

Strasbourg, 2 June 2025

CDBIO(2025)OT+OJ1 PROV2

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

# 7th meeting

## 3-5 June 2025

Room G01, Agora building, Strasbourg, France

# <u>Draft Agenda/Draft Order of Business</u>

# Decision to be taken:

- Agreement on the White paper on equitable and timely access to appropriate innovative treatments and technologies in healthcare with a view to its publication

# Guidance to be given on:

- The draft Strategic Action Plan (2026-2030) with a view to its finalisation and adoption at the 8th plenary meeting (November 2025)
- The draft programme for the Workshop on human rights and neurotechnologies with a view to its finalisation and identification of speakers

# **Designation of:**

- An expert to participate in the Drafting Group on human rights in drug policies (DH-PDA)
- A CDBIO representative in the European Committee on organ transplantation (CD-P-TO)

# Information to be provided on:

- Impact of the activities carried out under the SAP (2020-2025) in the member States

## LIST OF ITEMS

- 1. Adoption of the agenda
- 2. Neurotechnologies and human rights
- 3. Equitable and timely access to appropriate innovative treatments and technologies in healthcare
- 4. Strategic Action Plan
  - a. SAP (2020-2025)
    - Impact assessment
    - Final report
  - b. Preparation of SAP (2026-2030)
- 5. Artificial Intelligence
- 6. Other business
  - a. Human rights and drug policies
  - b. Human rights in mental healthcare
  - Session on "Children's participation in decisions about their health" of the Mid-Term Review Conference of the Strategy for the Rights of the Child (2022-2027) follow-up
  - d. Action Plan Armenia
  - e. Organ transplantation
- 7. Dates of the next meetings
- 8. Adoption of decisions taken at the 7th plenary meeting



# Points for information to be dealt only in writing

- **9.** Developments relevant to human rights in the fields of biomedicine and health
- 10. 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 Purposes
- **11.** Cooperation with other committees

# Tuesday 3 June 2025 (09.30-18.00)

# Allocution by Rafael Benitez Director of Social Rights, Health and Environment, DGI

# 1. Adoption of the draft agenda

- New CDBIO members invited to introduce themselves
- o Reminder about the main decisions to be taken during the meeting

# CDBIO(2025)OT+OJ1PROV2 Draft Order of Business and Draft Agenda CDBIO/BU RAP(2025)1 Meeting Report of the Bureau (Strasbourg, 2-4 April 2025) Meeting Report of the 6th CDBIO meeting (Strasbourg, 26-28 November 2024)

# 2. Neurotechnologies and human rights

# Objectives:

- Discussion on the proposal for a workshop made by the Preparatory group with a view to its finalisation

Essential document	
CDBIO(2025)6	Draft concept note and programme for the workshop on human rights and neurotechnologies
Useful documents	
CDBIO(2025)4	ECtHR Case Law in relation with document "Neurotech HR challenges table"
CDBIO(2024)23	Concept note on the Seminar on human rights legal framework and neurotechnologies
CDBIO(2024)16	Analysis of the existing European human rights framework concerning the human rights issues raised by neurotechnologies and their applications by Prof. Roberto Andorno (CH), Rapporteur

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

<u>Objective</u>: Examination of a revised draft White Paper with a view to its finalisation - Dissemination strategy – Possible follow up action(s)

Essential document	
CDBIO(2024)18 REV	Revised draft White Paper
Useful documents	
CDBIO(2024)25	Comments on the draft White Paper
CDBIO(2024)18	Draft White Paper
CDBIO/ITT(2024)RAP2	Report of the 2 <sup>nd</sup> Drafting Group meeting (Paris, 23-24 September 2024)
CDBIO(2024)14	Comments from the CD-P-TO on the Outline of a draft White Paper
CDBIO(2023)29	Note of the Bureau
CDBIO(2023)25	Discussion paper on equitable access and timely access to appropriate innovative treatments and technologies in healthcare
	CM/Rec (2023)1 on equitable access to medicinal products and medical equipment in a situation of shortage
	Explanatory memorandum to CM/Rec(2023)1

# Wednesday 4 June 2025 (09.30-18.00)

# 4. Strategic Action Plan

# a. SAP (2020-2025)

<u>Objective</u>: Preparation of an impact assessment of the SAP, to be integrated in the Final report

# b. Preparation of SAP (2026-2030)

<u>Objective:</u> Discussion on the draft SAP (2026-2030) to give guidance to the Drafting Group with a view to the finalisation and adoption at the 8<sup>th</sup> plenary meeting

Essential documents		
CDBIO(2025)2	Concept note on the Impact in member states of the strategic action plan on human rights and technologies in biomedicine (2020-2025)	
CDBIO(2025)7	Draft CDBIO Strategic Action Plan (2026-2030)	
Useful documents		
CDBIO(2025)1	CDBIO comments on missions and strategic objectives for the new SAP	
	CDBIO draft Action Plan Outline (PPT presentation)	
CDBIO(2025)3	Draft elements prepared by the Secretariat	
CDBIO(2023)5	SAP I Mid-term report	

# Thursday 5 June 2025 (09.00-12.30)

# 5. Artificial Intelligence

# Objectives:

- Summary of the outcome of the conference held in Helsinki on 21 May 2025
- Update on the CoE work in relation to the CoE Convention on AI

Essential document		
CDBIO(2025)9	Summary of the conference on Al healthcare and human rights	
Useful documents		
Web page of the conference	Programme of the conference on Al enabled healthcare and human rights	
Report web page	Artificial Intelligence - Human Rights and Biomedicine (coe.int)	
	Artificial intelligence and human rights	

