

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Strasbourg, 20 November 2025

CDBIO/RAP8

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

8th meeting

18-20 November 2025

Report

I. Adoption of the agenda

1. Tomas Dolezal (Czechia), 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. Rafael Benitez, Director of Social rights, Health and Environment, addressed the CDBIO at the opening of the meeting. He referred in particular to the outcome of the Conference on the Protection of Health held on 15 October 2025 which highlighted the holistic approach of the Council of Europe, placing human rights and ethics at the center of the health-related activities. He spoke of a new momentum for health, including public health and supported the pivotal role of the CDBIO in this context. The Conference pointed out to challenges and identified priority areas for action. These priority areas largely reflect those laid down in the new Strategic Plan that the CDBIO was about to approve. He praised the exemplarity of the working method of the CDBIO promoting transversality and suggested that the Chair of the Social Rights Committee of the CoE be invited to exchange with the Committee on areas of common interests. He pointed out that the declaration adopted at the Doha World Social Summit (October 2025) underlined the importance of equity, solidarity and human rights-centered approaches in global health. Finally, he stressed the increasing importance of health literacy; the lack of which has a heavy economical cost. He stressed the role of the CoE in helping Member states to address the challenge of health literacy through a mobilization of the all the sectors of the CoE leading possibly to a recommendation. He underlined again the pivotal role of the CDBIO in embracing the full breadth of the health field.
4. The CDBIO welcomed the outcome of the [Conference on health protection](#) 2025 and thanked Mr Benitez for the perspectives presented on the role of the CoE and the role of the Committee in the health field.
5. In the light of this exchange, the CDBIO held a brief exchange on its name and agreed not to propose any change as all the terms were considered relevant with regard to the main objective and scope of the work carried out.

II. Neurotechnologies and human rights

6. The CDBIO welcome the outcome of the workshop on human rights and neurotechnologies organised on 18 November 2025. The involvement of the three committees i.e. CDDH, T-PD and CDBIO, was considered particularly important. Delegations appreciated the insightful discussion and clear avenues for work pointed out which will contribute also to the general discussion on this topic at international level. In this respect, the expertise of the CoE in human rights would provide complementary perspectives to the work carried out by other intergovernmental organisations on neurotechnologies, such as UNESCO.
7. The need for urgent responses was underlined during the workshop. While acknowledging the existence of a relevant legal framework, actions to ensure its application were clearly called upon and the role of the CDBIO pointed out in this process. Support for national authorities to regulate and stay ahead of aggressive marketing by the private sector was particularly pointed out.
8. The Committee thanked the Group in charge of the preparation of the workshop, in particular Anne Forus who chaired it, as well as Timo Istace, Consultant.
9. The three rapporteurs designated respectively by the CDDH, the T-PD and the CDBIO will now prepare the report to be finalised by mid January 2026.

III. Strategic Action Plan

a. SAP (2020-2025)

10. The CDBIO welcomed the draft report, its approach and contents. Delegations underlined the need to include information on the workshop on human rights and neurotechnologies and to elaborate on the “practical approach”, “transversality” and “engagement” of actors by the Committee in its work.
11. Evaluating the impact of the Committee’s work was discussed. There was an exchange of views on the meaning of impact and how to overcome the difficulties in quantifying and measuring it at national level. This included the need for indicators of impact and the systematic collection of data therein. Despite the difficulties faced, delegations underlined the importance of dissemination of CDBIO documents and, looking ahead, the need to ‘design-in’ impact evaluation into the new Strategic Plan 2026-2030.
12. The CDBIO agreed to approve the final report of the SAP (2020-2025), subject to few editorial changes to be made by the Secretariat, in coordination with the Chair.
13. It also entrusted the Secretariat, in coordination with the Chair, to finalise the report on the impact of the SAP (2020-2025). **Delegations were invited to send their written contribution at the latest by 15 December 2025.** The report on impact will be appended to the final report of the SAP (2020-2025) before its presentation to the Committee of Ministers.

b. Strategic Plan on Human Rights in Biomedicine and Health (2026-2030)

