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CDBIO/RAP 3

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

3rd meeting

6-9 June 2023

Strasbourg

Report

Pilot youth forum on AI in healthcare

1. Siobhan O'Sullivan (IRL), Chair of the CDBIO, opened the pilot youth forum on AI in healthcare, welcoming the 14 youth participants. She recalled the CDBIO commitment to hosting a forum to provide young people with an opportunity to share their views on bioethical topics and to inform the work of the Committee.
2. The Ambassador, Permanent Representative of Ireland to the Council of Europe, Breifne O'Reilly, welcomed the forum initiative made possible by a financial contribution from the Irish government. As expressed by the Heads of state and government during the Council of Europe's Fourth Summit, held in Reykjavík on 16 and 17 May 2023, the Ambassador underlined the Organisation's commitment to supporting the participation of young persons in democratic life and decision-making processes, especially on the topic of AI in healthcare which is both relevant and timely. This was echoed in a video message by the Irish Chief Medical Officer, Breda Smyth, who stated that AI's potential to transform healthcare should be carried out mindful of the need to safeguard everyone's equitable access to healthcare and right to privacy.
3. The youth participants made presentations of their understandings, the key challenges and proposed solutions regarding AI systems in healthcare vis-à-vis the issues of bias mitigation, training, equal access, and responsibility/accountability.
4. As regards bias mitigation, the youth participants asserted that AI systems should be trained using a broad array of demographic data, so that the benefits of AI do not only benefit those whose data are used to train the algorithms used in AI systems. They suggested the way forward was through more diversity in how AI technologies are developed and how AI systems are trained, which includes the training of developers and health professionals on implicit bias, the review of standards for data collection especially those data used in training datasets, and greater public awareness activities among underrepresented groups.
5. The youth participants stressed that AI should not dehumanise the patient-doctor relationship, as empathy cannot be replaced. This is best achieved by informing and seeking the consent of the patient when AI is used, to help build trust in AI deployment in healthcare systems.
6. As regards training, the youth participants welcomed the potential efficiency gains when AI is used in healthcare but also raised concerns about the possible effect of "deskilling" health professionals. They stressed the need for the human doctor and the AI system to possess shared competencies. Proper training (and assessment) of AI systems using trustworthy data and literature was emphasised, with researchers and AI developers reviewing what and how they collect data.
7. On the issue of equality, the youth participants asserted the need for AI in healthcare to benefit everyone equally so that no one is left behind. They referred to the potential for AI systems to bridge gaps in access to healthcare, for example those who are harder to reach, but that this should not mean losing out on access to 'in-person' care. They suggested that individuals and groups in society, such as young people and the elderly, be included in deliberations on the development of different options for people accessing healthcare. To this end, they underlined the need for efforts to improve literacy and awareness raising, as well wide consultations at key stages in the development of AI systems.
8. As regards accountability, the youth participants highlighted the risks and uncertainties associated with AI in healthcare and expressed concern about who to trust in the chain of actors involved in the development, training and deployment of AI systems. They emphasised the need for a "shared responsibility" between AI developers and health professionals to 'do no harm', and in determining standards or protocols for when, where and how AI is used in various (sensitive) health settings to make AI systems more explainable and easier to assess.

During exchanges with delegations, youth participants also suggested that AI standards and protocols should be “living documents” which are under continuous assessment.

9. Following the close of the forum, the CDBIO briefly reflected on the discussions held. Delegations expressed great satisfaction with the rich discussions and insightfulness of the youth participants. They applauded the diversity of viewpoints brought forward by youth participants from different backgrounds which will provide the Committee with youth perspectives to inform its own work, including its strategic objectives and actions in the field of human rights and biomedicine.
10. The Chair concluded by highlighting the forum’s value in learning lessons for the planning of a larger scale youth forum in the coming years.

I. Adoption of the agenda

11. 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.
12. The agenda was adopted. It appears in Appendix II to this report.
13. The Irish authorities were thanked for their financial support of the Pilot Youth Forum.
14. Based on the experience of the Pilot Youth Forum, the Chair pointed out the importance of the preparation of the organisation of the Youth Forum foreseen in 2025 under the SAP. She invited delegations to consider the possibility of covering the cost of one or two young persons from each country to participate in the 2025 Youth Forum.

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

15. The Chair recalled that this work was postponed due to the Covid-19 pandemic and the ethical challenges it raised to prepare draft instruments on equitable access to vaccines and treatments, and equipment in a context of limited resources. The Chair gave the floor to Tomáš Doležal, Chair of the drafting group entrusted with preparing the Recommendation CM/Rec(2023)1 on equitable access to medicinal products and medical equipment in a situation of shortage, to recall the work already done on equity in healthcare. She asked the Secretariat to briefly introduce the Concept Note on Equitable and timely access to innovative treatments and technologies in healthcare (CDBIO (2023) 6).
16. Then, the Chair invited delegations to make general comments on the ethical issues to be considered when it comes to equitable access to innovative treatments and technologies, and on how to go further with the process and its possible achievements.
17. Delegations welcomed the Concept note, noting the factual elements that challenge the decision-making process at the national level. These elements include that clinical evidence supporting safety and efficacy is often limited, making the evidence-based decision-making process uncertain. Other factors relate to the problem of affordability due to high prices charged by manufacturers and, more generally, to the need for an overall assessment of the clinical value and appropriateness for patients in the context of the healthcare system.
18. Delegations noted that the scope of the work potentially includes a wide variety of healthcare products, processes, and medical procedures, and they supported keeping a high-level strategic view on the issue, not limiting the scope of the work to the case of expensive medicinal products. It was also noted that the term innovative does not necessarily endorse beneficence for patients and can raise unrealistic expectations.