# 6. Other business

a. Human Rights and drug policies

<u>Objective</u>: Designation of an expert to participate in the work of the DH-PDA In charge of developing a draft Recommendation on bringing human rights to the heart of drug and addiction policies

- b. Human rights in mental health care
  - <u>Objective</u>: Update on the examination process of the legal instruments by the Committee of Ministers
- c. Session on "Children's participation in decisions about their health" of the Mid-Term Review Conference of the Strategy for the Rights of the Child (2022-2027) follow-up
  - <u>Objective</u>: Summary of the outcome of the session held in Strasbourg on 4 April 2025
- d. Action Plan Armenia
  - Objectives: Information on the progress made in the cooperation activities
    - Presentation by the Directorate of Internal Oversight (DIO) of the Evaluation report of the cooperation project on "human rights in Biomedicine"
- e. Organ transplantation

<u>Objective</u>: Designation of a CDBIO representative in the European Committee on organ transplantation (CD-P-TO)

Useful documents		
a. Web page of the TOR	Terms of reference of the Drafting Committee on Human Rights and Drug Policies	
a. DH-PDA(2025)OJ1	Draft agenda of the 1 <sup>st</sup> meeting (1-2 July 2025) of the drafting Committee on human rights and drug policies (DH-PDA)	
b. <u>CDBIO(2025)5</u>	Committee of Ministers' decisions on Draft Additional Protocol concerning the protection of the human rights and dignity of persons with regard to involuntary placement and involuntary treatment within mental healthcare and on Draft Recommendation CM/Rec(2025) on respect for autonomy in mental healthcare	
С.	Child-friendly summary of the Guide to children's participation in decisions about their health	
c. Web page of the Session	Programme of the session on children participation held on 4 April 2025	
c. Web version of the Guide	Children's participation in decisions about their health - Human Rights and Biomedicine (coe.int)	
d.	Evaluation report of the cooperation on human rights in biomedicine in Armenia	
d.	Action Plan for the Republic of Moldova 2025-2028 and Press release	
d.	Action Plan for Georgia 2024-2027	
d.	Action Plan for Ukraine 2023-2026	
e.	CD-P-TO terms of reference	

# 7. Dates of the next meetings

- 8<sup>th</sup> meeting of the CDBIO: 18-21 November 2025, Strasbourg (Workshop on human rights and neurotechnologies on 18 November)
- o 9th meeting of the CDBIO: 2-5 June 2026, Strasbourg

# 8. Adoption of decisions taken by the CDBIO at its 7th meeting

Objective: Approval of the abridged meeting report

# POINTS TO BE DEALT WITH IN WRITING



# 9. Developments in the field of bioethics

Delegations, including observers, are invited to send information in writing.

- a. Developments in member states and other states
- b. Developments in the field of bioethics in international organisations
- c. Developments in other Council of Europe bodies
- d. Developments at the European Court of Human Rights
- e. Developments in the field of bioethics in the Decisions of the European Committee of Social Rights (ECSR)

Essential documents	
a. <u>CDBIO/INF(2025)4</u>	Developments in the field of bioethics in member states and other states
b. <u>CDBIO/INF(2025)3</u>	Developments in the field of bioethics in international organisations
c. <u>CDBIO(2025)10</u>	Developments in the field of bioethics in other Council of Europe bodies
d. <u>CDBIO/INF(2025)5</u>	Developments in the field of bioethics in the European Court of Human Rights
e. <u>CDBIO/INF(2025)6</u>	Developments in the field of bioethics in the Decisions of the European Committee of Social Rights (ECSR)



10. 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

Useful document	
CDBIO/INF(2024)4	Chart of signatures and ratifications



# 11. Cooperation with other committees

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

Use	eful documents	
CDI	BIO(2025)10	Developments in the field of bioethics in other Council of Europe bodies
CDI	DH	Terms of reference
CD-	-P-TO	Terms of reference
CD-	-P-TS	Terms of reference
T-P	D	Rules of procedure
CDE	ENF	Terms of reference
CD	CJ	Terms of reference

	DOCUMENTS FOR POSSIBLE UPDATE BY DELEGATIONS	
Delegations are invited to provide where appropriate updated information of the following documents		
		<u>Updated Questionnaire on Medically Assisted</u> <u>Procreation (MAP). Replies of delegations</u>
		Replies to the questionnaire on surrogacy
	CDBIO/INF(2024)12	Background document on preimplantation and prenatal genetic testing-legislation
	CDBIO(2024)21	Legislative developments on nuclear transfer and their relationship with Article 18.2 of the Convention

USEFUL DOCUMENTS FOR SEVERAL ITEMS	
CDBIO/RAP6	Meeting report of the 6th CDBIO meeting (Strasbourg, 26-28 November 2024)
CDBIO/BU RAP(2025)1	Meeting Report of the Bureau (Strasbourg, 2-4 April 2025)

GENERAL INFORMATION DOCUMENTS FOR REFERENCE	
	Strategy for the Rights of the Child (2022-2027)
CM/Res(2021)3	Resolution on intergovernmental committees and subordinate bodies, their terms of reference and working methods
CDBIO/INF(2025)1	Information document on the CDBIO
CDBIO/INF(2023)2	Texts of the Council of Europe on bioethical matters, Volume I
CDBIO/INF(2023)2	Texts of the Council of Europe on bioethical matters, Volume II
Please click on the respective link to open the Convention and its Protocols	Convention on Human Rights and Biomedicine (ETS 164)
	Explanatory Report to the Convention on Human Rights and Biomedicine
	Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings (ETS 168)
	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS 186)
	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research (CETS 195)
	Additional Protocol concerning Genetic Testing for Health Purposes (CETS 203)