

Strasbourg, 7 July 2025

CDBIO/RAP7

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

7th meeting

3-5 June 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, in an opening address, underlined the importance of the work of the CDBIO. He highlighted the priority challenges in the health field for the Council of Europe using, as a basis, the Reykjavik Declaration and the New Democratic Pact launched by the Secretary General.

II. Neurotechnologies and human rights

- 4. The CDBIO Chair gave a brief introduction, highlighting past CDBIO activities on neurotechnologies and human rights, including the 2021 roundtable co-organised with the OECD. He reiterated that this roundtable prompted the Bureau to establish a Preparatory Group to organise a workshop on neurotechnology and human rights to be held in November 2025.
- 5. The Chair of the Preparatory Group, Anne Forus (Norway), summarised key findings from the CDBIO's work on neurotechnology and human rights, referencing the expert report by Prof. lenca, the joint OECD roundtable report, and an expert report by Prof. Andorno currently being finalised. She outlined the objective, approach, and structure proposed for the draft workshop programme. The workshop would aim to assess how the existing human rights framework addresses the ethical and human challenges of neurotechnologies, exploring their meaning, scope, and protection gaps through in-depth analysis of key concepts in case law and human rights discourse. The intended outcome is a paper identifying possible avenues for human rights interpretation and, if appropriate, potential follow-up activities.
- 6. The Chair provided a detailed overview of the workshop structure, introducing the topics of the various sessions and the underlying concepts. Explanation was also provided regarding the envisaged speaker profiles. The practical approach proposed would be based on contributions from practitioners (notably lawyers and judges).
- 7. The delegations generally welcomed the Preparatory Group's proposed approach in the draft programme. Exchanges on the draft highlighted key issues that the Preparatory Group will consider as it refines the draft programme and prepares speaker briefings, including:
 - The need for a clear structure of the sessions, with well-defined topics based on precise notions, and an explanation of the rationale behind this structure;
 - The careful selection of speaker profiles, prioritising independent legal practitioners with the necessary expertise at national or international level, while ensuring all relevant domains of expertise are covered across the sessions;
 - The importance of balancing the potential and challenges of neurotechnologies (this could be emphasised in the introductory part of the concept note)
 - The identification of clear outcome objectives.
- 8. One delegation suggested not completely exclude academics considering that few have written very good document helping to clarify notions.
- 9. The CDBIO Chair referred to relevant legal cases at national level on neurotechnologies. Delegations were invited to look for such cases and send their reference to the Secretariat.

- 10. The CDBIO agreed on the principle of holding a workshop on neurotechnologies and human rights, to be held on 18 November 2025, as well as on the approach and draft programme proposed by the Preparatory Group.
- 11. Delegations were invited to send by 10 July 2025, the names of legal practitioners (notably judges, lawyers) who could be invited to participate in the workshop, where possible, indicating the topic for which the person is suggested.

III. <u>Equitable and timely access to appropriate innovative treatments and technologies in healthcare</u>

- 12. Tomas Dolezal (Czechia), Chair of the Drafting Group summarised the development of the white paper and highlighted the main changes to it since the last plenary, based on the written comments of delegations. This was concluded with an overview of the contents of the white paper and emphasis on its scope and objectives.
- 13. In greater detail, the consultant, Kristof Van Assche, explained the main changes to the document (appearing as bold and underlined text), notably the introduction of an executive summary and new sections on the impact of external factors in assessing quality (section 3.1.4.), social determinants of health (section 4.1), gaps in professional education and collaboration (section 4.3.4.) and principles for prioritisation at patient level (section 5.2.)
- 14. Exchanges with delegations resulted in the revision and/or deletion of certain wording in various parts of the document, including the need to:
 - Align the coherence of "Difficulties in balancing individual and public health interests" (section 3.2.1) and "Principles for resource allocation at a health system level (section 5.1)
 - Elaborate "Reciprocity for public investment" (section 4.2.2.a) regarding the expectations
 of reciprocity by pharmaceutical companies and manufacturers.
 - Strengthen "Mechanisms to control costs" (section 4.2.2.c) regarding the important role played by governments in collaborating in the procurement of innovative treatments and technologies, to facilitate equitable access to them.
 - Differentiate references in "Key considerations" (section 6, first para) regarding those who
 are "well informed/connected" from those who "are able to pay" in accessing the benefits
 of equitable access to healthcare.
- 15. Delegations agreed on the White paper on equitable and timely access to appropriate innovative treatments and technologies in healthcare, subject to <u>editorial changes</u> to be made in the light of the possible comments that **delegations were invited to send by 10 July 2025**.