19. The CDBIO agreed that Recommendation CM/Rec(2023)1 already covers most issues related to equitable access to innovative treatments and technologies. The Committee agreed therefore not to prepare a new draft recommendation but to work on a discussion paper to assess any outstanding ethical issues relevant to innovative treatments and technologies to be taken into account when designing the process. The discussion paper should examine how the general and procedural principles of Recommendation CM/Rec(2023)1 apply to the decision-making processes ensuring equitable access to innovative treatments and technologies. It should also map and briefly analyse the work done by other international organizations such as the WHO, OECD, and the EC to avoid duplication, taken into consideration that the paper should take a human rights patient focus approach.
20. The CDBIO agreed to benefit from the expertise of a consultant, supported by two or three CDBIO members, to prepare a preliminary draft. The Bureau will be responsible for leading the preparation of the draft discussion paper and presenting it to the CDBIO at its 4th plenary meeting.

III. Draft Recommendation for the promotion of voluntary measures

21. The Chair of the CDBIO introduced the text of the Draft Recommendation as prepared by the Bureau. She acknowledged receipt of the written comments sent by INGO representatives on 6 June.
22. CDBIO discussed the draft text and agreed on the following amendments to the text:
23. In the Preamble, reference should be made to the WHO's QualityRights Initiative.
24. In Article 1, the object should be complemented by adding the following phrase: "and to prevent the use of coercion", so as to reflect that the objective is to diminish and eventually put an end to the resort to involuntary measures.
25. In Article 2, the scope should be broadened, so that the text applies to all persons (by referring to "persons" instead of "adults", so as to include children), and regardless of the type of place where the care is delivered".
26. Article 3.1 should make a clearer link between autonomy and the notion of agreement on the part of the patient. Therefore, a suggestion is to replace the phrase "The provision of mental healthcare should respect the autonomy of persons receiving care" with "The provision of mental healthcare should be on a voluntary basis respecting the autonomy of persons receiving care.
27. It was also agreed to replace "safeguards provided for by law" with "legal safeguards", as these safeguards may not always be captured in national law as such.
28. Article 6 should be rephrased after the first sentence with the following wording: "Responsibility and accountability should be clearly defined in order to ensure practices within services reflect this goal". This may concern other persons that "those responsible for such services".
29. The provision of Article 7 should be modified to read by "Representative organizations of persons with lived experience and individual users of mental healthcare services should be involved in developing policies and practices that respect autonomy¹ and their involvement should be appropriately resourced."

¹ The EM could mention the importance of ensuring a wide range of sectors and stakeholders are involved in developing policy and practice in addition to persons with lived experience.

30. The CDBIO agreed to examine the remainder of the text at its next plenary meeting.
31. **Delegations were invited to send comments in writing on the entire text by 10 July 2023.**

IV. Artificial intelligence and biomedicine

32. The Chair of the drafting group, Joni Komulainen (FI), presented the draft report on the impact of AI on the patient-doctor relationship, which included the decision to target decision makers, health providers, health professionals and patient's (including patient associations), and the purpose of the report which is to consider how AI systems are used in healthcare, having regard to their human rights implications, as well as to develop and strengthen the therapeutic relationship.
33. Structured around the main themes of the report, the Chair of the drafting group presented the context, key challenges and recommended actions concerning AI's impact on (i) access to healthcare, (ii) patient autonomy, (iii) professional standards of health professionals, and (iv) the right to privacy and to information. Each main theme was then summarised with regard to the needs of patients and the corresponding responsibilities of health professionals and health authorities.
34. The CDBIO held an extensive exchange of views on the draft report, which resulted in comments on ways to refine, enrich and develop the text. This included reflection on the responsibility and liability for AI systems in healthcare, the ramifications of AI healthcare on people's access inter alia to insurance and employment, the right to know (and not to know) about incidental findings discoverable via AI systems, and the concept of 'human meaningful control' as developed by the European Group on Ethics in Science and New Technologies in its statement on AI, Robotics and 'Autonomous Systems'.
35. Mindful of the discussions during the pilot youth forum on AI in healthcare, the CDBIO also reflected on the extent of the autonomy of patients and of health professionals vis-à-vis the increasingly proficient deployment of AI systems in healthcare. The Committee also discussed the call made by the youth participants for AI developers and health professionals to exercise "shared responsibility" for AI systems.
36. The CDBIO noted with satisfaction the progress made by the drafting group, welcoming the general structure and content of its draft report. **Delegations were invited to provide any written comments on the draft report, to be sent to the Secretariat at the latest by 10 July 2023.**

V. Overview of legislation and practices on patients' rights

37. Dr Rumiana Yotova (Cambridge University, UK), Consultant, had been entrusted with the task of preparing an introductory report "identifying the main themes and provisions/measures to be included in legislation to promote/facilitate the implementation of a "human rights-based approach" in health care". She presented her report on "Human rights-based approaches to healthcare".
38. She pointed out that rather than going through the rights one by one she decided to go via principles: accessibility, availability, equality and non-discrimination, consent, privacy and personal information, primacy of the individual and no harm principle, prevention (newer principle still in progressive development) and participation in health-related decision making.
39. The CDBIO welcomed the report prepared by Dr Yotova.

40. Autonomy of the physician in case the patient refuses the treatment proposed and ask for another one, as well as end of life issues, were raised by delegations. Dr Yotova underlined in this context the margin of appreciation left to the states by international human rights law.
41. With regard to quality and safety, Dr Yotova underlined that not all states can afford to provide quality care at the level of the whole population. Special focus should be placed on marginal groups.
42. When it comes to the right to prevention, Dr Yotova considered it as an emerging theme on which the Covid crisis had a positive impact.
43. One delegation referred to the responsibility towards future generation. Another delegation noted the UNESCO's report published last year relevant to the rights of future generation. The reference to rights when it comes persons who are not yet born does however raise problems. The approach should rather be to think in terms of intergeneration responsibility.
44. The Chair then presented the draft questionnaire aiming at collecting data to provide an overview of national legislation on the protection and promotion of patients' rights. The draft questionnaire was designed on the basis of Dr Yotova's report.
45. Suggestions were made to clarify some questions and make the replies more useful for the CDBIO. Boxes would be introduced inviting delegations to also indicate possible difficulties of implementation as well as possible gaps and/or areas for future developments in legislations.
46. CDBIO agreed on a final version of the questionnaire to be sent to delegations just after the meeting. **Delegations were invited to send their replies by 10 October 2023.**