14. Siobhan O’Sullivan (Ireland), Chair of the Drafting Group for the new strategic plan, presented the document revised in the light of the comments received from delegations. She underlined the importance for the plan to serve member states (see Appendix III of this report).
15. Delegations welcomed the revised draft Strategic Plan.
16. One delegation suggested adding a reference to regular overview of the situation on some issues e.g. such as the one provided by questionnaire on MAP. Another stressed the need not to forget rare diseases and social care.
17. One delegation welcomed the fact that objectives were trying to engage national legislators and to be more effective.
18. If the issue of trust (to be distinct from misinformation) was highlighted in the preamble, one delegation considered that it should be more reflected in the objectives.
19. In response to a delegation stressing the fundamental importance of patient safety, the Chair of the Group acknowledged the intense discussion within the group on this issue as well as on environment. What can be done concretely by the CDBIO? That question was at the core of the discussion. It was eventually agreed to cover it under “patients’ rights” one of which was to receive quality care. This was still leaving the door open to reflect on action(s) not carried out by other organisations, that could be undertaken by the CDBIO.
20. At the end of the discussion, the point was made on the need not to go into too many details in some objectives to keep the balance of the text and considering that this level of precision should be for the actions to be developed on the basis of the Strategic Plan.
21. Finally, one delegation suggested moving the description of the mission of the CDBIO after the preamble.

22. The CDBIO approved its new Strategic Plan (2026-2030) subject to some editorial changes to be made by the Secretariat, in coordination with the Chair of the Drafting Group and CDBIO Chair.
23. The Chair of the Group suggested to consider a presentation the work carried out by the CDBIO, namely the Strategic Plan, to all permanent representations.

c. Implementation of the Strategic Plan

24. The CDBIO supported the proposal to set up a small drafting group (4 to 5 members, including members of the group which prepared the Plan) to prepare the list of actions responding to each objective of the Plan, on the basis of proposals made by delegations. The group would be chaired by Siobhan O’Sullivan (Ireland).
25. Some actions were already foreseen in particular the re-examination of Additional Protocols, starting in 2026 with the Additional Protocol concerning genetic testing for health purposes.
26. **Delegations were invited to send their proposals for action by 10 January 2026, using a template** which will be sent to them.

IV. Artificial Intelligence

27. The CDBIO took note of the information provided by the Secretariat concerning the completion of the mandate of the Committee on Artificial Intelligence (CAI), the creation of a new Steering Committee on New and Emerging Technologies (CDNET), and the progress made by states in signing and ratifying the Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law.
28. The CDBIO was informed about HUDERIA guidance on the assessment of risks and impacts of AI systems on human rights, including its ‘Context-Based Risk Analysis’ (COBRA) and HUDERIA Academy. This led to an exchange of views on the purpose, uses and users of HUDEIRA guidance and tools, including the need to bridge the gap between practical uses of AI in health and the human rights safeguards to be respected especially where it impinges on the patient-doctor relationship.
29. The CDBIO took note of the next HUDERIA Academy event, to be held in Strasbourg during the first quarter of 2026, which will focus specifically on the application of AI in healthcare. The Committee welcomed the invitation to collaborate in the implementation of this event, including the perspective of addressing AI use cases.
30. To facilitate the Committee’s work ahead on AI, notably its collaboration in the HUDEIRA event and the implementation of the Strategic Plan 2026-2030, the CDBIO decided to designate Siobhan O’Sullivan (Ireland) and Aurélia Schwander (Luxembourg) as its rapporteurs on AI.

V. Youth perspectives

31. The CDBIO welcomed the outcomes of the [10th Council of Europe Conference of Ministers responsible for Youth](#), held in Malta on 9 October 2025, namely the “Final Declaration” of the Conference of Ministers and the “Resolution on the Council of Europe Reference Framework on a Youth Perspective”, presented by the Chairs of the European Steering Committee for Youth (CDEJ) and Advisory Council on Youth (CCJ), respectively.
32. The Committee took note of the importance of inter alia acting with youth in building its public policy work. The CDBIO rapporteur for youth, Mark Bale, underlined the importance of engaging youth early in the implementation of the Strategic Plan 2026-2030, including the

development of an open community of youth to support and provide feedback to the Committee. To this end, the CDBIO took note of the written proposals by the rapporteur.

