action could focus on the collection of data in member states about how gender is assessed in healthcare (e.g. how women respond to therapies), how gender bias can be identified (e.g. in surveys and diagnostics), and whether gender bias is a cause for health disparities (e.g. in accessing healthcare). The collection of such data could then be measured and used in the auditing of healthcare practice thereby helping to raise awareness and promote better education and training of health professionals.
28. The Chair echoed the concerns raised by the rapporteur and underlined the need to address them. As follow-up, **delegations were invited to send, by 15 January 2025, their comments on the presentation of the rapporteur (see appendix IV to this report) with regard to main goals and approaches to be taken on gender equality in the framework of the new strategic action plan 2026-2030.**

V. Neurotechnologies

29. The Chair recalled the conclusions of the report of the rapporteurs of the roundtable held in November 2021 which were endorsed by the CDBIO i.e. the analysis of the existing human rights framework with regard to the human rights challenges raised by neurotechnologies. As a first step, Dr Roberto Andorno (CH) was entrusted with such analysis. And at its last plenary meeting, the CDBIO had 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 Roberto Andorno.
30. Delegations were invited to make general comments on this report.
31. One delegation considered that the approach taken in the report was not sufficiently referring to positive aspects of neurotechnologies. He made a reference to the notion of “self-determination” which was used by the European Court of Human Rights, which is part of the principle to autonomy and should not be set aside. Furthermore, he underlined that certain human rights cannot be limited and that it would be better to refer to “absolute rights” rather than “higher level of rights” in this context.
32. The question of the neural data and whether they can be considered as health-related data / cognitive biometrical data was raised.
33. Some remarks were made by a delegation about the recommendations and the language used. Regarding recommendation 2, requesting the “classic” consent may not be sufficient considering the nature of neural data. In recommendations 4 and 5 it would be preferable to refer to “the absence of interference in self-determination” instead of “ensuring self-determination”, and to “the protection of the conditions allowing for the free development of

personality”, instead of “guaranteeing the right to personal identity”. Finally, clarification would be useful on the nature, purpose and competencies of the proposed ‘specialised national agencies’ in recommendation 10.

34. Another delegation welcomed the report as presenting good expert views. He pointed out the danger of losing sight of what happen if people are collecting vast amounts of brain/neural data. Finally, he suggested to include some guide on terminology.
35. The Secretariat recalled the guidelines on the protection of neural data currently developed by the T-PD.
36. Those comments will be conveyed to Dr Andorno and the report will be published before the end of the year.
37. Anne Forus (N) presented the proposal from the Bureau taking into account the outcome of the round table co-organised with OECD, its outcome and the report by Dr Andorno (See Appendix V to this report).
38. The CDBIO could organize a workshop on neurotechnology and human rights, focusing on the assessment of existing international/European human rights legal provisions. The event would gather human rights practitioners (such as judges and lawyers) who could share their expertise and contribute to the analyses. Relevant case law of the ECtHR would be a useful basis. The objective would be to see whether the existing human rights legal provisions can respond to the human rights challenges that have been identified. The output would be a paper pointing to areas where the existing legal framework could be applicable and identifying possible gaps.
39. A small drafting group could be set up to prepare the workshop, define its objectives and output and design its programme to that end.
40. One delegation stressed the need to have an introduction presenting technical aspects to inform the lawyers.
41. Some delegations pointed out the importance of ensuring the added value of the event and its concrete outcome. Consideration could be given to the discussion on practical cases.
42. The CDBIO agreed to set up a small drafting group (around 5-6 persons) to prepare a workshop on human rights legal framework and neurotechnologies and invite the CDDH to be represented in the group. The event could also provide opportunity to work more closely with other relevant intergovernmental organisations, as well as the European Court of Human Rights. A draft programme should be prepared by March 2025 with a view to the event being organised in the fall. **Expression of interest to join the group should be sent to the Secretariat by 10 December 2024.**
43. The CDBIO also designated Anne Forus (N) as rapporteur for neurotechnologies. She will chair the drafting group but will also liaise with the other intergovernmental organisations working in the area, in particular OECD, UNESCO and WHO.

