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

DRAFT REPORT OF THE STRATEGIC ACTION PLAN
ON HUMAN RIGHTS AND TECHNOLOGIES IN BIOMEDICINE (2020-2025)

I. RATIONAL AND OBJECTIVES

1. The human rights challenges arising from the emergence of new technologies, as well as the evolution of established practices, were underscored at the International Conference held in Strasbourg on 24-25 October 2017, on the occasion of the [20th anniversary of the Convention on human rights and biomedicine](#) ('Oviedo Convention'). The Conference re-emphasised the unique position of the Council of Europe ('CoE') to address these challenges, using as a basis, the legal framework of the Oviedo Convention, thereby rooting solutions in human rights and shared European values.
2. The Strategic Action Plan on human rights and technologies in biomedicine 2020-2025 ('SAP') was developed by the Committee on Bioethics¹ ('the Committee') using, as a basis, the contributions made during the 20th anniversary conference, consultations with national and international stakeholders, exchanges with certain CoE intergovernmental committees and organisations, and a number of preparatory studies². The SAP consisted of four main pillars: Governance of Technologies, Equity in Healthcare, Physical and Mental Integrity, and Cooperation and Communication as a transversal pillar. Under each pillar, specific objectives and related priority actions were identified.
3. The priority actions were determined on the basis of specific criteria including the demonstrated need, the impact on CoE member States and their populations, the potential to elicit changes in policy or practice over the longer term and opportunities to pool resources and increase impact through co-operation with the other committees of the CoE and/or with other intergovernmental organisations. The feasibility in light of available resources, expertise, and time was taken into account. This resulted in a clear structure and specific objectives for the SAP (below).

¹ In 2022, the Steering Committee for Human Rights in the Fields of Biomedicine and Health (CDBIO) replaced the Committee on Bioethics (DH-BIO).

² [The Rights of Children in Biomedicine: Challenges posed by scientific advances and uncertainties](#) [The Rights of Children in Biomedicine From law to practice: towards a road map to strengthen the children's rights in the era of biomedicine - Research report: Bioethics and the Case law of the European Court of Human Rights](#)

Structure and specific objectives of the Strategic Action Plan



4. The SAP was adopted by the Committee at its 16th meeting (16-19 November 2019). The deliverables produced in relation to the objectives, and the specific actions identified in the SAP are outlined in the Appendix to this report. In terms of key performance indicators, the Committee met, and in some cases exceeded the work programme set out in the SAP, and has delivered on the actions, on time and within budget.

II. SYNERGIES, COOPERATION AND IMPACT

5. The SAP enabled the Committee to strengthen communication and cooperation with CoE committees and bodies, as well as other intergovernmental bodies. This allowed the Committee to rationalise its work programme and deploy its resources to ensure that it was able to make a unique and valuable contribution to addressing bioethical issues, having regard to synergy with others to foster a coherent approach to its work. This has also enabled the Committee to be more cross-cutting, as evidenced by its

work relating to gender and youth, and more transversal as demonstrated by its participation in the Council of Europe [Conference on health protection of health](#).

