Terms of reference of the

European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH)

Set up by the Committee of Ministers under Article 17 of the Statute of the Council of Europe and in accordance with Resolution CM/Res(2021)3 on intergovernmental committees and subordinate bodies, their terms of reference and working methods.

Category: Steering committee
Duration: 1 January 2024 - 31 December 2027[1]
Programme: Advancing social justice, good health and a sustainable environment
Sub-programme: Quality of medicines and healthcare

Main tasks

Under the authority of the Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia, the CD-P-PH is instructed to:

i. take due account of the Reykjavik Declaration[2] in conducting its activities and submit proposals for its implementation as appropriate;
ii. take account of the relevant key findings and challenges set out in the Secretary General's 2023 Report on the state of democracy, human rights and rule of law "An Invitation to Recommit to the Values and Standards of the Council of Europe";
iii. fulfil the tasks of the Public Health Committee set out in the Convention on the Elaboration of a European Pharmacopoeia (ETS 50), as amended by the Protocol (ETS 134), Articles 2, 3, 4 and 8;
iv. fulfil the tasks set out in Committee of Ministers' Resolution CM/Res(2018)1 on the classification of medicines as regards their supply;
v. minimise public health risks posed by falsification of medical products and similar crimes by developing and promoting the implementation of multi-sectorial approaches including co-operation among and within member States, risk management policies, knowledge transfer and awareness raising;
vi. support the capacity building of inspectors from national competent authorities in preventing and combating the falsification of medical products and similar crimes through annual training workshops and through promotion of the KnowX database on falsified medical products;
vii. elaborate technical and guidance documents for health authorities and other national competent authorities (where relevant) to prevent, detect and combat falsification of medical products and similar crimes, in accordance with the Council of Europe Convention on the counterfeiting[3] of medical products and similar crimes involving threats to public health (MEDICRIME Convention) (CETS 211), and to exchange regularly with its Committee of the Parties;
viii. maintain a network of experts in borderline products, establish framework to support Co-operation, to provide guidance on procedures of enforcement, and to facilitate the sharing of information;
ix. contribute to improving public health and access to good quality medicines and healthcare by developing harmonised provisions and practices for the appropriate use of medicines and promoting the implementation of the pharmaceutical care[4] philosophy and working methods;
x. ensure the transfer of knowledge and expertise as well as the dissemination of results through training and networking with a view to enhancing the safe and appropriate use of medicines;
xi. ensure and follow up appropriate implementation of the results of the relevant activities of the Council of Europe at national level;
xii. facilitate the development and maintenance of links with relevant European institutions and international organisations active in the field, in particular the European Commission and the World Health Organization (WHO);
xiii. draft proposals for recommendations and resolutions for adoption by the Committee of Ministers and prepare policies and guidance documents;
xiv. define strategies to minimise the impact of shortages of medicines during public health emergencies with a view to ensuring continuity of care and safeguarding timely access to safe and effective quality medicines;
xv. raise-awareness about Council of Europe standards and tools in its field of competence in the member States and beyond, through the neighbourhood policy and in other international and global fora where relevant;
xvi. hold an exchange of views annually in order to evaluate its activities and advise the Committee of Ministers and the Secretary General on future priorities in its sector, including possible new activities and those that might be discontinued;
xvii. take due account of the following mainstreamed perspectives in the performance of its tasks: gender, youth, children's rights, rights of persons with disabilities, and Roma and Traveller[5] issues;

[1] These terms of reference are approved for the first biennial period 2024-2025. For the second biennial period 2026-2027, they are approved on a provisional basis, subject to confirmation upon the adoption of the budget for 2026-2027.
[2] Reykjavík Declaration - United around our values.
[3] The term "counterfeit" as used in the Convention should be interpreted as "falsified", without any Intellectual Property Rights (IPR) meaning.
[4] Definition of pharmaceutical care: cf. Committee of Ministers Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services.
[5] The term "Roma and Travellers" is used at the Council of Europe to encompass the wide diversity of the groups covered by the work of the Council of Europe in this field: on the one hand a) Roma, Sinti/Manush, Calé, Kaale, Romanichals, Boyash/Rudari; b) Balkan Egyptians (Egyptians and Ashkali); c) Eastern groups (Dom, Lom and Abdal); and, on the other hand, groups such as Travellers, Yenish, and the populations designated under the administrative term "Gens du voyage", as well as persons who identify themselves as Gypsies. The present is an explanatory footnote, not a definition of Roma and/or Travellers.

xviii. where relevant, contribute to strengthening meaningful engagement with civil society organisations and national human rights institutions in its work;

xix. in accordance with decisions CM/Del/Dec(2013)1168/10.2 of the Committee of Ministers, carry out, at regular intervals, within the limits of the available resources and bearing in mind its priorities, an examination of some or all of the conventions for which it has been given responsibility, in co-operation, where appropriate, with the relevant convention-based bodies, and report back to the Committee of Ministers;

xx. contribute to the achievement of, and review progress towards, the UN 2030 Agenda for Sustainable Development, in particular with regard to Goal 3: Good health and well-being and Goal 5: Gender Equality.