IV. Strategic Action Plan

- a. SAP (2020-2025)
- 16. The Secretariat reminded about the request of the Committee of Ministers to give indicators of impact of the work carried out. The Bureau had discussed this issue and considered that such evaluation of impact would be relevant and useful for the CDBIO. A concept note was prepared on such process which would rather be a collection of information rather than a proper 'impact assessment'. To that end a broad range of indicators was proposed which could be extended by delegations, where appropriate.

- 17. It was for example suggested to add the use of or reference to CDBIO documents in academic cursus and papers. The invitation to present the work of the CDBIO to events could be another relevant information.
- 18. The CDBIO agreed to collect information from delegations on the impact of actions carried out in the framework of the current Strategic Action Plan (2020-2025) using, as a basis, the concept note prepared by the Bureau with a view to integrating a relevant section in the final report of the SAP to be presented to the Committee of Ministers at the end of the year.
- 19. Delegations are invited to send relevant information on the impact of actions carried out under the SAP (2020-2025) to the Secretariat before the next plenary meeting (18-20 November 2025).
 - b. Preparation of SAP (2026-2030)
- 20. Siobhan O'Sullivan (IRL), Chair of the Drafting Group on the new SAP, presented the proposals for the CDBIO mission, strategic goals and strategic objectives of the draft new SAP (The PPT used appears in Appendix III to this report). The actions would be defined once the CDBIO would have agreed on this first key part.
- 21. In response to a comment from another delegation on the reference to One Health, it was acknowledged that the CDBIO does not really have competence on animal and environment but the intention in this text was the contextualisation for human health.
- 22. Delegations commanded the Group for its work and generally welcome the proposals

Mission statement

23. One delegation pointed out the need to possibly clarified that the CDBIO first and foremost is looking at human rights in biomedicine as the current text may be interpreted as focusing only on scientific developments and technological innovations.

Strategic goals

- 24. One delegation suggested moving "Anticipating" before "Adapting" and another one that reference should be made to the horizon scanning exercise. It was pointed out that horizon scanning was clearly related to anticipating future challenges, but that those challenges could be related to very new elements or to developments in existing ones.
- 25. One delegation suggested indicating that the CoE was playing its role at international level with cooperation with other intergovernmental organisations to support human rights. This could be placed in the preamble. Reference was made in this context to the UN interagency committee on bioethics in which the CoE is associate member. Such cooperation could also be promoted by the member states sitting in the different organisations.
- 26. One delegation drew attention on the reference to the execution of the European Court of Human Rights decision and the need to clearly distinct the possible action of the CDBIO and the actual role of the CM.
- 27. One delegation will send some editorial suggestions for the preamble.

Strategic objectives

Safeguard

28. The reference to the case law of the Court in *objective 1* should be aligned with the relevant strategic goal.

- 29. It was suggested to underline the involvement of patients in objective 2.
- 30. In response to a comment by a delegation, it was proposed to deal with issue such as older person under *objective 3*.

Adapt

- 31. The Secretariat underlined that re-examination of a legal instrument, provided for in article 32 of the Oviedo Convention, was to necessarily leading to a revision (see re-examination of the Additional Protocol on transplantation of organ and tissues which the Committee decided to leave unchanged and just clarified some elements of the explanatory report).
- 32. It was suggested to add a reference to data from deceased persons and consider respect for the human body.
- 33. Finally, one delegation suggested moving education and training at the end.

