Extract from CM(2021)131-addfinal

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.

Type of committee: **Steering committee**
Terms of reference valid from: **1 January 2022 until 31 December 2025**[1]

PILLAR/PROGRAMME/SUB-PROGRAMME ▼

Pillar: Rule of Law
Programme: Action against crime, safety and security of citizens
Sub-programme: Quality of Medicines and Healthcare (EDQM, European Pharmacopoeia)

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) ensure the follow-up of the relevant decisions taken at the 131st Session of the Committee of Ministers (Hamburg, 21 May 2021),[2] and in particular contribute to the implementation of the key strategic priorities relating to its specific field of expertise as identified in the Strategic Framework of the Council of Europe, and respond to the respective key findings and challenges set out in the Secretary General's 2021 Report on the state of democracy, human rights and rule of law "A democratic renewal for Europe";

(ii) 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;

(iii) fulfil the tasks set out in Committee of Ministers' Resolution CM/Res(2018)1 on the classification of medicines as regards their supply;

(iv) 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;

(v) 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;

(vi) promote the Convention on the counterfeiting[3] of medical products and similar crimes involving threats to public health (MEDICRIME Convention) (CETS 211), and contribute to the follow-up mechanism ensured essentially by the Committee of the Parties to the above Convention;

(vii) 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;

(viii) 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;

(ix) ensure and follow up appropriate implementation of the results of the relevant activities of the Council of Europe at national level;

(x) 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);

(xi) draft proposals for recommendations and resolutions for adoption by the Committee of Ministers and prepare policies and guidance documents;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) where relevant, contribute to building cohesive societies and to strengthening the role and meaningful participation of civil society in its work;

---

[1] These terms of reference are approved for the first biennial period 2022-2023. For the second biennial period 2024-2025, they are approved on a provisional basis, subject to confirmation upon the adoption of the budget for 2024-2025.
[2] CM/Del/Dec(2021)131/2a, CM/Del/Dec(2021)131/2b, CM/Del/Dec(2021)131/2c and CM/Del/Dec(2021)131/3.
[3] The term "counterfeit" as used in the official title of 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.

(xvi) 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,[6] in co-operation, where appropriate, with the relevant convention-based bodies, and report back to the Committee of Ministers;

(xvii) 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:

	Deadline ▼
1. Report on best practices for reclassification of medicines	31/12/2022
2. Draft Recommendation on thefts/losses/diversions of medicinal products (including reporting to national health authorities and actions to be taken by them and other stakeholders)	31/12/2022
3. Draft Revised Resolution ResAP(2007)2 on good practices for distributing medicines via mail order	31/12/2022
4. Strategy document to disseminate and promote the implementation of resolutions related to pharmaceuticals and pharmaceutical care	31/12/2022
5. Handbook compiling knowledge transferred to inspectors from national competent authorities in the annual training workshops on detection of falsified medical products during routine inspections	31/12/2022
6. Best practices for traceability of medicines in hospital settings to minimise the occurrence of medication administration errors and ensure patient safety	31/12/2023
7. Guidance on definitions related to the fight against falsified medicines, accompanied by a compilation of relevant cases; primary target audience: national health authorities	31/12/2023
8. Guidance document on safe use of herbal products	31/12/2023
9. Guidance document to harmonise the medication review process in different care settings and for various target patient groups	31/12/2023
10. Report on implementation of pharmaceutical care activities (Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services) in a selected number of member States	31/12/2024
11. Best practices on borderline products in the enforcement of medical product legislations	31/12/2024
12. Best practices for cytotoxic medicine surveillance in Europe aimed at ensuring safe and appropriate use of cytotoxic medications	31/12/2025
13. 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.	31/12/2025
14. Concept paper listing potential strategies to address shortages of medicines during public health emergencies via optional and temporary use of standardised pharmacy preparations in hospital and community pharmacy settings	31/12/2025
15. Biannual revisions of the appendices of Resolution CM/Res(2018)1 on the classification of medicines as regards their supply	31/12 of each year
16. Compilation of evidence-based classification reviews focusing on therapeutic classes of medicines relevant for public health but not harmonised in terms of classification status	31/12 of each year
17. Biannual updates of the Melclass database with comprehensive data collection on classification of medicines in Council of Europe member States	31/12 of each year
18. Biannual monitoring of medication safety issues and their potential impact on the classification status of medicines	31/12 of each year

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.

[6] Cf. relevant decisions of the Committee of Ministers (CM/Del/Dec(2013)1168/10.2) and list of Conventions in document CM(2021)132.

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 (ii), 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 ▼

	Plenary meetings ▼		
	Members incl. Chair	Meetings per year	Days per meeting
2022	39	1	2
2023	39	1	2
2024	39	1	2
2025	39	1	2

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 rules of procedure of the committee are governed by Committee of Ministers 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 to enabling multidisciplinary working methods, the CD-P-PH may, in derogation of Resolution CM/Res(2021)3 and within the limit of budgetary attributions, create subordinate bodies.

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)
2022	1	2	1	6.2	-	-	1A, 1B
2023	1	2	1	6.2	-	-	1A, 1B
2024	*1*	*2*	*1*	↔	-	-	↔
2025	*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. They are calculated on the basis of the 2021 standard costs.