6. An example of successful cooperation is [Guide on children's participation in decisions about their health](#), developed jointly with the Steering Committee for the Rights of the Child (CDENF). Other examples include the cooperation with the Justice and Human Rights Training Division for the launching of the [HELP courses on key human rights principles in biomedicine](#)³, and on [mental health and human rights](#)⁴, as well as with the Office of the Special Representative of the Secretary General on Migration and Refugees for the development of the [Guide to Health Literacy](#).
7. In respect of cooperation with other intergovernmental organisations, it is worth highlighting the very good cooperation with the Organisation for Economic and Cooperation Development (OECD) with whom the Committee co-organised a [round table on human rights and neurotechnologies](#). The Committee also continued to enjoy very good working relations with the World Health Organisation (WHO)⁵ and United Nations Education Science and Culture Organisation (UNESCO)⁶, with whom there was collaboration on questions of common interest, such as genome editing, artificial intelligence and public dialogue regarding scientific and technological developments in the field of biomedicine.
8. The involvement of international non-governmental organisations (INGOs) in the work of the Committee was welcomed and encouraged. The CoE Conference of INGOs, which is an invited participant to CDBIO meetings, was regularly consulted on topics under consideration by the Committee. In the interests of transparency, draft versions of Committee documents were made publicly available and, as regards the development of legal instruments and guides, involved public and/or specific stakeholder consultations.
9. The Committee benefited from specific expertise in the academic sector, such as on patient's rights⁷, notably in the preparation of background information and analyses providing a basis for its work on topics, such as artificial intelligence, neurotechnologies and genome editing.
10. Engaging young people in the work of the Committee was an explicit aim of the SAP which resulted in [a pilot youth forum on AI](#), held in Strasbourg on 6 June 2023, made possible by a voluntary contribution from Ireland. This motivated and oriented the Committee's ongoing efforts to integrate youth perspectives in its work which is in line with 'Reykjavik Declaration' of the fourth Summit of Heads of States and Governments of the Council of Europe Member States, held in Reykjavik on 16-17 May 2023.

³ Available in 14 language versions: Armenian, Czech, English, French, German, Greek, Italian, Latvian, Macedonian, Polish, Romanian, Russian, Spanish, Ukrainian

⁴ Available in 6 language versions: Armenian, English, French, Georgian, Polish, Romanian

⁵ Between 2019-2021, the CDBIO and its Secretariat participated in the WHO expert advisory committee on developing global standards for governance and oversight of human genome editing.

⁶ In December 2024, the Committee provided UNESCO with written comments to its [draft Recommendation on the ethics of neurotechnologies](#).

⁷ In February 2024, a [report on Human Rights Based Approaches in Healthcare](#) was issued by the CDBIO, which provides an overview of the international human rights standards applicable to health care. The focus of this report is on the relevance of human rights for health care and on how international human rights standards can inform domestic patients' rights.

III. DELIVERABLES

11. The following key deliverables were produced by the Committee in accordance with the sections and strategic objectives referred to in the SAP.

Governance of technologies

12. Uncertainty exists about the impact and direction of technological innovation. The role of governance in biomedicine is often restricted to facilitating the applications of technology and to containing the risks that come to light. In this way, human rights considerations only come into play at the end of the process, when the technological applications are already established, and the technological pathways often have become irreversible. Ensuring that technological developments are from the outset oriented towards protecting human rights necessitates governance arrangements to steer the innovation process in a way which connects innovation and technologies with social goals and values.

Strategic objective - Embedding human rights in the development of technologies which have an application in biomedicine

13. The Committee re-examined [Article 13 of the Oviedo Convention](#), which addressed concerns regarding genetic “enhancement” or germline genetic engineering by limiting the purposes of any intervention on the human genome, including in the field of research, to prevention, diagnosis or therapy. The purpose was to clarify the scope of the provisions with regard to research and the purposes limitation provided for any intervention on the human genome. The Committee agreed that the scope of Article 13 and the purposes of limitation provided for any intervention on the human genome is applicable to research. The terms “preventive, diagnostic and therapeutic” were also clarified to avoid misinterpretation of the applicability of this provision to “research”.
14. The Committee organised important events in the field of neurotechnologies and human rights. The [round table](#), coorganised with the OECD in November 2021, brought together international experts from academia, industry and policy development to discuss human rights issues raised by the applications of neurotechnologies. Further, the workshop with legal practitioners, held in November 2025 explored whether and how the human rights legal framework in its current form can serve as an effective legal framework to address the challenges arising from the increasing use and development of neurotechnologies. These events explored the application of neurotechnologies from the standpoint of human rights, including privacy, freedom of thoughts, integrity and non-discrimination.
15. The Committee issued a [report on the impact of AI on the ‘patient-doctor’ relationship](#). Building on an expert report, the Committee explored the increasing deployment of AI systems in healthcare, and how it becomes ever more important to explore and understand the role of healthcare professionals in respecting the autonomy, and the right to information of the patient in order to maintain transparency and patient trust, as critical components of the therapeutic relationship. The report’s main findings were later discussed in a [Conference on AI healthcare and human rights - Supporting patients, enabling doctors, safeguarding the therapeutic relationship](#) organised by the Ministry of Social Affairs and Health of Finland in cooperation with the CoE. Key conference topics included AI’s impact on autonomy, professional standards, self-determination regarding health data, and equitable access to healthcare, as referred to in the Oviedo Convention.

