COMMITTEE OF EXPERTS ON MINIMISING PUBLIC HEALTH RISKS POSED BY FALSIFICATION OF MEDICAL PRODUCTS AND SIMILAR CRIMES (CD-P- PH/CMED)

Set up by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) in accordance with Resolution CM/Res(2011)24 on intergovernmental committees and subordinate bodies, their terms of reference and working methods.

Type of committee: Subordinate body

Terms of reference valid from: **1 January 2022 until 31 December 2025**

PILLAR/PROGRAMME/SUB-PROGRAMME ▼

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

DELIVERABLES ▼

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

	Deadline ▼
1. Revised Committee of Ministers Resolution ResAP(2007)2 on good practices for distributing medicines via mail order (in cooperation with the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) and Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO))	31/12/2022
2. Committee of Ministers Recommendation on thefts/losses/diversions of medicinal products (provisionary title)(including reporting to national health authorities and actions to be taken by them and other stakeholders)	31/12/2022
3. 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
4. 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
5. Best practices on borderline products in the enforcement of medical product legislations	31/12/2024
6. Organisation of an event to promote the co-operation among contacts within health, law enforcement and customs authorities on the EDQM SPOC network list (Single Point Of Contact)	31/12/2022
7. Maintain a network of experts in borderline products, establish framework to support cooperation, to provide guidance on procedures of enforcement, and to facilitate the sharing of information, in cooperation with CD-P-PH/PC	2022-2025
8. Yearly workshop to promote the transfer of good practices and building-up of specific expertise in the detection of falsified medical products during routine inspections through carrying out training events for health authority inspectors	2022-2025
9. Yearly workshop to promote and practice co-operation between enforcement officers from health, law enforcement and customs authorities (SPOC)	2022-2025
10. Promote and maintain inventory of cases of falsified medical products (“Know-X”-inventory) among member States’ health and law enforcement authorities, in particular authorities’ (single) points of contact.	2022-2025

COMPOSITION ▼

Members:

Governments of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia are invited to designate a representative from the relevant health authority, with relevant competencies and experiences as regards risk prevention and management in the field of combating falsification of medical products and similar crimes. Representatives may also belong to law enforcement authorities provided that they possess the relevant competencies and expertise as described above. Each member of the CD-P-PH/CMED shall have one vote. Where a government designates more than one member, only one of them is entitled to take part in the 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/CMED. The travel and subsistence expenses of the Chair for participating in the meetings of the CD-P-PH/CMED will be borne by the EDQM budget.

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 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;
- European Union;
- 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 cooperation activities;
- International professional societies, intergovernmental organisations (IGOs), and non-governmental organisations (NGOs) working on topics related to the tasks of the CD-P-PH/CMED.

Observer status is granted on the basis of a unanimous decision by the CD-P-PH. In the event where unanimity is not attained, the matter may be referred to the Committee of Ministers at the request of two-thirds of the members of the CD-P-PH.

WORKING METHODS ▼

	Plenary meetings ▼		
	Members	Meetings	Days
2022	39	2	2.5
2023	39	2	2.5
2024	39	2	2.5
2025	39	2	2.5

Representatives taking part in the CD-P-PH/CMED and, if applicable, its working groups shall complete a declaration of interest and confidentiality undertaking form.

The rules of procedure of the CD-P-PH/CMED are governed by Resolution CM/Res(2011)24 on intergovernmental committees and subordinate bodies, their terms of reference and working methods.

In addition, the following provisions shall apply:

The CD-P-PH/CMED will hold regular meetings and will carry out its programme of activities using scientific and public health orientated approaches, where applicable, and use structured and systematic approaches for proposals for new projects and for carrying out repeated activities such as surveys. Recurrent topics or temporary specific tasks requiring more attention will be dealt with by dedicated delegates in form of Teams under the supervision of the Secretariat and with regular reporting and discussion during meetings.

The orientation of the programme of activities is multi-sectorial, comprising public health and law enforcement, relevant private sectors and health professionals.

With a view to reaching its objectives, the CD-P-PH/CMED may arrange consultations, in particular with international and European associations representing for example the medical products' manufacturing and distribution chain, including manufacturers of ingredients for pharmaceutical purposes, health professionals, by means of hearings, conferences, seminars, if appropriate. The CD-P-PH/CMED may also consider holding dedicated meetings on a regular basis with relevant associations to facilitate interaction.

When appropriate, it will prioritise environmentally sound working methods, such as virtual meetings facilitated by information technology and written consultations.