VI. Mid-term review of the SAP

47. The Chair presented the draft mid-term review prepared by the Group composed of the Chair, Vice-Chair and a member of the Bureau as well as the former chairs of the Committee. The first part of the report focused on what was done and the second part indicated future avenues for actions. The latter section referred to follow up activities to those already achieved and agreed by the CDBIO, e.g. concerning neurotechnologies and human rights.
48. The delegations discussed the proposal to develop a new action plan to start in 2026 and to organize a horizon scanning event to this end. Lessons should be learnt from the lengthy exercise carried out for the development of the current SAP. It was suggested that, as this had been the case for the current SAP, a questionnaire be sent all delegations and stakeholders to identify priority issues. Other CoE committees could also be consulted.
49. The CDBIO agreed to develop a new strategic action plan by the end of 2025 and to organise, in 2024, an 'horizon scanning' exercise to that end. The CDBIO decided to set up a small preparatory group, composed of Bureau members and interested delegations, to propose a methodology for this exercise. Four members of the CDBIO already expressed their readiness to participate in this work. **Delegations were invited to express their interest in being part of the group as soon as possible and in any case by 1 September 2023.**
50. The delegations finalised the mid-term report of its Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025) and agreed to send it to the Committee of Ministers to take note.

VII. Guide on children participation in decision-making process on matters relevant to their health

44. Ms Ritva Halila (SF), Co-Chair of the Drafting group in charge of the file, gave an overview of the progress made on the Guide since the previous plenary meeting. An initial draft had been reviewed in the light of the feedback received during the stakeholders' consultation.
44. The revised text had then been examined by CDENF at the end of March and members submitted their comments in writing at the end of April. The Secretary of the CDENF indicated that these comments did not call for major changes.
45. CDBIO delegations shared the following observations on the text:
46. Several delegations brought clarification and/or correction to the factual information regarding national legislations in annex 2. Further, on the basis that the information in this section was largely incomplete (few countries had transmitted details), it was decided to remove the annex altogether and to move some of the information it contained to the actual text of the Guide (as illustrations of national situations).
47. It was suggested that some notions should be further elaborated upon in the text, such as, access to confidential counselling, research, and the right to an open future.
48. Regarding the section on Managing Disagreements, one delegation shared the view that the current text may wrongfully convey the idea that healthcare professionals had an obligation to take the side of the child; this should be avoided.
49. One delegation suggested to remove the phrase "matters that relate to sexual and reproductive health" at line 785, by closing the sentence after the word "misinformation".
50. A few additional editorial suggestions were made.
51. **Delegations were invited to send any written comments and national examples of practice to the Secretariat, by 20 June 2023.** A revised draft will be circulated in the Summer to CDENF and CDBIO in a view of its adoption by both Committees, in November 2023

VIII. Genomics and public dialogue

52. The rapporteur, Mark Bale (UK), presented his report of the workshop, held on 10 November 2022. Recalling the workshop objectives established by the CDBIO preparatory group, the rapporteur summarised the main discussions and results of the event which was divided into six sessions.
53. In his concluding remarks, the rapporteur underlined inter alia that public information is not the same as two-way dialogue which comprises a broad range of publics, also because everyone has a genome and thereby a valid perspective to share. Genomic initiatives should therefore consider issues of fairness, equity, social justice, equal moral worth and solidarity, at the local, national and global level. Also, the rapporteur recalled that trust and trustworthiness depend on effective regulation and oversight, as well as transparency about the purposes and protections in place regarding genomic developments.
54. The CDBIO took note of the rapporteur's report and supported the development of further work in this field, including on awareness raising activities among different stakeholders and, in the light of the outcome of the workshop, the re-examination of the Additional Protocol to the Oviedo Convention concerning Genetic Testing for Health Purposes. and of Rec(2016)6 on research on biological materials of human origin. This should be reflected in the mid-term

report of the CDBIO on the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025).

IX. Bureau election

58. With a view to facilitate yearly budget planning, namely with regard to the need for interpretation at Bureau meetings, the CDBIO agreed to postpone the election of a new Bureau member until the next plenary meeting, so as to hold, from now on, all Bureau elections during winter plenaries.

X. Adoption of decisions taken by the CDBIO at its 3rd meeting

59. The Delegations adopted the abridged report presented in doc CDBIO / abr RAP3.

XI. Dates of the next meetings

60. The CDBIO agreed to hold the next meetings on:
- 4th plenary meeting: 14-17 November 2023, in Riga at the invitation of the Latvian
 - 5th plenary meeting: 11-14 June 2024, in Strasbourg

XII. Other business

a. Dissemination of adopted documents

61. The Secretariat presented a document describing the actions that it has taken to give more visibility to adopted documents.
62. **Delegations were invited to contribute to the dissemination and further visibility of such documents at national level.**

b. Early intervention on intersex children

63. Mélodie Bernaux (France), Rapporteur for the seminar on early intervention on intersex children, presented her report.
64. One delegation referred to the opinion of the national ethics committee of her country on this issue which emphasized the criteria of the best interest of the child. Another underlined the importance of supporting parents to ensure that the child can take part in the decision.
65. Another delegation informed about two multidisciplinary seminars held in her countries with a view to organized appropriate care for the children and the parents.
66. The representatives of the Secretariat of the Steering Committee on Anti-Discrimination, Diversity and inclusion (CDADI) and of the SOGI Unit thanked for the work achieved. They noted the concepts of “medical necessity”, “best interest” and “consent” which were identified and will certainly be discussed in the context of the preparation of the draft recommendation on the rights of intersex persons with which the CDADI has been entrusted. The work will be organised around the following overarching themes: medical aspects, civil registry and anti-discrimination – awareness raising.
67. The CDBIO will be invited to designate a person to join the group in charge of the drafting. Four meetings of the group were foreseen starting in September 2023 until the end of 2025 where the draft will be presented to the CDADI. A public consultation on the draft will be organized during the process.