Strategic objective - Fostering public dialogue to promote democratic governance and transparency in the field of biomedicine

16. On 10 November 2022, the Committee organised a [workshop on promoting dialogue on genomic medicine](#) . Important objectives for this workshop were: to explore how public dialogue facilitates information, open exchanges, and better understanding of issues in genomic medicine, having regard to their implications for human rights, and for bioethical principles and to discuss how public dialogue can be employed to anticipate innovations and the need for regulation in genomic medicine. The Committee published a [report](#) on its main findings, positions and conclusions, including the added value of public debate for policy makers to help authorities and other responsible bodies.

Equity in healthcare

17. Increasing disparities in access to healthcare are especially harmful for individuals and groups who are already disadvantaged. Equitable access to healthcare, pursuant to Article 3 of the Oviedo Convention, necessitates measures to prevent discrimination, which thereby implies the identification, reduction, and ultimately elimination of disparities in access. This includes special efforts to improve access for disadvantaged individuals and groups, and to ensure that new developments do not create or exacerbate existing disadvantage.

Strategic objective - Promoting equitable and timely access to appropriate innovative treatments and technologies in healthcare

18. The Committee of Ministers adopted its Recommendation [Rec\(2023\)1](#) to promote equitable access to medicinal products and medical equipment in a situation of shortage and to safeguard the fundamental rights of individuals who need them for serious or life-threatening health conditions. In response to the COVID-19 pandemic and to the shortage of medicinal products and medical equipment engendered by the health crisis, the Recommendation lays down general human rights and procedural principles to ensure, inter alia, the absence of discrimination, through, for example, prioritisation based on medical criteria and compliance with the principles of accountability, transparency and inclusiveness. It also recommends ensuring that there is a system in place to prevent and mitigate situations of shortage and to better prepare for such shortages.
19. The Committee also published a [White paper on equitable and timely access to appropriate innovative treatments and technologies in healthcare](#). So that all individuals have fair and timely access to the benefits of the latest medical innovations, the white paper explores the availability, accessibility, affordability and acceptability of innovative treatments and technologies, and considers why they are more than just a technical or financial matter but also as a fundamental ethical and human rights concern.

Strategic objective - Combating health disparities created by social and demographic changes in Council of Europe member States

20. The Committee launched the “[Guide to health literacy – Contributing to trust building and equitable access to healthcare](#)”, as a practical tool to assist decision-makers, health providers and professionals in healthcare, disease prevention and health

promotion. The Guide, available in 11 language versions⁸, comprises five key components for health systems and users of health systems, namely: access to valid health information; access to appropriate care; communication between individuals, health professionals and health authorities; shared decision-making regarding treatments and care; access to digital spaces to understand and use health services. It also addresses ways to improve health literacy policy, research and practice, and refers to collaboration with health literacy communities. The Guide was also the subject of [three conferences on health literacy and human rights](#), organised in December 2023, 2024 and 2025 by the National Office Against Racial Discrimination of Italy, in cooperation with the Council of Europe, and with the support of the Minister for Family, Natality & Equal Opportunities of Italy and the Ministry of Health of Italy.

