

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 Committee of Ministers under Article 17 of the Statute of the Council of Europe and 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 of the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) (CD-P-PH)

Terms of reference valid from: **1 January 2020 until 31 December 2021**

PILLAR/PROGRAMME/SUB-PROGRAMME
<p>Pillar: Rule of Law Programme: Action against crime, safety and security of citizens Sub-Programme: European Directorate for the Quality of Medicines and Healthcare (EDQM)</p>
MAIN TASKS
<p>Under the authority of the CD-P-PH, the CD-P-PH/CMED will:</p> <ol style="list-style-type: none">i. provide a platform for constructive exchange of information, experience and knowledge for professionals who are active in combating falsification of medical products and similar crimes;ii. develop and promote the implementation of multi-sectorial approaches in the field of public health protection from falsified medical products and similar crimes, e.g. risk management and prevention, training, knowledge transfer programs and publications;iii. facilitate networking and co-operation among member States with focus on protecting the general public from falsified medical products and similar crimes through activities promoting recognised networks, e.g. the network of Single Points of Contact (SPOCs);iv. provide public health authorities with strategies for risk communication on falsification of medical products and similar crimes;v. as provided for in the Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention) (CETS No. 211),<ol style="list-style-type: none">a. support the Committee of the Parties in the collection, analysis and exchange of information, experience and good practice between States to improve their capacity to prevent and combat the falsification of medical products and similar crimes involving threats to public health.b. make available expertise to the Committee of the Parties, e.g. by supporting the preparation, implementation and follow-up of the Convention, contributing to the Committee's multi-sectorial follow-up mechanism and facilitating information exchange on significant legal, policy or technological developments in relation to the application of the provisions of the convention;vi. promote a favourable environment for the implementation of regional and international specific legal instruments in the field of falsified medical products and similar crimes at national and international levels;vii. establish and maintain links with national, European and international institutions and organisations being active in combating falsification of medical products and similar crimes;viii. develop supportive tools for information exchange on management, prevention and follow-up of the risks posed by falsification of medical products and similar crimes;ix. assess the impact of the results of its work programme in the States Parties to the Convention on the Elaboration of a European Pharmacopoeia.
SPECIFIC TASKS
<p>Taking into account the high risk for public health posed by falsified products and similar crimes, the need for a multi-sectorial approach and international cooperation, and the specific mention in the MEDICRIME Explanatory report referring to the CD-P-PH/CMED as a potential provider of expertise for the work of the Committee of the Parties, under the authority of the CD-P-PH, in 2020 and 2021 the CD-P-PH/CMED will pursue the following activities:</p>

- promote the MEDICRIME Convention on a European and global level, for its signature, ratification and implementation;
- support the Convention's Committee of the Parties by providing expertise where required and possible;
- promote exchange of relevant information pertaining to risk management and prevention;
- establish, maintain and promote the SPOC network in States Parties to the Convention on the Elaboration of a European Pharmacopoeia and in Observer states;
- promote the co-operation among SPOCs within health, law enforcement and customs authorities through carrying out multi-sectorial training events for officials from these authorities and other stakeholders; and support the transfer of good practices by establishing a Best Practice model;
- promote the co-operation between health and justice/law enforcement and resources permitting, support the organisation of transversal training events for officials from the relevant authorities;
- 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 inspectors;
- promote the transfer of proven practices and building-up of specific expertise in managing and preventing risks posed by falsification of medical products and similar crimes through the use of the 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;
- assess risk to public health posed by products other than falsified human medicines but covered by the convention, e.g. falsified veterinary medicines, falsified medical devices, borderline products, other situations considered under the term 'similar crimes'.
- in cooperation with the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC), revise the Resolution ResAP(2007)2 on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine, taking into account the current digital landscape in healthcare and observed related issues;
- help prevention of damage caused by falsified medical products and similar crimes through the provision of discussion fora, training and teaching materials;
- adapt relevant models and activities to further increase their applicability in the fight against falsified medical devices and similar crimes.

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 and law enforcement authorities, such as experts from health or law enforcement sectors e.g. from police and customs, with relevant competencies and experiences as regards risk prevention and management in the field of combating falsification of medical products and similar crimes. 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's participation in the meetings of the CD-P-PH/CMED are borne by specific budget appropriations for the CD-P-PH/CMED.

Participants:

Committees or other bodies of the Council of Europe engaged in related work, as well as the Parliamentary Assembly, the European Court of Human Rights, the Congress of Local and Regional Authorities of the Council of Europe, the Council of Europe Commissioner for Human Rights and the Conference of INGOs of the Council of Europe may send a representative, without the right to vote and at the expense of their corresponding administrative budgets.

Council of Europe member States other than mentioned above under "Members" and other States with observer status to the European Pharmacopoeia Commission may send a representative to the meetings of the CD-P-PH/CMED, without the right to vote or defrayal of expenses.

Observer States to the Council of Europe may send a representative, without the right to vote and without defrayal of expenses.

The European Union is entitled to appoint a representative to the meetings of the CD-P-PH/CMED, without the right to vote and without defrayal of expenses;

The World Health Organization (WHO) and other relevant international organisations active in the field of combating falsification of medical products and similar crimes may send a representative to the meetings of the CD-P-PH/CMED, without the right to vote or defrayal of expenses.

Observers:

Any non-governmental organisation active in the field may ask for observer status with the CD-P-PH/CMED and be allowed to send a representative to its meetings, without the right to vote or defrayal of expenses.

Observer status is granted on the basis of a unanimous decision by the Steering Committee 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

Meetings:

38 member States, 2 meetings in 2020, 2.5 days

38 member States, 2 meetings in 2021, 2.5 days

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.

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.

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.

Representatives taking part in the Committee of Experts and, if applicable, its subordinate working parties, shall complete a declaration of interest and confidentiality undertaking form (EDQM Form/226).