VI. Other business

a. Artificial Intelligence Report follow-up

44. As a follow-up to the CDBIO report on the application of AI in healthcare and its impact on the “patient-doctor” relationship, the chair of the drafting group, Joni Komulainen, updated the Committee on preparations for the conference on AI in healthcare, to be held in Helsinki on 21 May 2025 (See Appendix VI to this report). This included reference to high level opening

and keynote interventions, livestreaming of the event, and the outline programme which includes a series of roundtable panel sessions on various aspects of the report.

45. Delegations welcomed the event, including the possibility to propose national experts, other stakeholders, such as youth, industry and institutional collaboration (e.g. PACE, the Conference of INGOs, WHO, UNESCO). **Delegations were invited to send their proposals to the Secretariat who will send them to Joni komulainen.**

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

46. The Secretariat informed of the latest developments related to the follow up to the adoption of the Guide, including recent translations, on-going consultations with children to develop related child-friendly materials, and the planning of a session on the topic of the Guide as part of the Mid-Term review conference of the Strategy for the Rights of the Child (2022-2027), that will be held on 4 April 2025.

47. It was suggested to invite Youth organisations to this event.

48. Steps to be taken to further promote this piece of work were discussed.

c. Youth

49. Mark Bale, rapporteur for the integration of a youth perspective, informed the Committee about cooperation with the Advisory Council on Youth (CCJ) in the development of the Organisation's reference framework for the integration of a youth perspective (to be finalised in 2025), and about findings regarding youth engagement practices at the national level.

50. In summarising the replies to a Secretariat questionnaire to national ethics committees (June 2024), the rapporteur observed that approaches to youth engagement vary and that there is uncertainty as to whether youth perspectives change or otherwise influence policy making. Reflecting on his participation in the CCJ consultation meeting (September 2024), the rapporteur considered that a clearer vision was needed for the integration of a youth policy pathway and that there is an opportunity to embed this in the new strategic action plan 2026-2030.

51. Examples of youth engagement and the social media tools used to dialogue with them were highlighted by delegations. The importance of developing a youth network to capture a range of views was also stressed (not just those participating in formal events or those training to be health professionals). To this end, CCJ representatives recalled their mandate to outreach to youth to facilitate their participation in intergovernmental committees.

52. In summary, the Chair noted with satisfaction how CDBIO and CCJ representatives were already cooperating and that this will continue through the development and implementation of the strategic action plan 2026-2030.

d. Armenia Action Plan and other possible cooperation projects

53. The Secretariat informed the CDBIO of the results of the second cooperation project in Armenia which was coming to a close at the end of this year.

54. She referred in particular to the signature of the Oviedo Convention by Armenia in May 2024 and the important progress made towards the ratification to be discussed at the Parliament in January 2025.

55. The Armenian legislation was also adapted in the light of the provisions of the Oviedo Convention and a contribution were made to the execution of a European Court of Human

Rights case as well as to the implementation of the National Human Rights Action Plan 2023-2025. Capacity building activities were also initiated for healthcare professionals from the Karabakh region. Further information on the results achieved in the cooperation project appear in Appendix VII to this report.

e. Health literacy Guide follow-up

56. As a follow-up to the CDBIO Guide to health literacy and the first conference on health literacy and human rights (Rome, 12 December 2023), the representative of Italy, Elena Falcomata, provided an update on the second [Conference “Health literacy and human rights – connecting policy with practice to promote inclusion and combat discrimination”](#), to be held in Rome on 5 December 2024, organised by the National Office Against Racial Discrimination of Italy, in cooperation with the Council of Europe and with the support of the Minister of Family, Natality & Equal Opportunities of Italy and the Minister of Health of Italy.
57. The Committee was informed that the conference will discuss gaps in health literacy provision and how to address them by encouraging different stakeholders and systems (including equality bodies) to collaborate across sectors and disciplines. Roundtable panel sessions will consider how health literacy can promote inclusion and combat discrimination, and will discuss information and understanding that people need to access and consent to AI-enabled health services. The event will culminate in a forward-looking approach to setting-up a broad intersectoral coalition of stakeholders to promote best practice and initiatives in the field of health literacy and human rights to foster dialogue and social inclusion.