Physical and mental integrity

21. Technological developments in the field of biomedicine create new possibilities for intervention in individual behaviour (e.g. neurotechnologies, collection and sharing of genomic and health data, health monitoring of individuals). These developments raise novel questions relating to autonomy, privacy, and even freedom of thought. They also give rise to considerations regarding the protection and respect for autonomy of children, persons with mental health difficulties, and vulnerable older persons, with increased recognition of their decision-making capacities. Guaranteeing respect for a person's integrity in the sphere of biomedicine is one of the central tenets of the Oviedo Convention. This is understood as the ability of individuals to exercise control over what happens to them with regard to, inter alia, their body, their mental state, and the related personal data.

Strategic objective - Strengthening children's participation in the decision-making process on matters regarding their health

22. In collaboration with CDENF, the Committee issued the [Guide to children's participation in decisions about their health](#), available in 11 language versions, which provides information and advice, primarily for healthcare professionals, about how to involve children in decision-making processes regarding their health. The Guide describes important components of the decision-making process, helping health professionals to understand their role in supporting children, families, and other professionals to enact this in practice. Key concepts of consent, assent, and 'best interests' are discussed. A [child-friendly summary of the Guide](#)⁹, as well as a [video clip](#) designed by children, were subsequently prepared and presented during the [mid-term review Conference of the Strategy for the Rights of the Child \(2022-2027\)](#), under the Luxembourg Presidency of the Committee of Ministers of the CoE.

Strategic objective - Safeguarding children's rights in relation to medical practices which have future or long-term implications for them

23. On 31 May 2022, the Committee organised a [seminar](#) (and subsequently issued the report of the rapporteur) [on "Early intervention on Intersex Children – Promoting the Rights of the Child"](#). The seminar addressed four main areas, namely legislation, training, decision-making process and supporting measures from the standpoint of promoting the rights of the child, based on concrete examples.

⁸ Available in 11 language versions: Armenian, English, French, Greek, Hungarian, Italian, Latvian, Lithuanian, Romani, Romanian, Serbian

⁹ Available in 11 language versions: Armenian, English, French, German, Hungarian, Latvian, Lithuanian, Polish, Portuguese, Romanian, Spanish

Strategic objective - Safeguarding the rights of persons with mental health problems

24. The Committee finalised the [draft Additional Protocol to the Oviedo Convention concerning the protection of human rights and dignity of persons with regard to involuntary placement and involuntary treatment within mental healthcare services](#), and decided to present it to the Committee of Ministers with a view to its adoption.¹⁰
25. The Committee of Ministers instructed the CDBIO to complete additional deliverables pending its decision, namely a report on the case law of the European Court of Human Rights relevant to mental health, and a draft recommendation promoting the use of voluntary measures in mental health care services.
26. The [research report on the rights of persons in relation to involuntary placement and treatment in mental health facilities](#), was prepared by the Research Unit of the Court. It provides an overview of the relevant case-law under Articles 3, 5 and 8 of the European Convention on Human Rights related to mental health.
27. The CDBIO prepared and approved the [draft Recommendation on respect for autonomy in mental healthcare](#) submitted to the Committee of Ministers in December 2024, with a view to its adoption. The draft Recommendation calls on member States to align national laws, policies, and practices with human rights standards by embedding respect for autonomy at all levels of mental healthcare. It emphasises the primacy of free and informed consent, equitable access to services, involvement of persons with lived experience in development of practices etc., supportive care environments, and effective complaints procedures. Additionally, it highlights the importance of public education to combat stigma, professional training, research, exchange of good practices, and systematic review and monitoring to ensure the protection of human dignity and autonomy.
28. Prior to that, the Committee issued a [Compendium of good practices to promote voluntary measures in the field of mental healthcare](#), providing practical examples as well as serving as an inspiration for policymakers and service-providers.
29. In cooperation with the Ombudsman of the Republic of Latvia and the University of Latvia, under the auspices of the Latvian Presidency of the Committee of Ministers, the Committee organised a [conference on “Promoting autonomy in mental healthcare”](#), which took place in Riga on 14 November 2023.

Cooperation and communication

30. Effective and efficient co-operation with CoE committees and organs as well as external organisations and bodies is an opportunity to share knowledge, experience, and skills, with synergy and without duplication of resources. All actions should be visible, and achievements strategically communicated to raise awareness and to inform public policy.

