Terms of Reference of the 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 2018 until 31 December 2019**

**Main tasks**

Under the authority of the CD-P-PH, the CD-P-PH/CMED will

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) (ETS No. 211), make available scientific expertise to the Committee of the Parties to the convention, e.g. supporting the preparation, implementation and follow-up of the Convention, contributing to the multi-sectorial follow-up mechanism maintained by the Committee of the Parties and facilitating information exchange on significant legal, policy or technological developments in relation to the application of the provisions of the convention;

vi. establish and maintain links with national, European and international institutions and organisations that are active in combating falsification of medical products and similar crimes;

vii. develop supportive tools for information exchange on management, prevention and follow-up of the risks posed by falsification of medical products and similar crimes;

viii. assess the impact of the results of its work programme in the States Parties to the Convention on the Elaboration of a European Pharmacopoeia.
Expected Results

Under the authority of the CD-P-PH, in 2018 and 2019 the CD-P-PH/CMED will pursue the following activities:

i. promote the MEDICRIME Convention on a European and global level, for its signature, ratification and implementation;

ii. promote exchange of relevant information pertaining to risk management and prevention;

iii. establish, maintain and promote the Single Points of Contact network (SPOC) in Parties to the Convention on the Elaboration of a European Pharmacopoeia and in Observer states;

iv. promote the co-operation among SPOCs within health, law enforcement and customs authorities by carrying out multi-sectorial training events for officials from these authorities and other stakeholders;

v. promote the dissemination 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;

vi. promote the dissemination 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 case inventory of falsified medical products (“Know-X”-inventory) among member States’ health and law enforcement authorities, in particular authorities’ (single) points of contact (SPOC network);

vii. help prevention of damage caused by falsified medical products and similar crimes through the provision of discussion fora, training and teaching materials;

viii. 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 2018, 2 days

38 member States, 2 meetings in 2019, 2 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.

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 or by any other means, and organise conferences and seminars, as appropriate. Where necessary, in order to expedite the progress of its work, the CD-P-PH/CMED may entrust a limited number of its members with a specific task.

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).

Budgetary information

Amount foreseen in the draft Programme and Budget 2018-2019

2018

<table>
<thead>
<tr>
<th>Meetings per year</th>
<th>Number of days</th>
<th>Members (at sending authorities’ expense)</th>
<th>Plenary</th>
<th>Bureau</th>
<th>Subordinate structures/ Working groups</th>
<th>Secretariat (A, B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
<td>38</td>
<td>€9 400</td>
<td>-</td>
<td>-</td>
<td>1 A; 1 B</td>
</tr>
</tbody>
</table>

2019

<table>
<thead>
<tr>
<th>Meetings per year</th>
<th>Number of days</th>
<th>Members (at sending authorities’ expense)</th>
<th>Plenary</th>
<th>Bureau</th>
<th>Subordinate structures/ Working groups</th>
<th>Secretariat (A, B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
<td>38</td>
<td>€9 400</td>
<td>-</td>
<td>-</td>
<td>1 A; 1 B</td>
</tr>
</tbody>
</table>