68. The CDBIO took note of the rapporteur's report of the seminar on "Early intervention on intersex children - Promoting the rights of the child", held on 31 May 2022. The Committee agreed that its content reflected properly the outcome of the seminar.
69. Delegations were invited to express interest in participating in the Drafting group in charge of preparing a draft Recommendation on the rights of intersex persons, under the authority of the CDADI.
- c. Replies to questionnaire on medically assisted procreation, including surrogacy
70. **Delegations were invited to update their replies to the questionnaire on access to medically assisted procreation (MAP), on the right to know about their origin for children born after MAP and on surrogacy, with a view to their publication in December 2023 as requested by the Committee of Ministers.**
- d. Conference on "Promoting autonomy in mental health care" (Riga, 14 November 2023)
71. The delegations welcome the draft programme for the Conference entitled "Promoting person's autonomy in mental health care", to be organised in cooperation with the Ombudsman of the Republic of Latvia and the University of Latvia, under the auspices of the Latvian Chairmanship of the Committee of Ministers (Riga, 14 November 2023).
- e. Armenia Action Plan II
72. Ms Meri Katvalyan, in charge of the project at the level of the Secretariat, in CoE Yerevan Office, presented the activities carried out as part of the new Human Rights in Biomedicine II, under the second Armenia Action Plan. The presentation appears in Appendix III to this report.

Appendix I
List of participants

MEMBERS / MEMBRES

ALBANIA / ALBANIE	Awaiting nomination / <i>Nomination en attente</i>
ANDORRA / ANDORRE	David PÉREZ SURRIBAS Apologised/Excusé President of the National Committee of bioethics
ARMENIA / ARMENIE	Anna MKRTUMYAN Head of the Legal Department Ministry of Health
AUSTRIA / AUTRICHE	Sabine FASCHING Apologised/Excusée Federal Chancellery Secretariat of the Bioethics Commission Mariella STURZ, LL.M. LL.M. Department Family Law Ministry of Justice Andreas VALENTIN Member of the Bioethics Commission
AZERBAIJAN / AZERBAÏDJAN	Ismayil S ZULFUGAROV Head of Proteomics Lab Institute of Molecular Biology and Biotechnologies of the Azerbaijan National Academy of Sciences
BELGIUM / BELGIQUE	Katrien VAN WOUWE Apologised/Excusée Attachée au service Relations internationales du SPF Santé publique, Sécurité de la chaîne alimentaire et Environnement
BOSNIA AND HERZEGOVINA / BOSNIE-HERZÉGOVINE	Dunja PEJOVIC Apologised/Excusée Coordinator of the Regional Health Development Center for Mental Health in SEE Ministry of Civil Affairs
BULGARIA / BULGARIE	Vihra MILANOVA Head of Psychiatric Clinic Alexandrovska University Hospital
CROATIA / CROATIE	Vanja NIKOLAC Apologised/Excusée Head of Service, Service for blood, tissues and cells inspection Ministry of Health
CYPRUS / CHYPRE	Andrie PANAYIOTOU Member of the Cyprus National Bioethics Committee (CNBC) Associate Professor in Public Health Head Cardiovascular Epidemiology and Genetics lab Cyprus International Institute for Environmental and Public Health Constantinos N. PHELLAS Apologised/Excusé Chair of the Cyprus National Bioethics Committee University of Nicosia
CZECH REPUBLIC / REPUBLIQUE TCHEQUE	Tomáš DOLEŽAL Ph.D., LL.M., Head of the Department of Private Law and Head of the Research Unit for Medical Law and Bioethics

	<p>Czech Academy of Science, Institute of State and Law</p> <p>Hana KONEČNÁ Ph.D., University of South Bohemia in České Budějovice</p>
DENMARK / DANEMARK	<p>Berit Dea HVOLBY Head of Section, Personalized Medicine, Research and Privacy Ministry of Health</p>
ESTONIA / ESTONIE	<p>Aime KEIS Apologised/Excusée Vicechair of the National Committee on Bioethics and Human Research University of Tartu</p>
FINLAND / FINLANDE	<p>Maija MIETTINEN Ministerial Advisor Ministry of Social Affairs and Health General Secretary, National Advisory Board on Social Welfare and Health Care Ethics (ETENE)</p> <p>Tinja SCHRODER Apologised/Excusée Legal Officer Unit for Human Rights Courts and Conventions Legal Service, Ministry for Foreign Affairs</p> <p>Anneli TÖRRÖNEN Ministry of Social Affairs and Health</p>
FRANCE	<p>Kamyar ASSARI Consultant juridique Sous-direction des droits de l'Homme Direction des affaires juridiques Ministère de l'Europe et des Affaires étrangères</p> <p>Lucie BOZEC Chargée de mission greffe Bureau bioéthique, éléments et produits du corps humain (PP4) Direction générale de la Santé (DGS) Ministère de la Santé et de la Prévention</p> <p>Fadia DIB Médecin chargée de la procréation, embryologie et génétique humaine 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 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>Jacques MONTAGUT Ancien membre du CCNE</p>
GEORGIA / GÉORGIE	<p>Givi JAVASHVILI Apologised/Excusé Head of Family Medicine Department Tbilisi State Medical University Chairman of the National Council on Bioethics</p>