VI. Other business

- a. Access to origin for children born out of gametes donation
33. Tesi Aschan (Sweden) designated by the CDBIO to be a member of the DH-PDA, informed the CDBIO of the progress made towards the preparation of a draft Recommendation (see Appendix IV to this report).
- b. Organ transplantation
34. Lada Zibar (Croatia), who represented the CDBIO at the last meeting of the CD-P-TO, informed the CDBIO of the outcome of the discussion and projects planned in the field of transplantation and use of materials of human origin (see Appendix V to this report).
- c. Human rights in mental health care
35. The Secretariat informed the CDBIO that, at the request of the Committee of Ministers, the Parliamentary Assembly (PACE) was preparing its opinion on the draft Additional Protocol on the protection of human rights and dignity of persons with regard to involuntary measures within mental healthcare services. It is expected that the opinion will be adopted during the Winter Session of the PACE (26-30 January 2026).
36. The Secretariat informed the CDBIO of the developments regarding the HELP course on Mental health and human rights. It recalled that the course had been developed in 2024 within the framework of the cooperation project with Armenia and added that the course was currently available for self-study online in English, French, Armenian and Romanian, while Polish, Georgian, Ukrainian, and Latvian versions were underway. The CDBIO delegations were encouraged to promote this course within national frameworks.
- d. Guide to children's participation in decisions about their health
37. The Secretariat informed the CDBIO of the new linguistic versions of the Guide. By the end of the year, 12 languages will be available (English, French, Armenian, German, Hungarian, Latvian, Lithuanian, Polish, Portuguese, Romanian, Spanish, Croatian) and a Czech version was also planned for 2026. The child-friendly version of the Guide will also be available in these languages.
38. The Secretariat informed that three presentations of the Guide had been given during the last quarter of 2025, namely during the Summer school on Children's Rights of the University of Geneva, at a conference on children's rights in healthcare, organised by the Ombudsman for Children (OKAJU) and the Health Service Ombudsman (Médiateur Santé) of Luxembourg, and during the 29th Annual Conference of ENOC (European Network of Ombudspersons for Children) held in Romania.
- e. Health literacy
39. The CDBIO welcomed the information provided by Italy on the Conference on health literacy and human rights, to be held in Rome, on 5 December 2025.
- f. Action Plan Armenia
40. The representative of Armenia, Lusine Hayrapetyan, informed the CDBIO about the latest developments in the cooperation project and announced future activities as follow up to the

ratification of the Oviedo Convention to facilitate the implementation of its provisions (see Appendix VI to this report).

g. Events foreseen in 2026

41. The CDBIO welcomed the project of the Conference on children and social network considered by the CDENF in cooperation with the CDBIO, under Monaco Presidency of the Committee of Ministers on 4 June 2026.

VII. Bureau elections

42. The CDBIO elected:
- As Chair, Tomas Dolezal (Czechia) for a new term of one year
 - As Vice-Chair, Luisa Borgia (San Marino) for a term of one year
 - As Bureau members, Sanne Van Weezel (Netherlands) for a new term of two years and Maija Miettinen (Finland) for a term of two years.

VIII. Dates of the next meetings

43. The CDBIO agreed to hold its next meetings:
- 9th meeting of the CDBIO: 2-5 June 2026, in Strasbourg
 - 10th meeting of the CDBIO: 17-20 November 2026, in Strasbourg

IX. Adoption of decisions taken by the CDBIO at its 8th meeting

44. In the absence of opposition, the abridged report presented to delegations, was adopted by written procedure.

Appendix I
List of participants

MEMBERS / MEMBRES

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| ALBANIA / ALBANIE | Awaiting nomination / <i>Nomination en attente</i> |
| ANDORRA / ANDORRE | Cristina CASALS CASAS PhD en biologie |
| ARMENIA / ARMENIE | Lusine HAYRAPETYAN Head of the Department of Law Ministry of Health |
| 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>Marissa HUTTERER Legal expert Federal Ministry of Labour, Social Affairs Health, Care and Consumer Protection Directorate General VI - Human Medical Law and health telematics Directorate A/Department 4 – Legal affairs concerning pharmaceuticals, medical devices, pharmacies, hospitals and communicable diseases</p> <p>Ulrich PESENDORFER Apologised/Excusé Ministry of Justice and jurisdiction</p> <p>Petra STEFENELLI Apologised/Excusée Federal Chancellery Secretariat of the Bioethics Commission</p> <p>Andreas VALENTIN Member of the Bioethics Commission</p> |
| AZERBAIJAN / AZERBAÏDJAN | Shahbala YAGUBOV Head of the Pharmaceuticals and Medical Devices Department Ministry of Health |
| BELGIUM / BELGIQUE | <p>Valérie DUBOIS Apologised/Excusée 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 | Vlatka MARTINOVIĆ Apologised/Excusée Ph.D. med Pediatric surgery specialist of the University Hospital in Mostar |

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| BULGARIA / BULGARIE | Vihra MILANOVA Head of Psychiatric Clinic Alexandrovska University Hospital | Apologised/Excusée |
| 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 | Apologised/Excusé |
| | Zoe KYRIAKIDOU Member of the Cyprus National Bioethics Committee | |
| | Constantinos N. PHELLAS Chair of the Cyprus National Bioethics Committee University of Nicosia | Apologised/Excusé |
| 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 | Frida LANGGAARD JENSEN Ministry of the Interior and Health | |
| | Charlotte BEIERHOLM OLSEN Ministry of the Interior and Health | |
| ESTONIA / ESTONIE | Awaiting nomination / <i>Nomination en attente</i> | |
| 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 | Apologised/Excusée |
| FRANCE | Kamyar ASSARI Consultant juridique Sous-direction des droits de l'Homme Direction des affaires juridiques Ministère de l'Europe et des Affaires étrangères | |
| | Estelle FAUCHARD 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 | Apologised/Excusée |

