

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Strasbourg, 28 October 2022

CDBIO(2022)OT+OJ2 PROV

**STEERING COMMITTEE FOR HUMAN RIGHTS
IN THE FIELDS OF BIOMEDICINE AND HEALTH (CDBIO), 2nd meeting, 2-4 November
2022, Room 11 (Palais de l'Europe), Draft Agenda/draft Order of Business**

LIST OF ITEMS

1. Adoption of the agenda
2. Equitable access to medicinal products and medical equipment in shortage situation
3. Draft recommendation for the promotion of voluntary measures
4. Guide to health literacy: contributing to trust building and equitable access to healthcare
5. Guide on children participation in decision making process on matters relevant to their health
6. Neurotechnologies and human rights
7. Preparation of the mid-term review of the SAP
8. Youth Forum
9. Artificial intelligence and biomedicine
10. Overview of legislation and practices on patients' rights
11. Bureau elections
12. Adoption of decisions taken at the 2nd plenary meeting
13. Dates of the next meetings
14. Other business



Points for information to be dealt only in writing

15. Developments in the field of bioethics
16. 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
17. Cooperation with other committees

Wednesday 2 November 2022 (09.30- 13.00 / 14.30 - 18.00)

1. Adoption of the draft agenda

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

Essential documents

CDBIO(2022)OT+OJ2PROV	<i>Draft Order of Business and Draft Agenda</i>
CDBIO/BU RAP(2022)2	<i>Meeting Report of the Bureau (Paris, 20-21 September 2022)</i>
CDBIO/RAP1	<i>Meeting Report of the 1st CDBIO meeting (31 May-3 June 2022)</i>

2. Equitable access to medicinal products and medical equipment in shortage situation

Objectives:

- *Approval of the draft Recommendation on equitable access to medicinal products and medical equipment in shortage situation, with a view to its presentation to the Committee of Ministers for adoption*
- *Finalisation of the Explanatory Memorandum*


Essential documents

CDBIO(2022)9 REV2	<i>Draft Recommendation revised in the light of the comments at the consultation meeting on 20 September 2022</i>
CDBIO(2022)22	<i>Draft Explanatory Memorandum</i>

Useful documents

CDBIO(2022)23	<i>Comments from CDBIO delegations on the draft Recommendation (doc. CDBIO(2022)9REV)</i>
CDBIO(2022)19	<i>Comments from CDBIO delegations on the draft Recommendation (doc. CDBIO (2022) Misc 1 BIL)</i>
CDBIO (2022) Misc 1 BIL	<i>Draft Recommendation on equitable access to scarce medicinal products and medical equipment</i>
CDBIO(2022)2 REV	<i>SAP Update methodology and timeframe for the priority actions planned revised in the light of the priorities agreed</i>
CDBIO/TEQ/CONS RAP1	<i>Meeting report of the Consultation meeting (Paris, 20 September 2022)</i>
	<u>Statement on COVID-19 and vaccines: Ensuring equitable access to vaccination during the current and future pandemics</u>




3. Draft Recommendation for the promotion of voluntary measures Objective: <ul style="list-style-type: none"> Examination of the preliminary draft Recommendation prepared by the Bureau 	
Essential documents	
CDBIO(2022)27	<i>Draft Recommendation promoting the use of voluntary measures in mental health care services – key principles, Bureau proposal, document prepared by Dr Elaine Gadd, Consultant</i>
CDBIO(2022)28	<i>Preliminary outline of draft Recommendation promoting the use of voluntary measures in mental healthcare services, proposed by the Bureau, based on a document prepared by Dr Elaine Gadd, Consultant</i>
Useful documents	
CDBIO(2022)32	<i>Comments on Draft Recommendation promoting the use of voluntary measures in mental health care services</i>
CDBIO/BU RAP(2022)2	<i>Report of the Bureau meeting (20-21 September 2022)</i>
CM/Del/Dec(2022)1434/4.2	<i>Decision of the Committee of Ministers</i>
Thursday 3 November 2022 (9.00-13.00 / 14.30-18.00)	
4. Guide to health literacy: contributing to trust building and equitable access to healthcare Objective: <ul style="list-style-type: none"> Adoption of the Guide 	
Essential document	
CDBIO(2022)6 REV	<i>Draft “Guide to health literacy: contributing to trust building and equitable access to healthcare” revised in the light of the delegations’ comments received</i>
Useful documents	
CDBIO(2022)25	<i>Comments from the CDBIO delegations on the draft Guide (doc. CDBIO(2022)6 REV)</i>
CDBIO(2022)20	<i>Comments from the CDBIO delegations on the draft Guide (doc. CDBIO(2022)6)</i>
CDBIO(2022)6	<i>Draft “Guide to health literacy: contributing to trust building and equitable access to healthcare”</i>
CDBIO(2022)6 Addendum	<i>Addendum to the Draft Guide to health literacy: contributing to trust building and equitable access to healthcare</i>