<p>GERMANY / ALLEMAGNE</p>	<p>Elmar DOPPELFELD Honorary Chair of the "Permanent Working Party of Research Ethics Committees in Germany Inc."</p> <p>Carlo GRIMM Apologised/Excusé Division 611 Federal Ministry of Education and Research</p> <p>Ingo HÄRTEL Division 316 Federal Ministry of Health</p> <p>Thomas HEINEMANN Philosophical-Theological University of Vallendar (PTHV)</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>
<p>GREECE / GRECE</p>	<p>Andreas KARABINIS Intensivist, Professor of Emergency Medicine Athens Medical School National and Kapodistrian University of Athens</p>
<p>HUNGARY / HONGRIE</p>	<p>Tamás KARDON Associate professor, Secretary of the Scientific and Research Ethics Committee of Medical Research Council</p>
<p>ICELAND / ISLANDE</p>	<p>Rögvaldur G. GUNNARSSON Apologised/Excusé Legal Advisor Ministry of Welfare</p> <p>Kristín Ninja GUDMUNDSÓTTIR Apologised/Excusée Legal Advisor Ministry of Health</p>
<p>IRELAND / IRLANDE</p>	<p>Siobhán O’SULLIVAN Royal College of Surgeons</p>
<p>ITALY / ITALIE</p>	<p>Assunta MORRESI Prof. Associato di Chimica Fisica, Dipartimento di Chimica, Biologia e Biotecnologi Università degli Studi di Perugia</p> <p>Laura PALAZZANI Apologised/Excusée Lumsa, Facoltà di giurisprudenza Roma</p>
<p>LATVIA / LETTONIE</p>	<p>Vents SĪLIS Associate Professor & Chairman of Central Medical Ethics Committee of Latvia Department of Humanities Riga Stradins University</p>

LIECHTENSTEIN	Awaiting nomination / <i>Nomination en attente</i>	
LITHUANIA / LITUANIE	Asta ČEKANAUSKAITĖ Director of Lithuanian Bioethics Committee	
LUXEMBOURG	Awaiting nomination / <i>Nomination en attente</i>	
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	
	Ion PRISACARU Secretary of State Ministry of Health	Apologised/Excusé
MONACO	Thomas ALTHAUS Médecin de Santé Publique Direction de l'Action Sanitaire	Apologised/Excusé
MONTENEGRO / MONTÉNÉGRO	Olivera MILJANOVIĆ MD, PhD, Head of Centre for Medical Genetics and Immunology – Clinical Centre of Montenegro, Chief lecturer of biomedicine, bioethics, clinical genetics and pediatrics at the Faculty of Medicine University of Montenegro	
NETHERLANDS / PAYS-BAS	Harrie STORMS Ministry of Health, Welfare and Sports	
	Sanne VAN WEEZEL Ministry of Health, Welfare and Sports	
NORTH MACEDONIA / MACÉDOINE DU NORD	Awaiting nomination / <i>Nomination en attente</i>	
NORWAY / NORVEGE	Anne FORUS Senior Adviser, ph.d, Biotechnology and health legislation department Division of specialised health care services Norwegian Directorate of Health	
POLAND / POLOGNE	Mariola GROCHULSKA Département des droits de l'homme Ministère de la Justice	
PORTUGAL	Jorge SOARES Conseiller au Conseil National d'Ethique pour les Sciences de la Vie	Apologised/Excusé
ROMANIA / ROUMANIE	Gheorghe BORCEAN Président de l'Ordre des Médecins et Prof. Ass. à l'Université de Médecine et Pharmacie " Victor Babes" de Timisoara Vice-President of the Romanian College of Physicians	

	<p>Spitalul Municipal Caransebes</p> <p>Beatrice Gabriela IOAN Associate Professor President of the Bioethics Commission of the Romanian College of Physicians Institutul de Medicina Legala</p>
SAN MARINO / SAINT-MARIN	<p>Luisa BORGIA <u>Professor of Bioethics, Polytechnic University of Marche</u> <u>President of National Bioethics Committee</u></p>
SERBIA / SERBIE	<p>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</p>
SLOVAKIA / SLOVAQUIE	<p>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</p>
SLOVENIA / SLOVÉNIE	<p>Marjeta TERČELJ ZORMAN Apologised/Excusée Vice President of the National Ethics Commission</p>
SPAIN / ESPAGNE	<p>Carlos M. ROMEO-CASABONA Professor of Penal Law, Head Inter-University Chair in Law and the Human Genome</p>
SWEDEN / SUÈDE	<p>Tesi ASCHAN Legal Adviser The National Board of Health and Welfare, Socialstyrelsen</p>
SWITZERLAND / SUISSE	<p>Carola CHRISTEN International Affairs Division</p>
TÜRKIYE / TÜRKIYE	<p>Tuna İLBARS Unit Coordinator Department of Blood and Blood Products Directorate General of Health Services Ministry of Health</p>
UKRAINE	<p>Iuliia DAVYDOVA Professor, Head of High-Risk Pregnancy Department Institute of Pediatrics, Obstetrics and Gynecology, member of Local Bioethics Committee</p>
UNITED KINGDOM / ROYAUME-UNI	<p>Mark BALE Advisor to the Science Research and Evidence Directorate Department of Health and Social Care</p>

PARTICIPANTS / PARTICIPANTS

CDCJ	Rodrigo RODRIGUEZ Apologised/Excusé Département fédéral de justice et police DF Office fédéral de la Justice OFJ Domaine de direction Droit privé
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OECD / OCDE	David WINICKOFF STI/STP	Apologised/Excusé
WHO / OMS	Andreas REIS Technical Officer HIS/KER Cluster of Health Systems and Innovation	Apologised/Excusé
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CONFERENCE OF EUROPEAN CHURCHES (CEC) / CONFERENCE DES EGLISES EUROPEENNES (CEC)	Elizabeta KITANOVIC Membre du Groupe de travail	Apologised/Excusée
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EUROPEAN DISABILITY FORUM (EDF)	John Patrick CLARKE , EDF Vice-President Kristijan GRDJAN , Mental Health Europe Vice-President Olga KALINA , Chair of the European Network of (Ex)Users and Survivors of Psychiatry Helen PORTAL , Advocacy and Policy Officer of Inclusion Europe	