Anticipate

- 34. One delegation pointed out the need to clarify the reference to synthetic biology. It was suggested looking at OECD possible definition.
- 35. In relation to objective 2, one delegation highlighted the importance of preparing research ethics committees to the use of new technologies in research.

Engage

36. There was no comment on the objectives proposed under this strategic goal.

- 37. The discussion was initiated on possible actions under each strategic objective.
- 38. The Chair of the Drafting Group underlined the need to be clear on the level the CDBIO wants to act. She suggested that over the span of five years there could be an evolution in this respect.
- 39. The question of the number of actions was also raised. The feasibility to deliver should be a guiding concern. Furthermore, some margin of manoeuvre should be kept to react to new elements as this was the case with theeh Covid-19 pandemic.
- 40. One delegation reminded the 30th anniversary of the Oviedo Convention in 2027 which would provide an opportunity for high visibility to the work.
- 41. One delegation referred to gamete's donation as a point to be addressed. In this context, the Secretariat informed the CDBIO about the survey undertaken by the European Commission (EC), under the SOHO regulation, about voluntary and non-remunerated donation and the way it was implemented. The EC would consider possible cooperation with the CoE on this topic namely based on the guide on prohibition of financial gain.

42. The CDBIO agreed, subject to some editorial changes, on the approach, strategic goals and objectives proposed by the Drafting Group for the new Strategic Action Plan (2026-2030).

43. Delegations were invited to send proposals for possible actions under each strategic objective <u>by10 July 2025</u>.

Artificial Intelligence

- 44. The CDBIO welcomed the outcomes of the Conference "Al healthcare and human rights supporting patients, enabling doctors, safeguarding the therapeutic relationship", held in Helsinki on 21 May 2025; and thanked the Ministry of Social Affairs and Health of Finland for organising the event in cooperation with the Council of Europe.
- 45. The main outcomes of the Conference were presented by Maria do Céu Patrão Neves (see doc: CDBIO(2025)9) who played an active role in different sessions, including in summarising discussions.
- 46. The Representative of Finland expressed great satisfaction with the Conference. Other CDBIO members having attended in-person and/or having followed online also expressed their satisfaction, notably its pertinence, timeliness and value as a contribution to good practice in healthcare. In conclusion, the Chair thanked the Secretariat for the work and efforts which contributed to the success of the event.
- 47. The CDBIO took note of the information provided by a member of the CoE Digital Unit; concerning the Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law and its implementation, notably the guidance on risk and impact assessment for AI systems ("HUDERIA") specifically tailored to the protection and promotion of human rights, democracy and the rule of law. To this end, the cooperation with different sectors of the Council of Europe, including the CDBIO, would be welcomed.

V. Other business

- a. Human Rights and drug policies
- 48. The CDBIO designated Aristotelis Constantinides (Cyprus) as member of the Drafting Committee on Human Rights and Drug Policies (DH-PDA).
 - b. Human rights in mental health care
- 49. The Secretariat informed the CDBIO about the progress made in the preparation of its opinion on the draft Protocol on the protection of human rights and dignity of persons with regard to involuntary placement and involuntary treatment within mental healthcare services. The Pace Committee on Social Affairs, Health, Sustainable Development has now held two hearing with a representative of the CRPD, the vice chair of the CDBIO, a representative of the European Disability Forum and a representative of the European Association of Psychiatry.
- 50. The draft opinion to be prepared will be discussed at the PACE session on 29 September to 3 October 2025.
 - c. <u>Session on "Children's participation in decisions about their health" of the Mid-Term</u> Review Conference of the Strategy for the Rights of the Child (2022-2027) follow-up
- 51. The CDBIO welcomed the outcomes of the session "Children participation in decision about their health" at the Mid-Term review Conference of the Strategy for the Rights of the Child (2022-2027).
- 52. The Vice Chair underlined the exemplarity of the session namely due to the participation of children. She highlighted the value of the synergy between committees to inform new audiences about their respective work. She indicated that contact was taken with paediatric hospitals in her country with excellent feedback on the guide.