VII. Bureau elections

58. The CDBIO elected by acclamation for a one-year term renewable once, Tomas Dolezal (CZ) as Chair of the Committee, and Damaris Carnal (CH) as Vice-Chair of the Committee; for a term of two years renewable once, Iuliia Davydova (Ukraine) as member of the Bureau, and re-elected in the Bureau Anne Forus (Norway), Andreas Valentin (Austria) and Luisa Borgia (San Marino) for a second two years term.

VIII. Dates of the next meetings

59. The CDBIO agreed to hold its next meetings on:
- 7th meeting of the CDBIO: 3-6 June 2025, in Strasbourg
 - 8th meeting of the CDBIO: 18-21 November 2025, in Strasbourg

IX. Adoption of decisions taken by the CDBIO at its 6th meeting

60. In the absence of opposition, the abridged report resented to delegations at the end of the meeting, was adopted on Monday 2 December 2024.

Appendix I
List of participants

MEMBERS / MEMBRES

ALBANIA / ALBANIE	Awaiting nomination / <i>Nomination en attente</i>
ANDORRA / ANDORRE	Cristina CASALS CASAS PhD en biologie
ARMENIA / ARMENIE	Izabel ABGARYAN Chair of the Medical Ethics Committee
AUSTRIA / AUTRICHE	<p>Benjamin BACHL Head of Competence Center Federal Ministry of Social Affairs, Health Care and Consumer Protection Section VI - Human Medical Law Department VII/A/2 – Competence Center for Genetic Engineering</p> <p>Sabine FASCHING Apologised/Excusée Federal Chancellery Secretariat of the Bioethics Commission</p> <p>Lilo MARTINI Apologised/Excusée 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</p> <p>Ulrich PESENDORFER Apologised/Excusé Ministry of Justice and jurisdiction</p> <p>Petra STEFENELLI Federal Chancellery Secretariat of the Bioethics Commission</p> <p>Andreas VALENTIN Member of the Bioethics Commission</p>
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	<p>Valérie DUBOIS Service des Relations Internationales - SPF Santé publique Sécurité de la Chaîne alimentaire et Environnement</p> <p>Arno DE POTTER Service des Relations Internationales - SPF Santé publique Sécurité de la Chaîne alimentaire et Environnement</p>
BOSNIA AND HERZEGOVINA / BOSNIE- HERZÉGOVINE	<p>Dalibor PEJOVIĆ Apologised/Excusé Head of Unit for Statistics and Analytical Affairs and Reporting in Health Department for Health</p> <p>Dunja PEJOVIC Apologised/Excusée</p>

	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	Lada ZIBAR Full Professor, internist nephrologist, Department for Nephrology, Internal Clinic, University Hospital, Zagreb & Department for Pathophysiology School of Medicine University Osijek & Head of Committee for Medical Ethics and Deontology, Croatian Medical Chamber
CYPRUS / CHYPRE	Aristotelis CONSTANTINIDES Member of the Cyprus National Bioethics Committee 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 Apologised/Excusée Ph.D., University of South Bohemia in České Budějovice
DENMARK / DANEMARK	Frida LANGGAARD JENSEN Ministry of the Interior and Health Charlotte BEIERHOLM OLSEN Apologised/Excusée Ministry of the Interior and 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 Apologised:Excusée 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