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| | <p>Camille GRONAU Juriste 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 Apologised/Excusée 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>Baptiste MESSMER Juriste 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 Apologised/Excusée Juriste 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>Gérard CABOLET Legal Officer Federal Ministry of Research, Technology and Space</p> <p>Elmar DOPPELFELD Honorary Chair of the "Permanent Working Party of Research Ethics Committees in Germany Inc."</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> |

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| GREECE / GRECE | Alexandra TSAROUCOA Professor of Experimental Surgery, School of Medicine, Democritus University of Thrace Chair of the Research Ethics Committee, Democritus University of Thrace |
| HUNGARY / HONGRIE | Tamás KARDON Associate professor, Secretary of the Scientific and Research Ethics Committee of Medical Research Council |
| ICELAND / ISLANDE | Áslaug EINARSDÓTTIR Apologised/Excusée The National Bioethics Committee Kristín Ninja GUDMUNDSÓTTIR Apologised/Excusée Legal Advisor Ministry of Health |
| IRELAND / IRLANDE | Siobhán O'SULLIVAN Royal College of Surgeons |
| ITALY / ITALIE | Emanuele BILOTTI Apologised/Excusé Professeur auprès de l'Université européenne de Rome Marino DI NARDO Apologised/Excusé Expert de la Présidence du Conseil des Ministres du gouvernement italien Elena FALCOMATA Apologised/Excusée Senior Expert at the Presidency of the Council of Ministers Dept. for Equal Opportunities Lorenzo MONTRASIO Expert de la Présidence du Conseil des Ministres Assunta MORRESI Apologised/Excusée Prof. Associato di Chimica Fisica Dipartimento di Chimica, Biologia e Biotecnologi Università degli Studi di Perugia Eva SALA Apologised/Excusée Avocate |
| LATVIA / LETONIE | 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 Gita LABANAUSKAITĖ Senior Specialist of the 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 |

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| | <p>Consultative Committee Ministry of Health Coordinator, Bioethics Research Programme, Univ. of Malta, President, Malta College of Family Doctors</p> |
| REPUBLIC OF MOLDOVA / RÉPUBLIQUE DE MOLDOVA | <p>Vadim AFTENE Apologised/Excusé Head General Department of Policies in the Field of Integrated Medical Services Ministry of Health</p> <p>Ion PRISACARU Secretary of State Ministry of Health</p> |
| MONACO | <p>Thomas ALTHAUS Médecin de Santé Publique Direction de l'Action Sanitaire</p> |
| MONTENEGRO / MONTÉNÉGRO | <p>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</p> |
| NETHERLANDS / PAYS-BAS | <p>Harrie STORMS Ministry of Health, Welfare and Sports</p> <p>Sanne VAN WEEZEL Ministry of Health, Welfare and Sports</p> |
| NORTH MACEDONIA / MACÉDOINE DU NORD | <p>Jovan GRPOVSKI Apologised/Excusé State Counsellor Ministry of Health</p> |
| NORWAY / NORVEGE | <p>Anne FORUS Senior Adviser, ph.d, Biotechnology and health legislation department Division of specialised health care services Norwegian Directorate of Health</p> |
| POLAND / POLOGNE | <p>Mariola GROCHULSKA Département des droits de l'homme Ministère de la Justice</p> |
| PORTUGAL | <p>Maria do Céu PATRÃO NEVES DE FRIAS MARTINS Full Professor of Ethics Universidade dos Açores</p> |
| ROMANIA / ROUMANIE | <p>Beatrice Gabriela IOAN Associate Professor President of the Bioethics Commission of the Romanian College of Physicians Institutul de Medicina Legală</p> <p>Carmen PANTIȘ Vice President of the Romanian College of Physicians, and coordinator of the Professional Ethics and Deontology Commission and the Professional Jurisdiction Commission</p> |
| SAN MARINO / SAINT-MARIN | <p>Luisa BORGIA Professor of Bioethics, Polytechnic University of Marche President of National Bioethics Committee</p> |