PILOT YOUTH FORUM / FORUM PILOTE DE LA JEUNESSE

Campus Engage	Harry GRIBBEN , University of Limerick Niamh HICKEY (National Student Engagement Program), University of Limerick Rebecca LANE , University of Galway
Digital Policy Msc	Jennifer WATERS (DDen Summer Instructor), University College Dublin
Jigsaw	Niamh FENNELL (Youth Voice & Engagement officer in Jigsaw) Sam KELLY , Trinity College Dublin Niamh PETRIE , Maynooth University
SFI Adapt Centre	Iva-Nicole MAVRLJA , Maynooth University
National Youth Council of Ireland	Aisha ALAMEEN BETRO , Royal College of Surgeons

Spunout	Aisling COMISKEY Eva O'BYRNE, University of Galway Alyssa RYAN, University of Galway
Union of Students of Ireland	Agata CYLWICH , East Technological University Megan GRIFFITHS , Hibernia College

CONSULTANTS / CONSULTANTES

UNITED KINGDOM / ROYAUME-UNI	Elaine GADD (7/06 via ZOOM) Consultant for the Draft Recommendation for the promotion of voluntary measures Rumiana YOTOVA (8/06 via ZOOM) Consultant for the Overview of legislation and practices on patients' rights
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INVITED GUESTS / INVITES

FINLAND / FINLANDE	Joni KOMULAINEN (7/06) Chair of the Drafting group on AI in healthcare
	Ritva HALILA (8/06) Co-Chair of the Drafting group on developing a guide for the participation of children in decision-making in matters regarding their health
FRANCE	Mélodie BERNAUX (9/06) Rapporteur of the Seminar on early intervention on intersex children

SECRETARIAT / SECRETARIAT

PARLIAMENTARY ASSEMBLY / ASSEMBLÉE PARLEMENTAIRE	Tanja KLEINSORGE Apologised/Excusée Head of Secretariat Committee on Social Affairs, Health and Sustainable Development
	Anita GHOLAMI Committee on Social Affairs, Health and Sustainable Development
	Cristina CALVANO (trainee) Committee on Social Affairs, Health and Sustainable Development
	Yulia PERERVA Apologised/Excusée Committee on Social Affairs, Health and Sustainable Development

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OFFICE OF THE SPECIAL REPRESENTATIVE OF THE SECRETARY GENERAL ON MIGRATION AND REFUGEES / BUREAU DE LA REPRESENTANTE SPECIALE AUPRES DE LA SECRETAIRE GENERALE SUR LES MIGRATIONS ET LES REFUGIES	Anne KAYSER Administrator Sylvie BOLLINI (for the Pilot Youth Forum) Administrator	Apologised/Excusée Apologised/Excusée
COMMITTEE ON ARTIFICIAL INTELLIGENCE / COMITE SUR L'INTELLIGENCE ARTIFICIELLE (CAI)	Kristian BARTHOLIN Secretary	
STEERING COMMITTEE ON ANTI DISCRIMINATION, DIVERSITY AND INCLUSION / COMITE DIRECTEUR SUR L'ANTI-DISCRIMINATION, LA DIVERSITE ET L'INCLUSION (CDADI)	Wolfram BECHTEL Secretary Evgenia GIAKOUMOPOULOU	
SEXUAL ORIENTATION AND GENDER IDENTITY UNIT / UNITE ORIENTATION SEXUELLE ET IDENTITE DE GENRE (SOGI)	Eleni TSETSEKOU Head of Unit	Apologised/Excusée
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COMMITTEE OF THE CONVENTION FOR THE PROTECTION OF INDIVIDUALS WITH REGARD TO AUTOMATIC PROCESSING OF PERSONAL DATA / <i>COMITÉ CONSULTATIF DE LA CONVENTION POUR LA PROTECTION DES PERSONNES À L'ÉGARD DU TRAITEMENT AUTOMATISÉ DES DONNÉES A CARACTÈRE PERSONNEL (T-PD)</i>	Isabelle SERVOZ-GALLUCCI Secretary	Apologised/Excusée
STEERING COMMITTEE FOR THE RIGHTS OF THE CHILD / <i>COMITE DIRECTEUR POUR LES DROITS DE L'ENFANT (CDENF)</i>	Katrin UERPMANN Secretary	
EUROPEAN COMMITTEE ON BLOOD TRANSFUSION / <i>COMITE EUROPEEN (ACCORD PARTIEL) SUR LA TRANSFUSION SANGUINE (CD-P-TS)</i>	Richard FORDE Secretary	Apologised/Excusé
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HUMAN RIGHTS, JUSTICE AND LEGAL COOPERATION, STANDARD SETTING ACTIVITIES DEPARTMENT - HUMAN RIGHTS AND BIOMEDICINE DIVISION / <i>SERVICE DES ACTIVITES</i>	Laurence LWOFF Secretary of the CDBIO / <i>Secrétaire du CDBIO</i> Tel: +33 (0) 388 41 22 68, Email: laurence.lwoff@coe.int Lee HIBBARD Administrator / <i>Administrateur</i> Tel: +33 (0) 388 41 31 04, Email: lee.hibbard@coe.int	

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<p>INTERPRETING, TRAVEL, EVENTS AND MULTIMEDIA DEPARTMENT (ITEM) / SERVICE DE L'INTERPRETATION, DES VOYAGES, DES EVENEMENTS ET DU MULTIMEDIA (ITEM)</p>	<p>Amanda BEDDOWS</p> <p>Lucie DE BURLET</p> <p>Corinne McGEORGE</p>

Appendix II
Agenda

Tuesday 6 June 2023 (09.30-13.00 / 14.30-18.00)

[Pilot Youth Forum on AI in healthcare](#) (9.30 – 13.00)

Brief exchange following the Pilot Youth Forum

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 access to appropriate innovative treatments and technologies in healthcare

Objective: Decision on the way forward

9. Bureau election

Objective: Decision on the possible postponement of the election to the November meeting

- The organisation of any Bureau election at the end of the year would facilitate the yearly budget planification for interpretation at Bureau meetings. It is therefore proposed to extend the current mandate of Mark Bale by 6 months and proceed with the election of a new member of the Bureau at the 4th plenary meeting.