	<p>Bureau bioéthique, éléments et produits du corps humain (PP4) Direction générale de la Santé (DGS) Ministère de la Santé et de la Prévention</p> <p>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</p> <p>Caroline MATKO Bureau bioéthique, éléments et produits du corps humain (PP4) Direction générale de la Santé (DGS) Ministère de la Santé et de la Prévention</p> <p>Jacques MONTAGUT Ancien membre du CCNE</p> <p>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</p>
GEORGIA / GÉORGIE	<p>Givi JAVASHVILI Head of Family Medicine Department Tbilisi State Medical University Chairman of the National Council on Bioethics</p>
GERMANY / ALLEMAGNE	<p>Elmar DOPPELFELD Honorary Chair of the "Permanent Working Party of Research Ethics Committees in Germany Inc."</p> <p>Carlo GRIMM Division 611 Federal Ministry of Education and Research</p> <p>Ingo HÄRTEL Division 316 Federal Ministry of Health</p> <p>Thomas HEINEMANN Institute for Medical Humanities Universitätsklinikum Bonn (UKB)</p> <p>Judith MENTGEN Apologised/Excusée Head of Division III A 6 – Insurance law; IOPC-Funds; UNCITRAL; bioethics; genetic diagnostics Federal Ministry of Justice</p> <p>Vincent WÄCHTER III A 6 – Insurance law; IOPC-Funds; UNCITRAL; bioethics; genetic diagnostics Federal Ministry of Justice</p>
GREECE / GRECE	<p>Alexandra TSAROUCHEA Professor of Experimental Surgery School of Medicine Democritus University of Thrace</p>

HUNGARY / HONGRIE	Tamás KARDON Associate professor, Secretary of the Scientific and Research Ethics Committee of Medical Research Council
ICELAND / ISLANDE	Kristín Ninja GUDMUNDSÓTTIR Apologised/Excusée Legal Advisor Ministry of Health
IRELAND / IRLANDE	Siobhán O'SULLIVAN Royal College of Surgeons
ITALY / ITALIE	Elena FALCOMATA Senior Expert at the Presidency of the Council of Ministers Dept. for Equal Opportunities Assunta MORRESI Apologised/Excusée Prof. Associato di Chimica Fisica, Dipartimento di Chimica, Biologia e Biotecnologi Università degli Studi di Perugia Laura PALAZZANI 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 / <i>Nomination en attente</i>
LITHUANIA / LITUANIE	Asta ČEKANAUSKAITĖ Apologised/Excusée Director of Lithuanian Bioethics Committee
LUXEMBOURG	Aurélia SCHWANDER Attachée - data protection officer Direction de la Santé - Service de protection des données
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 paediatrics at the Faculty of Medicine University of Montenegro

NETHERLANDS <i>/ PAYS-BAS</i>	Harrie STORMS Ministry of Health, Welfare and Sports Sanne VAN WEEZEL Ministry of Health, Welfare and Sports
NORTH MACEDONIA / <i>MACÉDOINE DU NORD</i>	Jovan GRPOVSKI State Counsellor Ministry of Health
NORWAY / <i>NORVEGE</i>	Anne FORUS Senior Adviser, ph.d, Biotechnology and health legislation department Division of specialised health care services Norwegian Directorate of Health
POLAND / <i>POLOGNE</i>	Mariola GROCHULSKA Département des droits de l'homme Ministère de la Justice
PORTUGAL	Maria do Céu PATRÃO NEVES DE FRIAS MARTINS Full Professor of Ethics Universidade dos Açores
ROMANIA / <i>ROUMANIE</i>	Beatrice Gabriela IOAN Associate Professor President of the Bioethics Commission of the Romanian College of Physicians Institutul de Medicina Legala Carmen PANTIȘ College of Physicians from Romania (CMR) Vice-president and coordinator of the Professional Ethics and Deontology Commission and the Professional Jurisdiction Commission
SAN MARINO / <i>SAINT-MARIN</i>	Luisa BORGIA <u>Professor of Bioethics, Polytechnic University of Marche</u> <u>President of National Bioethics Committee</u>
SERBIA / <i>SERBIE</i>	Zvonko MAGIC Apologised/Excusé 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 / <i>REPUBLIQUE DE SLOVAQUIE</i>	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 / <i>SLOVÉNIE</i>	Marjeta TERČELJ ZORMAN Vice President of the National Ethics Commission
SPAIN / <i>ESPAGNE</i>	Awaiting nomination / <i>Nomination en attente</i>
SWEDEN / <i>SUÈDE</i>	Tesi ASCHAN Legal Adviser The National Board of Health and Welfare, Socialstyrelsen