¹⁰ In February 2025, the Committee of Ministers agreed to transmit to the Parliamentary Assembly a comprehensive set of work, namely the draft Additional Protocol and its draft Explanatory Report, the draft Recommendation on respect for autonomy in mental healthcare and its draft Explanatory Memorandum, as well as the report on the case law of the European Court of Human Rights relevant to mental health and the Compendium of Good Practices to promote voluntary measures in mental health services. It [invited](#) the Parliamentary Assembly to give an opinion on the draft Additional Protocol as soon as possible.

Strategic objective - Developing long-term strategic co-operation with Council of Europe committees and other intergovernmental bodies working in the field of bioethics

31. The 'HELP' online course "[Key human rights principles in biomedicine](#) for legal and health professionals" was launched in Italy, Greece and Poland. The course consists of eight modules: Introduction; Free and Informed Consent; Medical Confidentiality and Protection of Health-Related Data; Protection of the Embryo and Procreation; End of Life; Genetic Testing; Biomedical Research; Transplantation of Human Organs and Tissues.
32. The HELP Course "[Mental Health and Human Rights](#)" was launched in Armenia and Romania. Comprising 8 modules, the course aims to strengthen the knowledge and raise awareness among healthcare and legal professionals on applicable European human rights standards relevant for persons with mental health issues.

Strategic objective - Ensuring the communication and dissemination of the outputs of the Committee on Bioethics to internal and external stakeholders in order to maximise their uptake and utility

33. To increase visibility, raise awareness, and maximise the uptake and impact of the Committee's work, guides were prepared and translated into non-official languages. This was complemented by filmed interviews with Committee members and other experts summarising findings and recommendations, such as the [rapporteurs' report of the round table on human rights and neurotechnologies¹¹](#) and the [expert report on the application of AI in healthcare](#).
34. The Committee also organised a [pilot youth forum on AI in healthcare](#), to provide a space for youth to interact with policy makers in an intergovernmental setting. The aim of the forum was to 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. Youth participants and Committee delegations exchanged views, perspectives, and suggestions on the mitigation of bias in AI, the training and education of health professionals and patients, equal access to the benefits of AI, and the responsibility/accountability for AI systems used in healthcare settings.

Gender equality and respect for diversity

35. The Committee published an [expert report on gender equality in biomedicine](#) which analysed equitable access to biomedical research, gender bias in the quality of health services, gender bias and gender inequity in AI-based decision tools, and the protection of dignity and (gender) identity.

COVID-19

36. The SAP was adopted before the COVID-19 pandemic. In the face of this public health crisis, the Committee reacted quickly to reaffirm principles and values that needed to be protected and upheld in responding to the complex challenges confronting member States. The Committee adopted a first [Statement on human rights considerations relevant to the COVID-19 pandemic](#). When vaccines became available, several member States took the decision to introduce "vaccine passes" which restricted access to public spaces and/or activities based on vaccination status. In response to this policy

¹¹ The rapporteurs' report included proposals to facilitate an inclusive societal deliberation on how such technologies should be deployed and regulated, and to develop an Interpretative Guide to Adapting Existing Human Rights to neurotechnologies throughout the entire process of research, development and application.

development, the Committee prepared the [Statement on human rights consideration relevant to “vaccine pass” and other similar documents](#).