Wednesday 7 June 2023 (09.30-13.00 / 14.30-18.00)

3. Draft Recommendation for the promotion of voluntary measures

Objective: Guidance to the Bureau for the further development of the draft Recommendation, including with regard to a possible consultation on the draft

- Examination of the draft Recommendation prepared by the Bureau

4. Artificial intelligence and biomedicine

Objective: Guidance to the Drafting Group for the further development of the report

- Examination of a draft report

Thursday 8 June 2023 (9.30-13.00 / 14.30-18.00)

5. Overview of legislation and practices on patients' rights

Objective: Agreement on the draft questionnaire

- Discussion on the introductory document prepared by the Consultant
- Examination of the draft questionnaire prepared by the Consultant

6. Mid-term review of the SAP

Objective: Finalisation of the SAP mid-term report

- Examination of the draft mid-term report prepared by the Drafting Group

7. Guide on children participation in decision-making process on matters relevant to their health

Objective: Guidance to be given to the Drafting Group for the finalisation of the draft Guide with a view to its adoption at the CDBIO 4th plenary meeting and the CDENF 8th plenary meeting

- Examination of the draft Guide revised in the light of the comments received during the consultations of stakeholders and children

Friday 9 June 2023 (9.30-13.00)

8. Genomics and public dialogue

Objective: Presentation of the rapporteur report and discussion on its proposals

9. Bureau election (Subject to the decision of the CDBIO on the postponement of the election)

Objective: Election of a new Bureau member for a two-years term renewable once

Submission for nominations should be sent in writing to the Secretariat by Thursday 8 June 2023 at 2.00 pm.

12. Other business

f. Dissemination of adopted documents

Objective: Information about the measures taken by the Secretariat to contribute to the further dissemination and information on adopted documents

g. Early intervention on intersex children

Objective: Presentation of the rapporteur report of the Seminar (31 May 2022)

h. Replies to questionnaire on medically assisted procreation, including surrogacy

Objective: Inviting delegations to check the information provided with a view to their publication at the request of the Committee of Ministers

i. Conference on "Promoting autonomy in mental health care" (Riga, 14 November 2023)

Objective: Presentation of the draft programme

j. Armenia Action Plan II

Objective: Information on the cooperation project Human Rights and Biomedicine II




10. Adoption of decisions taken by the CDBIO at its 3rd meeting

Objective: Approval of the abridged meeting report which includes the decisions

11. Dates of the next meetings

- *4th meeting of the CDBIO: 14-17 November 2023 (Riga)*
- *5th meeting of the CDBIO: 11-14 / 18-21 June 2024*

POINTS TO BE DEALT WITH IN WRITING

	<p>13. 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">Developments in member states and other statesDevelopments in the field of bioethics in international organisationsDevelopments in other Council of Europe bodiesDevelopments at the European Court of Human Rights
	<p>14. 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>
	<p>15. Cooperation with other committees</p> <ol style="list-style-type: none">Steering Committee for Human rights (CDDH)European Committee on Organ Transplantation (CD-P-TO)European Committee on Blood Transfusion (CD-P-TS)Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD)Steering Committee for the Rights of the Child (CDENF)Steering Committee for Legal Cooperation (CDCJ)

Appendix III Armenia Action Plan

HUMAN RIGHTS, DEMOCRACY AND THE RULE OF LAW / DROITS DE L'HOMME, DÉMOCRATIE ET ÉTAT DE DROIT

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Cooperation project “Protection of Human Rights in Biomedicine ii”

Plenary meeting of the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO)


09/06/2023 Meri Katvalyan
Senior Project Officer 1

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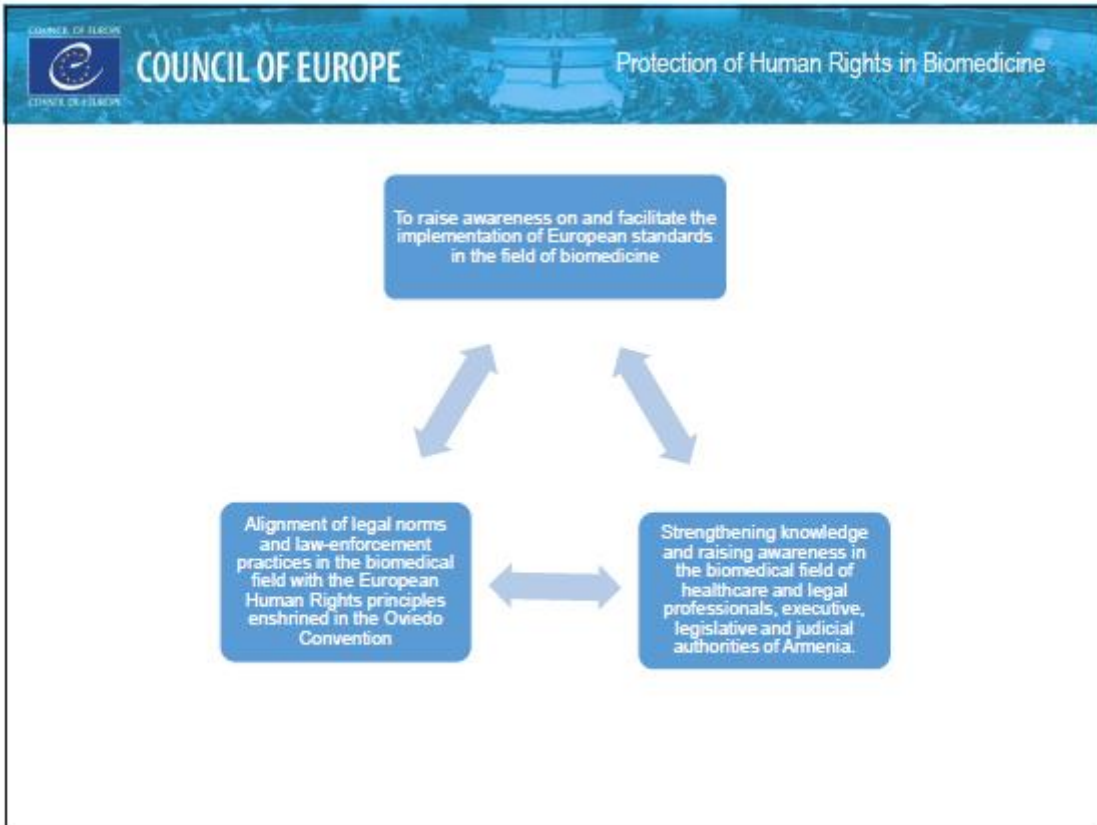
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Protection of Human Rights in Biomedicine