53. A delegation suggested to think about children participation when it comes to participation in research and the revision of the Guide for research ethics committee published some years ago.

d. Action Plan Armenia

- 54. The CDBIO took note of the evaluation report carried out with the support of the Directorate of Internal Oversight (DIO), on the cooperation project on "Human rights in Biomedicine", carried out in the framework of the Armenian Action Plan.
- 55. The Representative of Armenia thanked for the work achieved and underline its impact on the healthcare system and the change the practices of healthcare professionals.
- 56. One delegation stressed the importance of evaluation being embedded in the CDBIO projects and invited the CDBIO to reflect on this point. She also stressed the importance of a feedback from people participating in HELP courses.

e. Organ transplantation

57. The CDBIO designated Lada ZIBAR (Croatia) as representative of the CDBIO to participate in the meetings of the European Committee on Organ Transplantation (CD-P-TO), as observer.

f. Health literacy

- 58. The Representative of Italy provided information on the follow-up to the second Conference "Health literacy and human rights connecting policy with practice to promote inclusion and combat discrimination", held in Rome on 5 December 2024, which was organised by the National Office Against Racial Discrimination of Italy, in cooperation with the Council of Europe and with the support of the Minister of Family, Natality & Equal Opportunities of Italy and the Minister of Health of Italy.
- 59. The Committee was informed of Italy's intention to set-up a broad intersectoral coalition of stakeholders on health literacy and human rights to bring together best practice, policy and action in the field which is anchored in the legal instruments and human rights framework of the Council of Europe. The launch event of the Coalition is expected to be held in Rome in December 2025.

VI. Dates of the next meetings

- 60. The CDBIO agreed to hold its next meetings:
- 8th meeting of the CDBIO: 18-21 November 2025, in Strasbourg
- o 9th meeting of the CDBIO: 2-5 June 2026, in Strasbourg

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

61. In the absence of opposition, the abridged report presented to delegations at the end of the meeting, was adopted on 5 June 2025.

Appendix I List of participants

MEMBERS / MEMBRES

ALBANIA / ALBANIE	Awaiting nomination / Nomination en attente	
ANDORRA / ANDORRE	Cristina CASALS CASAS PhD en biologie	
ARMENIA / ARMENIE	Izabel ABGARYAN Chair of the Medical Ethics Committee	
AUSTRIA / AUTRICHE	Benjamin BACHL Head of Competence Center Federal Ministry of Social Affairs, Health Care and Co Section VI - Human Medical Law Department VI/A/2 – Competence Center for Genetic	
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		ologised/Excusée
	Legal Officer Federal Ministry of Social Affairs, Health, Care and C Directorate General VI – Human medicine law and he A/4 – Department of legal affairs concerning med devices, pharmacies, hospitals and communicable di	ealth telematics ical products, medical
	Ulrich PESENDORFER Apo Ministry of Justice and jurisdiction	ologised/Excusé
	Petra STEFENELLI Federal Chancellery Secretariat of the Bioethics Commission	ologised/Excusée
	Andreas VALENTIN Member of the Bioethics Commission	
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	Sécurité de la Chaîne alimentaire et Environnement	uniique

BOSNIA AND HERZEGOVINA / BOSNIE- HERZÉGOVINE	Dalibor PEJOVIĆ Head of Unit for Statistics and Analytical Affairs and Reporting in Health Department for Health
BULGARIA / BULGARIE	Vihra MILANOVA Apologised/Excusée Head of Psychiatric Clinic Alexandrovska University Hospital
CROATIA / CROATIE	Lada ZIBAR Full Professor, internist nephrologist, Department for Nephrology, Internal Clinic, University Hospital, Zagreb & Department for Pathophysiology School of Medicine University Osijek & Head of Committee for Medical Ethics and Deontology, Croatian Medical Chamber
CYPRUS / CHYPRE	Aristotelis CONSTANTINIDES Member of the Cyprus National Bioethics Committee
	Zoe KYRIAKIDOU Apologised/Excusée Member of the Cyprus National Bioethics Committee
	Constantinos N. PHELLAS Apologised/Excusé Chair of the Cyprus National Bioethics Committee University of Nicosia
CZECHIA / TCHEQUIE	Tomáš DOLEŽAL Ph.D., LL.M., Head of the Department of Private Law and Head of the Research Unit for Medical Law and Bioethics Czech Academy of Science, Institute of State and Law
	Hana KONEČNÁ Ph.D., University of South Bohemia in České Budějovice
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	Charlotte BEIERHOLM OLSEN Apologised/Excusée Ministry of the Interior and Health
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	Katja PASANEN Legal Officer Unit for Human Rights Courts and Conventions Legal Service Ministry for Foreign Affairs Apologised/Excusée Apologised/Excusée Apologised/Excusée Apologised/Excusée