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| 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 | José Antonio JURADO RIPOLL Apologised/Excusé Co-Agent for the Kingdom of Spain before the European Court of Human Rights and the European Committee of Social Rights Senior State Attorney-Human Rights Area of the Constitutional & Human Rights Department Office of the General State Attorney Ministry of Justice Heide NICOLAS MARTINEZ State Lawyer Sub directorate General of Constitutional Affairs and Human Rights Ministry of Justice María del Carmen SANCHEZ GONZALEZ President of the Research Ethics Committee Carlos III Health Institute / Instituto de Salud Carlos III Ministry of Health |
| 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 Federal Office of Public Health |
| TÜRKIYE / TÜRKIYE | Mürvet Hafsatur TOK 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

| | |
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| 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> |
| CONFERENCE OF INGOS / CONFERENCE DES OING | Thierry MATHIEU Président de l'Association Internationale pour la Recherche en Hygiène Hospitalière (AIRHH) |

OTHER PARTICIPANTS / AUTRES PARTICIPANTS

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| EUROPEAN UNION / UNION EUROPEENNE | Awaiting nomination / <i>Nomination en attente</i> |
| CANADA | Awaiting nomination / <i>Nomination en attente</i> |
| HOLY SEE / SAINT- SIEGE | Leonardo NEPI Official - Dicastery for Laity, Family and Life |
| JAPAN / JAPON | Tetsushi HIRANO Apologised/Excusé Chargé de mission |
| MEXICO / MEXIQUE | Eva PIZANO CEJKA Apologised/Excusée Adjointe à l'Observateur Permanent auprès du Conseil de l'Europe |
| USA / ETATS-UNIS D'AMERIQUE | Awaiting nomination / <i>Nomination en attente</i> |
| UNESCO | Dafna FEINHOLZ Apologised/Excusée Chief of the Bioethics Section |
| OECD / OCDE | David WINICKOFF Apologised/Excusé STI/STP |
| WHO / OMS | Katherine LITTLER Apologised/Excusée Co-Unit Head Health Ethics & Governance Unit Research for Health Department Science Division Andreas REIS Apologised/Excusé Co-Unit Head Health Ethics & Governance Unit Research for Health Department Science Division |

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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CONSULTANT / CONSULTANT

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| BELGIUM / BELGIQUE | Kristof VAN ASSCHE (19/11) Consultant for the SAP | |
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SECRETARIAT / SECRETARIAT

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| PARLIAMENTARY ASSEMBLY / ASSEMBLÉE PARLEMENTAIRE | Catherine DU BERNARD ROCHY Committee on Social Affairs, Health and Sustainable Development Aiste RAMANAUSKAITE Committee on Social Affairs, Health and Sustainable Development | Apologised/Excusée |
| OFFICE OF THE COMMISSIONER FOR HUMAN RIGHTS / BUREAU DU COMMISSAIRE AUX DROITS DE L'HOMME | Patricia OTVOS Adviser | Apologised/Excusée |
| COMMITTEE ON ARTIFICIAL INTELLIGENCE / COMITE SUR L'INTELLIGENCE ARTIFICIELLE (CAI) | Albina OVCEARENCO Secretary | |
| STEERING COMMITTEE ON ANTI DISCRIMINATION, DIVERSITY AND INCLUSION / COMITE DIRECTEUR SUR L'ANTI-DISCRIMINATION, LA DIVERSITE ET L'INCLUSION (CDADI) | Wolfram BECHTEL Secretary | Apologised/Excusé |
| 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 Apologised/Excusée |

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| <p>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)</p> | <p>Hugh CHETWYND Head of Division</p> | <p>Apologised/Excusé</p> |
| <p>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)</p> | <p>Peter KIMPIAN Secretary Data Protection</p> | <p>Apologised/Excusé</p> |
| <p>STEERING COMMITTEE FOR THE RIGHTS OF THE CHILD / COMITE DIRECTEUR POUR LES DROITS DE L'ENFANT (CDENF)</p> | <p>Agnes VON MARAVIC</p> | <p>Apologised/Excusée</p> |
| <p>EUROPEAN COMMITTEE ON BLOOD TRANSFUSION / COMITE EUROPEEN (ACCORD PARTIEL) SUR LA TRANSFUSION SANGUINE (CD-P-TS)</p> | <p>Richard FORDE Secretary</p> | <p>Apologised/Excusé</p> |
| <p>EUROPEAN COMMITTEE ON ORGAN TRANSPLANTATION / COMITE EUROPEEN SUR LA TRANSPLANTATION D'ORGANES (CD-P-TO)</p> | <p>Marta LOPEZ-FRAGA Secretary</p> | <p>Apologised/Excusée</p> |