SWITZERLAND <i>/ SUISSE</i>	Damaris CARNAL Deputy Head of Section International Affairs Division
TÜRKIYE / TÜRKIYE	Mustafa CELAYİR Legal counselor Représentation Permanente de Türkiye Murat DERİN PhD. Social Worker Ministry of Health General Directorate of Health Services Department of Patient Rights and Medical Social Services
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

PARTICIPANTS / PARTICIPANTS

PARLIAMENTARY ASSEMBLY / ASSEMBLÉE PARLEMENTAIRE	Stefan SCHENNACH Committee on Social Affairs, Health and Sustainable Development
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 / <i>Nomination en attente</i>

OTHER PARTICIPANTS / AUTRES PARTICIPANTS

EUROPEAN UNION / UNION EUROPEENNE	Awaiting nomination / <i>Nomination en attente</i>
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) Anne-Marie CHAVANON Chair of the Inclusive Territories, Environment and Health Committee
CANADA	Peter MONETTE Apologised/Excusé Health Canada

HOLY SEE / SAINT-SIEGE	Leonardo NEPI Official - Dicastery for Laity, Family and Life	
JAPAN / JAPON	Tetsushi HIRANO Chargé de mission	Apologised/Excusé
MEXICO / MEXIQUE	Eva PIZANO CEJKA Adjointe à l'Observateur Permanent auprès du Conseil de l'Europe Patricio J. SANTILLAN DOHERTY National Commissioner of Bioethics Gustavo Fernando OLAIZ BARRAGAN Deputy Director on Public Policy and Bioethics National Commission of Bioethics	Apologised/Excusé Apologised/Excusé
USA / ETATS-UNIS D'AMERIQUE	Awaiting nomination / <i>Nomination en attente</i>	
UNESCO	Dafna FEINHOLZ Chief of the Bioethics Section	
OECD / OCDE	David WINICKOFF STI/STP	Apologised/Excusé
WHO / OMS	Katherine LITTLER Co-Unit Head Health Ethics & Governance Unit Research for Health Department Science Division Andreas REIS Co-Unit Head Health Ethics & Governance Unit Research for Health Department Science Division	Apologised/Excusé

OBSERVERS / OBSERVATEURS

CONFERENCE OF EUROPEAN CHURCHES (CEC) / CONFERENCE DES EGLISES EUROPEENNES (CEC)	Elizabeta KITANOVIC Membre du Groupe de travail	Apologised/Excusée
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INGOS / OINGS (26/11)

REHABILITATION INTERNATIONAL (RI)	Regina ERNST RI National Secretary for Germany Gustav WIRTZ	Apologised/Excusée Apologised/Excusé
EUROPEAN ASSOCIATION OF SERVICE PROVIDERS FOR PERSONS WITH DISABILITIES (EASPD)	Jose Maria SOLÉ I CHAVERO Board Member of 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 Kristijan GRĐAN , Mental Health Europe Stephanie WOOLEY , ENUSP
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CONSULTANTS / CONSULTANTS

BELGIUM / BELGIQUE	Kristof VAN ASSCHE (26/11) Consultant for the Equitable and timely access to appropriate innovative treatments and technologies in healthcare
FINLAND/FINLANDE	Joni KOMULAINEN (28/11) Chair of the drafting group on the application of artificial intelligence in healthcare