37. Several resources were made available to member States to support a human rights centred approach to public health emergencies. The Committee collated relevant guidance documentation from its delegations and international bodies¹², and made them available on a dedicated web portal. In addition, the Committee organised webinars exploring the ethical considerations pertaining to [COVID-19 and testing](#), [COVID-19 and health literacy](#) and [COVID-19 and public debate](#).
38. Furthermore, in the light of the pandemic, the Committee reaffirmed the importance of equity in health care and, to complement the SAP actions already foreseen, prepared a [Statement on COVID-19 and vaccines – Ensuring equitable access to vaccination during current and future pandemics](#) and the aforementioned [Recommendation of the Committee of Ministers on equitable access to medicinal products and medical equipment in situation of shortage](#).
39. Under the auspices of the Italian presidency of the Committee of Ministers, the Committee organised a [Conference on Social Resilience and Health Equity: A human right prospective for better resilience and preparedness](#). The event raised awareness of the importance of human rights protection during public health crises and how to support member States in their resilience and preparedness for such crises. The event was an opportunity to identify needs and ways to protect people and groups in vulnerable situations groups who experience difficulties in accessing healthcare.
40. In summary, the global pandemic highlighted the importance of upholding human rights and reinforced the importance of transparent, equitable value-based decisions in addressing this public health emergency. The actions and more specifically the timelines for those actions were adhered to despite the challenges presented by the pandemic, including remote working. Moreover, the Committee successfully re-oriented resources to ensure it could address and advise member States on the human rights and ethical challenges posed by the pandemic in real-time.

IV. LESSONS LEARNED

41. The SAP was the first strategic action plan drafted by the Committee. It provided a framework to prioritise goals, maximise resources and increase efficiency and effectiveness. The SAP ensured that the Committee took a more long-term view in relation to its work programme, allowing it to shape agendas in the bioethics sphere rather than by simply responding to issues arising. Measures were taken to enable the Committee to track progress towards goals and concretely assess the impact of its work were developed. Capacity was also built into the SAP to evolve with challenges and opportunities encountered, as amply demonstrated by the work on COVID-19.
42. The implementation of the SAP was characterised by four key features, namely ‘adaptability’, ‘practical approach’, “engagement” and its ‘transversality’.
43. As regards its ‘adaptability’, the Committee adapted to new ways of working during the pandemic, making it possible to continue safeguarding the protection of human rights, while making progress in the implementation of the SAP. The Committee’s work on COVID-19 (see above) illustrates its ability to provide timely and relevant responses to emerging challenges.

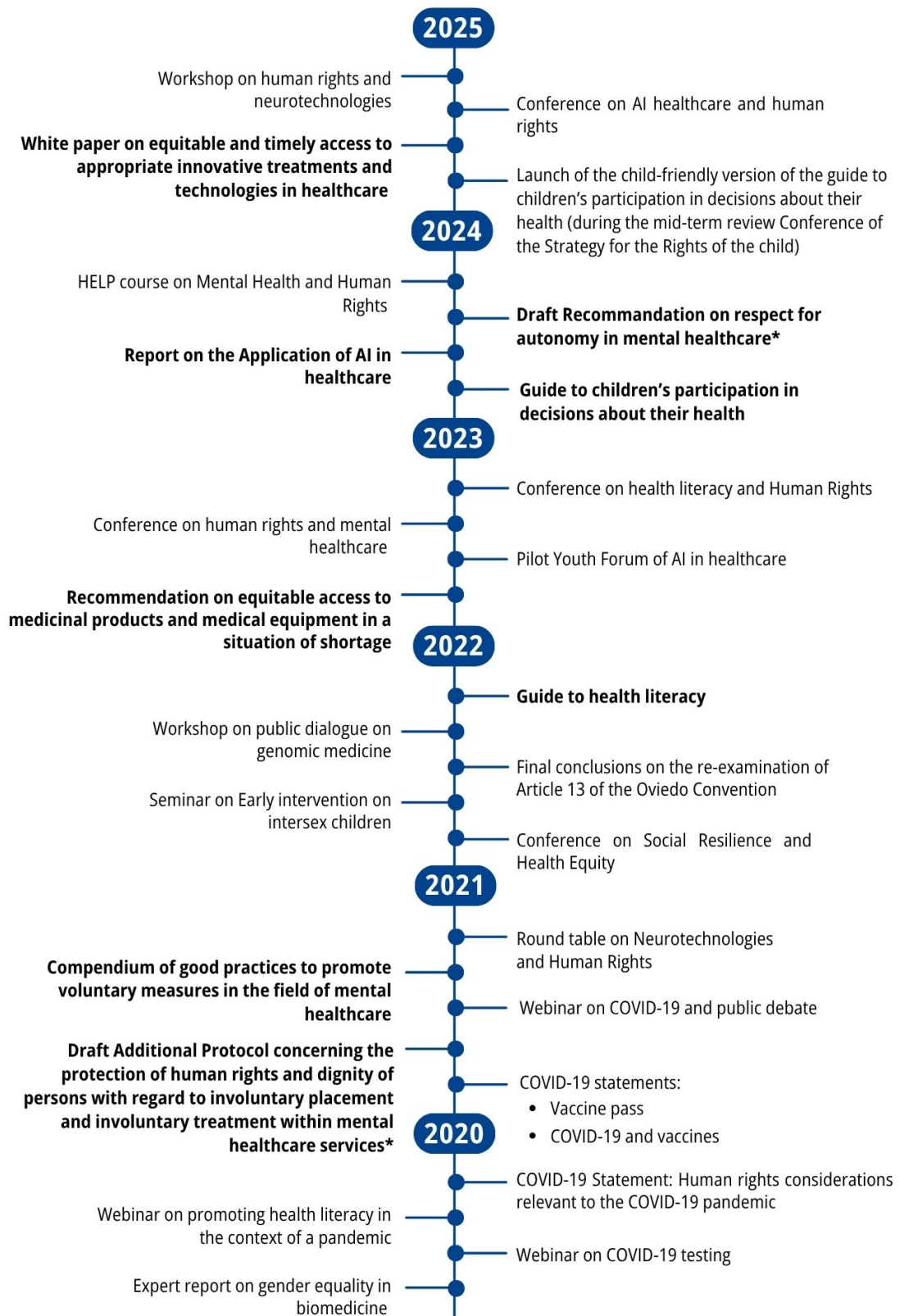
¹² <https://www.coe.int/en/web/bioethics/COVID-19>