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| <p>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</p> | <p>Elda MORENO Senior Advisor for the Integration of the Youth Perspective</p> <p>Sylvia IVANOVA Youth Policy Division</p> <p>Nina GRMUSA (20/11) Chairperson of the CCJ</p> <p>Miriam TEUMA (20/11) Chairperson of the CDEJ</p> |
| <p>DIRECTORATE GENERAL OF HUMAN RIGHTS AND RULE OF LAW - DIVISION ON MIGRATION AND REFUGEES / DIRECTION GENERALE DES DROITS HUMAINS ET ETAT DE DROIT - DIVISION MIGRATION ET REFUGIES</p> | <p>Victoria KARPATSKY Administrator</p> |
| <p>DIRECTORATE OF SOCIAL RIGHTS, HEALTH AND ENVIRONMENT, DGI / DIRECTION DES DROITS SOCIAUX, DE LA SANTE ET DE L'ENVIRONNEMENT, DGI</p> | <p>Rafael BENITEZ Director / <i>Directeur</i></p> |
| <p>HUMAN RIGHTS, JUSTICE AND LEGAL COOPERATION, STANDARD SETTING ACTIVITIES DEPARTMENT - HEALTH DIVISION / SERVICE DES ACTIVITES NORMATIVES EN MATIERE DE DROITS DE L'HOMME, JUSTICE ET COOPERATION JURIDIQUE - DIVISION DE LA SANTE (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>INTERPRETING, TRAVEL, EVENTS AND MULTIMEDIA DEPARTMENT / SERVICE DE</p> | <p>Lucie DEBURLET-SUTER</p> <p>Amanda LARIVIERE</p> <p>Claudine PIERSON</p> |

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| <i>L'INTERPRETATION, DES VOYAGES, DES EVENEMENTS ET DU MULTIMEDIA (ITEM)</i> | |
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Appendix II
Agenda

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| Tuesday 18 November 2025 (09.00-18.00) | |
| Workshop on human rights and neurotechnologies | |
| Wednesday 19 November 2025 (9.30-18.00) | |
| | <p>1. Opening and adoption of the draft agenda</p> <ul style="list-style-type: none">○ Opening address by Rafael Benitez, Director for Social Rights, Health and Environment, on the outcome of the Conference on the Protection of Health (15 October 2025)○ New CDBIO members invited to introduce themselves○ Reminder about the main decisions to be taken during the meeting |
| | <p>2. Neurotechnologies and human rights</p> <ul style="list-style-type: none">- <i>Short exchange on the outcome of the workshop held on 18 November 2025</i> |
| | <p>3. Strategic Action Plan</p> <p>a. SAP (2020-2025)</p> <p><i>Objective: Finalisation of the final report of the SAP including impact assessment</i></p> <p>b. Strategic Plan on Human Rights in Biomedicine and Health (2026-2030)</p> <p><i>Objectives:</i></p> <ul style="list-style-type: none">- <i>Approval of the Strategic Plan (2026-2030)</i>- <i>Agreement on the approach for the definition of the actions under each strategic objective</i>- <i>Where time allowed, preliminary discussion on possible actions</i> |
| | <p>4. Artificial Intelligence</p> <p><i>Objective: Presentation of the HUDERIA academy 2026</i></p> |

Thursday 20 November 2025 (09.30-12.30)

5. Youth perspectives

Objective: Presentation of the newly adopted reference framework for a youth perspective

6. Other business

a. Access to origins

Objective: Brief report on the outcome of the meeting of the Committee of Experts on Access to Origins (CJ-OR)

In charge of developing a draft Recommendation on access to origin for children born out of gametes/embryo donation

b. Organ transplantation

Objective: Brief report on the last meeting of the European Committee on organ transplantation (CD-P-TO)

c. Human rights in mental health care

Objectives:

- Update on the examination process of the legal instruments by the Committee of Ministers
- Update on HELP course on mental health and human rights

d. Guide to children's participation in decisions about their health

Objective: Update of follow-up activities

e. Health literacy

Objective: Information on the 3rd Conference on health literacy and human rights, 5 December 2025 in Rome

f. Action Plan Armenia

Objective: Information on the progress made in the cooperation activities

g. Events foreseen in 2026




7. Bureau elections

Objectives:

- Election of the Chair and Vice Chair (the Chair and Vice Chair first term is ending. The Chair is re-eligible for second term of one year. The Vice-Chair is not running

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| | <p>for re-election as she is leaving the CDBIO)</p> <ul style="list-style-type: none"> - Subject to the outcome of the election of the Chair and Vice Chair, election of one Bureau member (Sanne Van Weezel first term in the Bureau is ending. She is re-eligible for a second term of two years) |
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| | <p>8. Dates of the next meetings</p> <ul style="list-style-type: none"> ○ 9th meeting of the CDBIO: 2-5 June 2026, Strasbourg ○ 10th meeting of the CDBIO: 17-20 November 2026, Strasbourg |
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| | <p>9. Adoption of decisions taken by the CDBIO at its 8th meeting</p> <p><u>Objective:</u> Approval of the abridged meeting report</p> |

POINTS TO BE DEALT WITH IN WRITING

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|  | <p>10. Developments in the field of bioethics</p> <p>Delegations, including observers, are invited to send information in writing.</p> <ol style="list-style-type: none"> 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) |
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|  | <p>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</p> |
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|  | <p>12. Cooperation with other committees</p> <ol style="list-style-type: none"> 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 (Ireland)
Chair of the Drafting Group for the new SAP



CDBIO_Strategic_Plan_2026_2030_Presentation

Appendix IV
Presentation by Tesi Aschan (Sweden)
on Access to origin for children born out of gametes donation

The objective of CJ-OR is to draft a recommendation on the rights of donor-conceived persons to know their origins.