SECRETARIAT / SECRETARIAT

PARLIAMENTARY ASSEMBLY / ASSEMBLÉE PARLEMENTAIRE	Catherine DU BERNARD ROCHY Apologised/Excusée Committee on Social Affairs, Health and Sustainable Development Aiste RAMANAUSKAITE Committee on Social Affairs, Health and Sustainable Development
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	Victoria KARPATSKY Apologised/Excusée Administrator
COMMITTEE ON ARTIFICIAL INTELLIGENCE / COMITE SUR L'INTELLIGENCE ARTIFICIELLE (CAI)	Kristian BARTHOLIN Apologised/Excusé 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 Head of Unit	Apologised/Excusée
GENDER EQUALITY COMMISSION / COMMISSION POUR L'EGALITE DE GENRE (GEC)	Cécile GREBOVAL Yanna PARNIN	Apologised/Excusée
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 OVAOCA 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

<p>DIRECTORATE GENERAL OF DEMOCRACY AND HUMAN DIGNITY - YOUTH POLICY DIVISION <i>/ DIRECTION GENERALE POUR LA DEMOCRATIE ET LA DIGNITE HUMAINE – DIVISION DE LA POLITIQUE POUR LA JEUNESSE</i></p>	<p>Stéphanie BUREL Youth Policy Division</p> <p>Margo VORYKHAVA Advisor on Youth Policy and Students Advisory Council on Youth – Council of Europe</p> <p>Jessý JÓNSDÓTTIR (online 28/11) LUF – National Youth Council of Iceland</p>
<p>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 HUMAINS ET DE LA BIOMEDECINE (CDBIO)</p>	<p>Laurence LWOFF Secretary of the CDBIO / <i>Secrétaire du CDBIO</i> Tel: +33 (0) 388 41 22 68, Email: laurence.lwoff@coe.int</p> <p>Lee HIBBARD Administrator / <i>Administrateur</i> Tel: +33 (0) 388 41 31 04, Email: lee.hibbard@coe.int</p> <p>Aurélie PASQUIER Administrator / <i>Administratrice</i> Tel: +33 (0) 390 21 52 75, Email: aurelie.pasquier@coe.int</p> <p>Catherine FORNE Assistant / <i>Assistante</i> Tel: +33 (0) 388 41 22 20, Email: catherine.forne@coe.int</p> <p>Laura HENNINGER Assistant / <i>Assistante</i> Tel: +33 (0) 388 41 30 05, Email: laura.henninger@coe.int</p> <p>Tatiana WINTER Assistant / <i>Assistante</i> Tel: +33 (0) 388 41 33 67, Email: tatiana.winter@coe.int</p> <p>Garance LE SAUX Trainee / <i>Stagiaire</i> (France)</p>
<p>INTERPRETING, TRAVEL, EVENTS AND MULTIMEDIA DEPARTMENT / SERVICE DE L'INTERPRETATION, DES VOYAGES, DES EVENEMENTS ET DU MULTIMEDIA (ITEM)</p>	<p>Barbara GRUT</p> <p>Julia TANNER</p> <p>Amanda LARIVIERE</p>

Appendix II
Agenda

Tuesday 26 November 2024 (09.30-18.00)

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 a draft White Paper with a view to give guidance to the Drafting Group for its finalisation*

3. Draft Recommendation on respect for autonomy in mental healthcare

Objectives:

- *Approval of the draft Recommendation to be sent to the Committee of Ministers for adoption*
- *Finalisation of the draft Explanatory Memorandum*

Wednesday 27 November 2024 (09.30-18.00)

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

Objectives:

- *Discussion on an outline of the new SAP (2026-2030) with a view to give guidance to the Drafting Group*
- *Presentation of proposals, based on the Gender Equality Strategy of the Council of Europe, for possible activities to be included in the new SAP*

5. Neurotechnologies

Objectives:

- *Examination of the proposal from the Bureau with a view to an agreement on the way forward*
- *Finalisation of the comments on the UNESCO draft Recommendation on the Ethics of Neurotechnology*