Chargée de mission greffe Bureau bioéthique, éléments et produits du corps humai Direction générale de la Santé (DGS) Ministère de la Santé et de la Prévention Estelle FAUCHARD Apolog 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 Caroline MATKO Bureau bioéthique, éléments et produits du corps humai Direction générale de la Santé (DGS) Ministère de la Santé et de la Prévention Jacques MONTAGUT Ancien membre du CCNE Diane RICHARD Apolog Bureau du droit des personnes et de la famille Sous-direction du droit civil Direction des affaires civiles et du sceau (DACS) Ministère de la Justice GEORGIA / GÉORGIE Givi JAVASHVILI Head of Family Medicine Department Tbilisi State Medical University Chairman of the National Council on Bioethics GERMANY / ALLEMAGNE Elmar DOPPELFELD Honorary Chair of the "Permanent Working Party Committees in Germany Inc." Carlo GRIMM Division 611 Federal Ministry of Education and Research Ingo HÄRTEL Division 316	
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(CEC) / CONFERENCE	-	
DES EGLISES		
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CONSULTANT / CONSULTANT

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	Consultant for the Equitable and timely access to appropriate	
	innovative treatments and technologies in healthcare	

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OFFICE OF THE	Patricia OTVOS	Apologised/Excusée
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BUREAU DU		
COMMISSAIRE AUX		
DROITS DE L'HOMME		
OFFICE OF THE	Victoria KARPATSZKY	
SPECIAL	Administrator	
REPRESENTATIVE OF		
THE SECRETARY		
GENERAL ON		
MIGRATION AND		
REFUGEES / BUREAU		
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COMMITTEE ON	Albina OVCEARENCO	
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INTELLIGENCE /		
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ARTIFICIELLE (CAI)	Walter DECLITE	:!/ -
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ON ANTI	Secretary	
DISCRIMINATION,		
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L'INCLUSION (CDADI)		

SEXUAL ORIENTATION	Eleni TSETSEKOU	Apologised/Excusée
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UNIT / UNITE		
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COMMISSION /	Varia BARNIN	An alone of a UF
COMMISSION POUR	Yanna PARNIN	Apologised/Excusée
L'EGALITE DE GENRE		
(GEC)		
EUROPEAN	Hugh CHETWYND	Apologised/Excusé
COMMITTEE FOR THE	Head of Division	
PREVENTION OF		
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COMMITTEE OF THE	Peter KIMPIAN	Apologised/Excusé
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	Alejandro PARRA
	Trainee / Stagiaire (USA)
	Arthur RIERA
	Trainee / Stagiaire (France)
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INTERPRETING,	Amanda LARIVIERE
TRAVEL, EVENTS AND	
MULTIMEDIA	Corinne MCGEORGE
DEPARTMENT /	
SERVICE DE	Lucie DEBURLET-SUTER
L'INTERPRETATION,	
DES VOYAGES, DES	
EVENEMENTS ET DU	
MULTIMEDIA (ITEM)	

Appendix II Agenda

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

2. Neurotechnologies and human rights

Objectives:

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

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)

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 8th plenary meeting

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 Al

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

 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

<u>Objectives</u>: - 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)

7. Dates of the next meetings

- 8th 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)



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



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)

Appendix III Presentation by Siobhan O'Sullivan, Chair of the Drafting Group for the new SAP