I acceded to the expert committee as a representative of the CDBIO beginning from its 2nd meeting which took place in Strasbourg on the 28th – 30th October. The meeting included a presentation by the British Infertility Counselling Association (BICA) and the Donor Conception Network describing how donor conceived persons may access their rights in Britain today.

The discussion on the draft concerned in particular; definitions and the scope of a recommendation. The terminology of donor vs parent, donor-conceived person vs child, embryo donation vs transfer, and whether the scope meant by "donation" should only apply within a medically assisted reproduction treatment or also outside of a medical context. Adoption would be excluded but surrogacy perhaps not.

However, the right to know those circumstances around one's conception would only concern Member states where surrogacy is lawful. Similarly, mitochondrial transfer was mentioned as such a circumstance. These details are yet to be discussed more closely.

Some main messages are that

- MS shall encourage a culture of transparency and openness among parents (who need to inform their child in the first place).
- MS should establish legal mechanisms enabling any person to access information on their genetic origin (balancing competing individual rights so anonymous donors will not retroactively be disclosed without consent).
- MS shall provide reliable secure and long-term systems for collecting and storing detailed data (including health data, non-identifying and identifying data) concerning donors, parents and DCP, including information about the no of children born per donor and relevant treatment details.
- Encourage interstate cooperation to facilitate cross-border traceability of data related to MAR involving donors.

The CDBIO could specifically contribute by adding references to relevant international legal instruments in the preamble, perhaps also by exploring the "right to identity" in the Oviedo Convention in this context. Does it include information about a donor and how much information? Some other questions to think about: Why should adopted children not be included? What access to a donor's health data is proportionate considering a donor's privacy? In comparison, how much information do we have on our parents' health data? Do we need harmonized regulations on how long the data must be stored? (The working proposal is 120 years).

Appendix V
Presentation by Lada Zibar (Croatia)
on the progress in the work of committees in which the CDBIO is represented

34th CD-P-TO, 9-10 Oct 2025 Kalamata, Greece

Two important position papers were formally adopted:

- 1. Online Promotion and Facilitation of Unethical International Travel for Transplantation**
- 2. Risks to Safety and Quality in Donor Screening and SoHO Preparations Due to Poor Implementation of the Medical Devices Regulation (MDR) and In Vitro Devices Regulation (IVDR) and the Resulting Shortage of Essential CE-Marked Devices**

Ad 1. Recent media reports have revealed cases where online platforms and websites offer transplant tourism packages. Desperate patients are thus lured into unsafe and unlawful transplant procedures, in exchange for substantial fees, where vulnerable individuals are exploited as sources of organs.

Reaffirming the Council of Europe and WHO previous supporting acts, the paper states that we are urged to combat against cybercrime related to the unethical international travel for transplantation and describes the levels and areas where there are possibilities to act: coordination with authorities, international coordination, training cybercrime agencies on the topic, work on patients literacy, informing patients and families about the threats and use of the Council of Europe instruments as legal framework against human and human organ trafficking.

Ad 2. There are the EU regulations from 2017 called MDR and IVDR, which apply to medical devices and in vitro diagnostic medical devices (MD & IVD) placed on the EU market that generated unintended consequences for the Substances of Human Origin (SoHO) sector: the time, complexity and cost of conformity assessment under the regulations. It adversely affected the ability of manufacturers to place niche MDs and IVDs on the market for SoHO applications. The regulations want to minimise the risks of transmission of any disease to the recipient and to avoid any action which might affect the suitability of an organ, tissue or cell for implantation. According to the MedTech Europe IVDR & MDR survey a quarter to a third of IVD and MD manufacturers in orphan and niche markets plan to transition fewer than 5% of their devices to compliance under the alleged regulations. The paper recommends simplifying conformity assessment procedures, reduce documentation requirements for such devices that are critical for public health but not commercially viable under current rules. European Commission should urgently provide clear, harmonised guidance on the use of off label and research-use-only (RUO) devices in the context of in-house manufacturing.