6. Other business

- a. Artificial Intelligence Report follow-up
- b. Follow up to the Guide to children’s participation in decisions about their health
Information on the preparation of related child-friendly materials and of an event in the context of the Mid Term Conference on the Strategy for the Rights of the Child
- c. Youth
Information by the Rapporteur for the integration of a Youth perspective on the cooperation with the Youth Advisory Council and outcome of the survey undertaken with NEC and *possible proposals* on the way forward
Information on the progress on a reference framework on the integration of a youth perspective at the level of the Council of Europe and member States.
- d. Action Plan Armenia and other possible cooperation projects
- e. Health literacy Guide follow-up

7. Bureau Election

- Election of the Chair and Vice Chair
- Election of a new Bureau member (Assunta Morresi terms have come to an end)

Submission for nominations should be sent in writing to the Secretariat by Wednesday 27 November 2024 at 2.00 pm.

8. Dates of the next meetings

- *7th meeting of the CDBIO: 3-6 June 2025, Strasbourg*
- *8th meeting of the CDBIO: 18-21 November 2025, Strasbourg*

9. Adoption of decisions taken by the CDBIO at its 6th 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
- e. Developments in the field of bioethics in the Decisions of the European Committee of Social Rights (ECSR)



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 Siobhan O’Sullivan
on preliminary elements for the new SAP (2026-2030)



CD-BIO Strat Plan
2026-2030.pdf

Appendix IV
Presentation by Iuliia Davydova, Gender Equality Rapporteur



Yuliya Plaksenko PPT
gender equality 27 N

Appendix V
Presentation by Anne Forus of the Bureau proposal
on neurotechnologies and human rights



Presentation
Neurotech Plenary no

Appendix VI
Presentation by Joni Komulainen, Chair of the Preparatory Group on AI



AI report_
Joni_Komulainen_CDB

Appendix VII

Overview of the results of the cooperation project “Human rights in biomedicine II” carried out under the Armenia Action Plan of the Council of Europe

The signature of the Oviedo Convention:

- Armenia [has signed](#) the Council of Europe Oviedo Convention on 16 May 2024. On 10 October 2024 the Government of RA has approved the draft RA law on the *ratification* of the Oviedo Convention and sent to the Constitutional Court. In the meantime, the Parliamentarians and the staff of the Standing Committee on Protection of Human Rights and Public Affairs and Standing Committee on Healthcare of the National Assembly of the Republic of Armenia are applying the improved capacities on the Oviedo Convention and its Additional Protocols in their law-making activities. Parliament will be started hearings from January 2025.

Harmonisation of national legislation with the European standards enshrined in the Oviedo Convention:

- The Project has contributed to the improvement of the main legal acts in the field of healthcare, including the draft RA Laws on “Comprehensive health insurance system”, «Individual licensing of healthcare professionals” and “Medical Care and Assistance to the Population” as a priority for the Government of RA.
- In the meantime, the procedure of “The implementation of providing information to the population about the meaning of **organs and tissue transplantation**, donation prerequisites and other issues related to transplantation, as well as the right to disagree to act as **deceased donor**, the right of **deceased donor’s** family members to give consent” has been approved by the Order N 262-N of the Minister from 19 August 2024
- Several by-laws have been developed for RA Law on with the Council of Europe expertise aligning with the European standards.

Execution of the ECtHR judgement “Nikolyan vs Armenia”.

- An extensive report on the [“Analysis of domestic legal framework and practice on the restriction of legal capacity of persons with mental health issues: Execution of ECtHR judgement Nikolyan vs Armenia”](#) was published. It provides recommendations for national authorities on proper assessment of legal capacity, establishment of tailor-made restrictions of legal capacity, review of restrictions of legal capacity, as well as improvement of guardianship and trusteeship system in Armenia. The recommendations served a basis for the draft RA law on “Revisions of the institute of legal capacity of persons with mental health issues”. As a part of the abovementioned judgement and National Human Rights Strategy 2023-2025 the Project has also supported the Ministry of Justice in the revision of the RA Law on “Involuntary placement and treatment in psychiatric institutions with a specific focus on the procedural safeguards”.