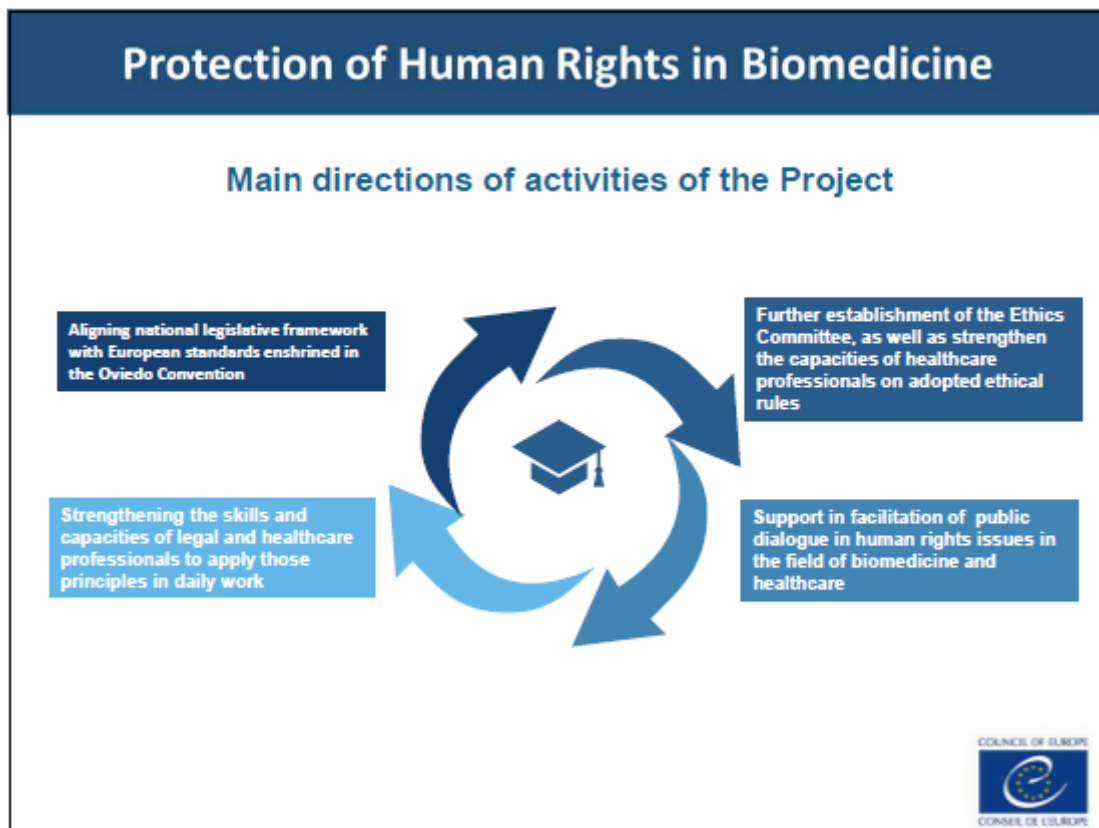


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Protection of Human Rights in Biomedicine

The main list of activities

Improvement of legislation, included:

- Comprehensive health insurance system;
- Licensing of medical professionals;
- Registry of donors of transplantation of organs and tissues



-HELP training sessions on "Key Ethical Principles on Health";
-Development of HELP Course on HR in mental health services;
- Capacity-buildings, training sessions



- Development of the Guide on health literacy;
- Adaptation of the Guide on Public Debate on Human Rights and Biomedicine



Raise public awareness on human rights principles in the field of biomedicine

- Strengthening capacities of ethics committees
- Further strengthening capacities of healthcare professionals on ethical rules



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Protection of Human Rights in Biomedicine

The main list of activities

Develop the legal base for the use of Artificial Intelligence in the field of healthcare;



Implement the national mental health care programme in order to protect the rights of people with mental health problems



Capacity building activities dedicated to the specific needs of health and legal professionals, including staff of the HRD Office and the Ministry of Health, civil servants, judges, advocates;



Train journalists in the field of human rights and biomedicine

Further develop the capacities and skills of Research Ethics Committees, as well as platform for exchange between the Armenian Research Ethics Committees, and the European Network of Research Ethics Committees



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Protection of Human Rights in Biomedicine

The Project will contribute to the following specific outcomes of the Council of Europe Action Plan for Armenia for 2023-2026



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Work in Progress

- Legislative**
 - Provision of legal expertise on the introduction of Comprehensive Health Insurance system in Armenia;
 - Provision of legal expertise on possible amendments in the RA Law on "Reproductive health rights"
- Ethics Committees**
 - The representative of the Ministry of Health and Research Ethics Committee member from the National Institute of Health has participated in the Annual meeting of National Ethics Councils held in Stockholm, Sweden.
- HELP Course**
 - Needs assessment on the development of a new HELP Course on "Human Rights in Mental Health";
 - Development of the HELP Course
- Capacity Building**
 - Capacity Building for the Standing Committee on Human Rights and Social Affairs;
 - Capacity-building on newly appointed members of ethics committee for healthcare professionals

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THANK YOU FOR YOUR ATTENTION!

We would be glad to stay in contact with you:

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46 MEMBER STATES
46 ÉTATS MEMBRES



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