	CDBIO(2022)2 REV	SAP Update methodology and timeframe for the priority actions planned revised in the light of the priorities agreed
	5. Guide on children participation in decision-making process on matters relevant to their health <ul style="list-style-type: none"> Information on the progress of the Consultation process being carried out 	
	Useful documents	
	BIO/ENF-CP (2022)1 REV2	Revised Draft Guide to good practice concerning the participation of children in the decision-making processes on matters regarding their health, sent for stakeholders and children consultation
	BIO-ENF/CP (2022) 4	Comments children participation
	BIO-ENF/CP (2022)3 REV3	Compilation of examples of practices aimed at promoting children's participation in the decision-making process in matters regarding their health
	CDBIO(2022)8 CDENF(2022)09	Draft Guide to good practice concerning the participation of children in the decision-making processes on matters regarding their health
	BIO-ENF/CP (2021) 2 REV5	Timeline of the BIO/ENF-CP Drafting Group
	BIO/ENF-CP RAP (2022)3	Report of the 3rd meeting of the Joint Drafting Group BIO/ENF-CP (22-23 September 2022)
	CDBIO(2022)2 REV	SAP Update methodology and timeframe for the priority actions planned revised in the light of the priorities agreed
6. Neurotechnologies and human rights <p>Objectives:</p> <ul style="list-style-type: none"> Presentation of the report of the Round table Information on the communication strategy for the report 		
Essential document		
		Report of the Round table on human rights and neurotechnologies
Useful document		
		Neurotechnologies and human rights framework: do we need new human rights?
7. Preparation of the mid-term review of the SAP <p>Objectives:</p> <ul style="list-style-type: none"> Agreement on the methodology for the preparation of the mid-term report planned in the SAP Early discussions on possible future priorities with a view to the mid-term review requested in spring 2023 by the Committee of Ministers for the quadrennium 2022-2025 		

	Essential document	
	CDBIO(2022)30	<i>Proposal from the Bureau on the methodology for the preparation of the mid-term report planned in the SAP</i>
	Useful documents	
	CDBIO/BU RAP(2022)2	<i>Report of the Bureau meeting (20-21 September 2022)</i>
	CDBIO(2022)2 REV	<i>SAP Update methodology and timeframe for the priority actions planned revised in the light of the priorities agreed</i>
	8. Youth Forum	
	Objective: <ul style="list-style-type: none"> ○ <i>Examination of the proposal prepared by the preparatory group for the (pilot) Youth Forum to be held in Spring 2023</i> 	
	Essential document	
	CDBIO(2022)21	<i>Concept note for the (pilot) Youth Forum</i>
	Useful document	
	CDBIO(2022)2 REV	<i>SAP Update methodology and timeframe for the priority actions planned revised in the light of the priorities agreed</i>
Friday 4 November 2022 (9.00- 13.00)		
	9. Artificial intelligence and biomedicine	
	Objective: <ul style="list-style-type: none"> ○ <i>Presentation of the conclusions of the first meeting of the drafting group and guidance from the CDBIO on the way forward</i> 	
	Essential document	
	CDBIO/AI(2022)RAP1	<i>Report of the 1st meeting of the Drafting Group (3 October 2022)</i>
	Useful documents	
	CDBIO/INF(2022)5	<i>Report on the impact of artificial intelligence on the doctor-patient relationship by Brent Mittelstadt</i>
	CDBIO(2022)2 REV	<i>SAP Update methodology and timeframe for the priority actions planned revised in the light of the priorities agreed</i>
	10. Overview of legislation and practices on patients' rights	
	Objective: <ul style="list-style-type: none"> ○ <i>Examination of the proposal from the Bureau</i> 	

Essential document		
	<u>CDBIO/BU RAP(2022)2</u>	<i>Report of the Bureau meeting (20-21 September 2022), Paragraphs 16-25</i>
11. Bureau elections		
<p>Objectives:</p> <ul style="list-style-type: none"> ○ <i>Election of the Chair and Vice Chair for a one-year term renewable once</i> ○ <i>Subject to the result of the election of the Chair and Vice Chair, election of three Bureau members:</i> <ul style="list-style-type: none"> - <i>The terms of three Bureau members are coming to an end. Two are not re-eligible (Pierre Mallia and Rodica Gramma) and one is re-eligible for another term of two years (Assunta Morresi)</i> <p>Submission for nominations should be sent in writing to the Secretariat by <u>Thursday 3 November 2022 at 2.00 pm.</u></p>		
Essential document		
	<u>CDBIO(2022)29</u>	<i>Bureau elections</i>
12. Adoption of decisions taken by the CDBIO at its 2nd meeting		
<ul style="list-style-type: none"> ○ <i>Approval of the abridged meeting report which includes the decisions</i> 		
13. Dates of the next meetings		
<ul style="list-style-type: none"> ○ <i>3rd meeting of the CDBIO: 6-9 June 2023</i> ○ <i>4th meeting of the CDBIO: 14-17 November 2023</i> 		
14. Other business		
<ul style="list-style-type: none"> ○ <i>Equitable and timely access to innovative treatments and technologies in the healthcare system: setting up of a Drafting group</i> 		