PositionPaper_PA-P
H-TO-25-23-DEF_EN



PositionPaper_PA-P
H-TO-24-18-DEF_EN

Appendix VI
Presentation by Lusine Hayrapetyan (Armenia)
on the cooperation project as part of the Armenia Action Plan

1. Developments in the field of bioethics

The first important step is Armenia's ratification of the Convention, which truly required significant effort from our country and will enter into force for Armenia on 1 February 2026.

Although Armenian legislation mostly complies with the principles and provisions of the Oviedo Convention, we are currently conducting a detailed analysis of the alignment between the Convention and our national legislation, and all necessary legislative amendments will be carried out in Armenia before the Convention enters into force.

2. Recent legislative amendments and some of the key achievements

Prior to conducting the analysis of the legislation, Armenia had already introduced certain legislative amendments, in particular concerning the legal framework governing transplantation. In early 2024, Armenia launched a major revision of the Law on Transplantation to address practical challenges and align it with health sector regulations. These amendments were also undertaken to bring our national legislation closer in line with the principles of the Oviedo Convention, ensuring higher standards of protection for donors and recipients. The amendments, adopted in April 2024, introduced the concepts of both brain death and biological death, enabling clearer and broader regulation of organ retrieval. The Ministry of Health was empowered to define which organs may be retrieved after each type of death, and a new order was issued accordingly. The rights of living donors were strengthened, including guaranteed continuous medical follow-up. The amendments also improved public awareness mechanisms regarding donor consent and clarified consent procedures for recipients, including allowing 16–18-year-olds to provide informed consent for transplantation.

In connection with the adoption of the Law of the Republic of Armenia HO-144-N of 11 April 2024 "On Making Amendments and Additions to the Law on Transplantation of Human Organs and/or Tissues" (<https://www.arlis.am/DocumentView.aspx?DocID=192455>), many other legal acts also have been developed and approved by the government and by the Ministry of health.

3. According to the Law of the Republic of Armenia "On Medical Assistance and Services to the Population," a person's written consent for a medical intervention is a necessary requirement in cases defined by the authorized body, and it is also established that the cases in which written consent for a medical intervention is required shall be determined by the Minister of Health. Within the scope of these regulations, by Order No. 215-N (<https://www.arlis.am/hy/acts/195322/latest>) the Minister of Health dated **10 July 2024**, the **Cases Requiring Written Consent for Medical Intervention** have been approved.

4. Again with the support of the Council of Europe, and with the involvement of local and international experts, methodological guidelines on the proper handling of medical confidentiality were developed and approved by Order of the Minister of Health (<https://www.moh.am/images/legal-1737.pdf> Order No. 7592-N, 27 December 2024). The guidelines provide a comprehensive description of the **general concept of medical confidentiality**, the **legal framework**, **free and informed consent**, the **disclosure of medical confidentiality** and **limitations on medical secrecy**, as well as the **challenges, best practices**, and a number of other important matters.

5. The next important point, and a significant achievement for our country, is the Development of the new HELP course on Human Rights in Mental health services in Armenian.

6. In 2024, the Council of Europe, in close cooperation with the Secretariat of the Steering Committee on Human Rights in Biomedicine and Health (CDBIO), developed the HELP Course on “Mental Health and Human Rights.” The course aims to strengthen the knowledge of healthcare professionals and legal experts and to raise awareness regarding the relevant applicable European human rights standards concerning persons with mental health issues, including those in vulnerable situations such as migrants, refugees, or persons deprived of liberty.
7. Armenian adaptation of the abovementioned course to the Armenian legal order is already free available, providing an opportunity for representatives of public authorities as well as sector professionals to improve their understanding of European and national standards in the field of mental health and to apply them in their daily work. 19 tutors are certified for conducting tutored HELP Course on Mental Health and Human Rights. As of today, nearly 85 healthcare and legal professionals, mainly working in the field of mental health have successfully completed the Course.
8. Additionally, a report on involuntary hospitalization and treatment in mental health facilities has been developed, focusing particularly on procedural safeguards in national legislation and practice. This document is also expected to contribute to the implementation by Armenia of the European Court of Human Rights judgment in *Nikolyan v. Armenia*, and to support the effective implementation of the National Human Rights Strategy and Action Plan 2023–2025.
9. An Ethics Committee has been established in Armenia and is actively carrying out its work. Ethical guidelines have also been approved by a Government Decision (No. 182-N of February 17, 2022) (<https://www.arlis.am/hy/acts/160369/latest>). The Committee, operating on a public basis, is established in accordance with the procedure prescribed by the Law of the Republic of Armenia “On Medical Care and Services to the Population” for the purpose of examining violations of the rules of professional ethics of healthcare workers.