Contribution to the implementation of National Human Rights Action Plan 2023-2025

- Manual on Medical Secret and Confidentiality has been developed in line with the European Standards.
- Report on the European best practices with regard to regulation of non-consensual treatment with a specific focus on the right to access to justice, as well as package of draft laws on “Amendments and Additions to the Civil Procedure Code”; on “Additions to the Law on Mental Health Services and Servicing”; on “Amendments and Additions to the Law on State Duty” has been developed.

Ethics committee for healthcare professionals successfully examines the cases of possible violations of code of conduct for healthcare professionals.

- The regulatory and operational framework of the ethics committee for healthcare professionals developed in accordance the Council of Europe recommendations provided by the group of local and international consultants and approved by the Order of the Minister of Health of RA.
- The members of the Ethics Committee for healthcare professionals have raised their awareness for the proper functioning of ethics committee within 31st; 32nd and 33rd meetings of National Ethics Councils discussing ethical issues and sharing best practices of other European countries.

- The website of the Ethics Committee for healthcare professionals was developed with the support of the Council of Europe and available at www.mec.am

Development of the Council of Europe new HELP Course

- “Human Rights in Mental Health Services” new HELP Course was developed as part of the Project, which will be useful not only for Armenian context, but for other Council of Europe member-states as well.

Healthcare and legal professionals applying the knowledge gained through capacity-building organised

- Around 35 capacity-buildings events were organised on various topics for different groups of professionals, including Parliamentarians, chief advisors of the Ministry of Health, staffs of national stakeholders, healthcare and legal professionals (around 1000 participants).

Public dialogue on health issues is increased

- To promote public dialogue on health issues, a several expert-discussions were organized on different topics including promotion of autonomy of persons with mental health issues, human-rights-based approaches to healthcare, involvement of children in decision-making processes concerning their health which are very innovative and news approaches to be implemented.

Study visits organised

- A high-level delegation from National Assembly of the RA visited Strasbourg to discuss the possibilities of the ratification of the Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention) by Armenia.
- As part of the Council of Europe activities for enhancing human rights framework and institutional capacities through insights into the human rights mechanisms of the Council of Europe a delegation from the Office of Human Rights Defender and Standing Committee on Human Rights and Public Affairs of the National Assembly visited the Council of Europe institutions in Strasbourg, and the Office of the Defender of Rights of France in Paris.
- As part of the ongoing healthcare reforms in Armenia and Armenia-Council of Europe cooperation, a high-level delegation from the National Assembly of Armenia visited the Council of Europe institutions in Strasbourg and the World Health Organisation collaborative centre for research and training in mental health and a mental health facility in Lille, France.

Activities with journalists

- Capacity-building made it possible for 15 journalists to acquire the knowledge and skills to promote the work of Ethics Committee for healthcare professionals in Armenia.
- 35 public relations specialists from different healthcare institutions acquired the knowledge and skills to promote the work of Ethics Committee for healthcare professionals in Armenia.
- A two-day capacity-building strengthened the capacities and skills of 35 representatives from different medical associations on the European standards in the field of human rights and biomedicine.

Refugee healthcare professionals are supported to ensure their full integration into Armenian healthcare system*

- Between March and July of 2024, around 150 refugee healthcare professionals have strengthened their knowledge and capacities on key human rights principles in healthcare and biomedicine effectively applying in course of their daily work.
- Activities focusing on the provision of essential mental health support and fostering overall recovery were implemented between July-November for nearly 150 refugee healthcare professionals.

**These activities are part of the Council of Europe comprehensive response package to the refugee influx in Armenia and aimed to support the Government of Armenia in its efforts to integrate healthcare professionals from Karabakh region into the healthcare system in Armenia.*