POINTS TO BE DEALT WITH IN WRITING

	<p>15. 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 states Developments in the field of bioethics in international organisations Developments in other Council of Europe bodies Developments at the European Court of Human Rights 												
	<p>Essential documents</p> <table> <tr> <td data-bbox="300 636 794 703">a. CDBIO/INF(2022)15</td><td data-bbox="810 636 1509 703"><i>Developments in the field of bioethics in member states and other states</i></td></tr> <tr> <td data-bbox="300 710 794 777">b. CDBIO/INF(2022)16</td><td data-bbox="810 710 1509 777"><i>Developments in the field of bioethics in international organisations</i></td></tr> <tr> <td data-bbox="300 784 794 851">c. CDBIO(2022)31</td><td data-bbox="810 784 1509 851"><i>Developments in the field of bioethics in other Council of Europe bodies</i></td></tr> <tr> <td data-bbox="300 857 794 925">d. CDBIO/INF(2022)14</td><td data-bbox="810 857 1509 925"><i>Developments in the field of bioethics in the European Court of Human Rights</i></td></tr> </table>	a. CDBIO/INF(2022)15	<i>Developments in the field of bioethics in member states and other states</i>	b. CDBIO/INF(2022)16	<i>Developments in the field of bioethics in international organisations</i>	c. CDBIO(2022)31	<i>Developments in the field of bioethics in other Council of Europe bodies</i>	d. CDBIO/INF(2022)14	<i>Developments in the field of bioethics in the European Court of Human Rights</i>				
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	<p>16. 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>Useful document</p> <table> <tr> <td data-bbox="300 1211 794 1256">CDBIO/INF(2022)4</td><td data-bbox="810 1211 1509 1256"><i>Chart of signatures and ratifications</i></td></tr> </table>	CDBIO/INF(2022)4	<i>Chart of signatures and ratifications</i>										
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	<p>17. Cooperation with other committees</p> <ol style="list-style-type: none"> 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) <p>Useful documents</p> <table> <tr> <td data-bbox="300 1615 794 1682">CDBIO(2022)31</td><td data-bbox="810 1615 1509 1682"><i>Developments in the field of bioethics in other Council of Europe bodies</i></td></tr> <tr> <td data-bbox="300 1688 794 1756">CD-P-TO</td><td data-bbox="810 1688 1509 1756">Terms of reference</td></tr> <tr> <td data-bbox="300 1762 794 1830">CD-P-TS</td><td data-bbox="810 1762 1509 1830">Terms of reference</td></tr> <tr> <td data-bbox="300 1836 794 1904">T-PD</td><td data-bbox="810 1836 1509 1904">Rules of procedure</td></tr> <tr> <td data-bbox="300 1910 794 1977">CDENF</td><td data-bbox="810 1910 1509 1977">Terms of reference</td></tr> <tr> <td data-bbox="300 1984 794 2051">CDCJ</td><td data-bbox="810 1984 1509 2051">Terms of reference</td></tr> </table>	CDBIO(2022)31	<i>Developments in the field of bioethics in other Council of Europe bodies</i>	CD-P-TO	Terms of reference	CD-P-TS	Terms of reference	T-PD	Rules of procedure	CDENF	Terms of reference	CDCJ	Terms of reference
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DOCUMENTS FOR POSSIBLE UPDATE BY DELEGATIONS		
	Delegations are invited to provide where appropriate updated information of the following documents	
	CDBIO/INF(2022)9	<i>Updated Questionnaire on Medically Assisted Procreation (MAP). Replies of delegations</i>
	CDBIO/INF(2022)9 Addendum	<i>Replies to the questionnaire on surrogacy</i>
	CDBIO/INF(2022)10	<i>Background document on preimplantation and prenatal genetic testing -legislation</i>
	CDBIO(2022)14	<i>Legislative developments on nuclear transfer and their relationship with Article 18.2 of the Convention</i>
USEFUL DOCUMENTS FOR SEVERAL ITEMS		
	CDBIO/RAP1	<i>Report of the 1st meeting of the CDBIO (31 May-3 June 2022)</i>
	CDBIO/BU RAP(2022)2	<i>Meeting Report of the Bureau (Paris, 20-21 September 2022)</i>
GENERAL INFORMATION DOCUMENTS FOR REFERENCE		
		Strategy for the Rights of the Child (2022-2027)
	CM/Res(2021)3	<i>Resolution on intergovernmental committees and subordinate bodies, their terms of reference and working methods</i>
	CDBIO/INF(2022)2	<i>Information document on the CDBIO</i>
	CDBIO/INF(2022)3	<i>Texts of the Council of Europe on bioethical matters, Volume I</i>
	CDBIO/INF(2022)3	<i>Texts of the Council of Europe on bioethical matters, Volume II</i>
Please click on the respective link to open the Convention and its Protocols		<i>Convention on Human Rights and Biomedicine (ETS 164)</i>
		<i>Explanatory Report to the Convention on Human Rights and Biomedicine</i>
		<i>Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings (ETS 168)</i>
		<i>Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS 186)</i>
		<i>Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research (CETS 195)</i>
		<i>Additional Protocol concerning Genetic Testing for Health Purposes (CETS 203)</i>