44. As regards its 'practical approach', the Committee placed emphasis on the development of practical tools, sharing of examples of good practice with a view to facilitating the implementation of legal principles, and targeting relevant stakeholders, notably legal and health professionals as well as patients and families. This was enabled by online presentations which increased functionality, visibility and impact.
45. As regards its 'engagement', the Committee increased its interactions with policy makers at member States level and with NGOs working in the fields and civil society. It also pursued fruitful cooperation with other CoE committees and intergovernmental organisations to ensure complementarity of competences and increased potential for impact.
46. As regards its 'transversality', the Committee improved its communication and dissemination of documents and legal instruments. This was made possible namely by specific and structured strategic contacts with Committee delegations, the CoE Conference of INGO's, and other participants and observers to the Committee.
47. A major source of 'lessons learned' by the Committee was the results of an 'horizon scanning' of its past SAP work with a view to the development of its new SAP 2026-2030. By way of a questionnaire to member states, ethics bodies, human rights institutions, as well as an 'in-person' meeting of experts and thought leaders, an independent rapporteur prepared a report to inform the Committee's thinking. This enabled the Committee to reflect on longer term planning for its key challenges ahead, notably public perceptions about human rights in biomedicine, impact and responsiveness to societal needs, meaningful interactions with a more diverse array of stakeholders, and collaboration with private sector actors.

V. LOOKING AHEAD

48. The SAP was developed and implemented during a time of noticeable inequities in healthcare, both within and across countries, exacerbated by demographic shifts such as ageing populations and migration and the digital transformation of health systems. Looking ahead, these challenges are being compounded with the spread of mis- and disinformation in the health field, amplified by social media and AI-generated content, which is eroding the bond of trust between people and institutions and therein evidence-based policymaking. Therefore, as innovation accelerates and structural inequalities persist, there is a need to shape policy debates and provide strategic foresight to address uncertain futures, protecting the health and rights of both current and future generations.

APPENDIX



*(pending adoption by the Committee of Ministers)