Main deliverables

Under the authority of the Committee of Ministers, the CD-P-PH is instructed to complete the following deliverables, within the following deadlines:

	Category ▼	Priority ▼	Deadline ▼
1. Best practices for traceability of medicines in hospital settings to minimise the occurrence of medication administration errors and ensure patient safety	A	2	31/12/2024
2. Guidance "Falsified medicines – What does it mean?", accompanied by a compilation of relevant cases; primary target audience: national health authorities	A	2	31/12/2024
3. Guidance documents on safe use of herbal products	A	2	31/12/2024
4. Draft Recommendation on best practices for the remote and online provision of medicines	A	2	31/12/2024
5. Guidance document on the classification of supply of an active substance used in a medicinal product for a specific therapeutic purpose	C	2	31/12/2024
6. Guidance document on reporting of unaccounted disappearances of medicinal products for human and veterinary use from the legal supply chain	C	2	31/12/2025
7. Mapping of hospital pharmacy practices related to the preparation of chemotherapy medicines	C	2	31/12/2025
8. Best practices on borderline products in the enforcement of medical product legislations	A	2	31/12/2025
9. Methodological guide for selecting medicines at risk of shortage during public health emergencies, guiding on how to address these shortages via the optional and temporary use of standardised pharmacy preparations in hospital and community pharmacy settings	A	1	31/12/2025
10. Guidance document for healthcare professionals on providing appropriate advice to patients undergoing cytotoxic treatment	C	3	31/12/2026
11. Guidance document on providing a harmonised pharmaceutical care service in different care settings and for various target patient groups (supplementing Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services)	C	3	31/12/2027
12. Follow-up to the joint initiative with the South-eastern Europe Health Network (SEEHN) focusing on the implementation of pharmaceutical care (Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services) in daily practice in a selected number of member States	C	3	31/12/2027
13. Biannual revisions of the appendices of Resolution CM/Res(2018)1 on the classification of medicines as regards their supply	A	2	31/12 of each year
14. Compilation of evidence-based classification reviews focusing on therapeutic classes of medicines relevant for public health but not harmonised in terms of classification status	A	2	31/12 of each year
15. Biannual updates of the Melclass database with comprehensive data collection on classification of medicines in Council of Europe member States	A	2	31/12 of each year
16. Biannual monitoring of medication safety issues and their potential impact on the classification status of medicines	A	2	31/12 of each year

Key
A: deliverable under preparation (2022-2023 terms of reference or Committee of Ministers' decision) or deliverable foreseen in the terms of reference provisionally approved for 2024-2025 and reviewed where relevant in the framework of the preparation of the draft Programme and Budget 2024-2027
B: review of implementation/re-examination foreseen by the recommendation/protocol/convention
C: newly proposed deliverable

Composition

- Members

Governments of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia are invited to designate one representative of the highest possible rank with expertise in a field covered by these terms of reference. Each member of the committee shall have one vote. Where a government designates more than one member, only one of them is entitled to take part in voting.
The sending authorities of the member States will bear the travel and subsistence expenses for their representatives' participation in the meetings of the CD-P-PH. The travel and subsistence expenses of the Chair for participating in the meetings of the CD-P-PH will be borne by the EDQM budget.
In accordance with decisions CM/Del/Dec(2013)1168/10.2 of the Committee of Ministers, in cases where there is no convention-based body including all the Parties, non-member States are invited to take part, with a right to vote, in the committee meetings pertaining to the conventions to which they are Parties.

- Participants

The following may send representatives, without the right to vote and at the charge of their corresponding administrative budgets:

- Parliamentary Assembly of the Council of Europe;
- Congress of Local and Regional Authorities of the Council of Europe;
- European Court of Human Rights;
- Council of Europe Commissioner for Human Rights;
- Conference of INGOs of the Council of Europe;
- Committees or other bodies of the Council of Europe engaged in related work, as appropriate.

The European Union is entitled to appoint a representative to the meetings of the CD-P-PH, without the right to vote except for the fulfilment of the tasks mentioned under item (iii), and without defrayal of expenses.

The following may send representatives, without the right to vote and without defrayal of expenses:

- Council of Europe member States other than those mentioned above under "Members" and other States with observer status to the European Pharmacopoeia Commission;
- Observer States to the Council of Europe: Canada, Holy See, Japan, Mexico, United States of America;
- World Health Organization (WHO).

- Observers

The following may send representatives, without the right to vote and without defrayal of expenses:

- non-member States with which the Council of Europe has a Neighbourhood Partnership including relevant co-operation activities.

Observer status may be requested in accordance with Article 8 of Resolution CM/Res(2021)3 on intergovernmental committees and subordinate bodies, their terms of reference and working methods.

Working methods

The rules of procedure of the committee are governed by Resolution CM/Res(2021)3 on intergovernmental committees and subordinate bodies, their terms of reference and working methods. However, with a view to reaching its objectives and enabling multidisciplinary working methods, the committee may, in derogation of Resolution CM/Res(2021)3 and within the limit of budgetary attributions, create subordinate bodies.

	Plenary meetings ▼		
	Members incl. Chair	Meetings per year	Days per meeting
2024	39	1	1.5
2025	39	1	1.5
2026	39	1	1.5
2027	39	1	1.5

Extraordinary meetings of the CD-P-PH may be convened upon request by the Chair.
Representatives taking part in the committee and its subordinate bodies shall complete a declaration of interest and confidentiality undertaking form.
The CD-P-PH will appoint from amongst its members up to 5 Rapporteurs on mainstreamed perspectives, including a Gender Equality Rapporteur.

Budgetary information *

	Meetings per year	Days per meeting	Members reimbursed	Plenary in €K	Bureau in €K	Working groups in €K	Secretariat (A, B)
2024	1	1.5	1	8.1	-	-	1 A; 1 B
2025	1	1.5	1	8.1	-	-	1 A; 1 B
2026	1	2	1	↔	-	-	↔
2027	1	2	1	↔	-	-	↔

*The costs include the per diem and travel costs of the Chair for participating in the meetings of the committee and interpretation. These costs are calculated on the basis of standard costs.