EUROPEAN COMMITTEE OF PHARMACEUTICALS AND PHARMACEUTICAL CARE (PARTIAL AGREEMENT) (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(2011)24 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 2018 until 31 December 2019**

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) fulfil the tasks of the Public Health Committee set out in the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50), as amended by the Protocol (ETS No. 134), Articles 2, 3, 4 and 8;

(ii) fulfil the tasks set out in Resolution ResAP(2007)1 on the classification of medicines as regards their supply;

(iii) contribute to improving public health and access to good quality medicines and healthcare via developing harmonised provisions and practices for the rational use of medicines and promoting the implementation of the pharmaceutical care[1] philosophy and working methods in Europe;

(iv) minimise public health risks posed by falsification of medical products and similar crimes through:

a. support to the preparation, implementation and follow-up of relevant national legislation and international legal instruments, in particular the Convention on the Counterfeiting[2] of Medical Products and Similar Crimes Involving Threats to Public Health (Medicrime Convention) (ETS No. 211),

b. the preparation and implementation of specific multisectorial prevention and risk management policies and strategies based on coordinating competent health, police and customs authorities through the network of Single Points of Contact (SPOC) specified in Articles 17 and 22 of the Medicrime Convention,

c. contribution to the multisectorial follow-up mechanism maintained by the Committee of the Parties to the Medicrime Convention;

(v) ensure and follow up appropriate implementation of the results of the relevant activities of the Council of Europe and at national level in States Parties to the Convention on the Elaboration of a European Pharmacopoeia;

(vi) 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);

(vii) draft legal instruments, including resolutions for adoption by the Committee of Ministers, and define policies and guidelines;

(viii) while taking account of the progress of its work, prepare under its responsibility, proposals for the programme of activities for the coming years;

(ix) take due account of a gender perspective in the performance of its tasks;

(x) take the pertinent aspects of the European Convention on Human Rights into consideration in its thematic work;

(xi) 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 the convention for which it has been given responsibility[3], in co-operation, where appropriate, with the relevant convention-based bodies, and report back to the Committee of Ministers.

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[1] "Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (source: Hepler C.D. and Strand L.M. Opportunities and Responsibilities in Pharmaceutical Care. Am. J. Hosp. Pharm. 1990; 47: 533-543).

[2] The wording "counterfeit" as used in the official title of the Convention should be interpreted as "falsified", without any Intellectual Property Rights (IPR) meaning.

[3] Cf. Relevant decision of the Committee of Ministers (CM/Del/Dec(2013)1168/10.2) and list of Conventions in Appendix 1.

PILLAR/SECTOR/PROGRAMME

Pillar: Human Rights
Sector: Ensuring Social Rights
Programme: European Directorate for the Quality of Medicines and HealthCare (EDQM)

SPECIFIC TASKS

(i) Contribute to patient safety, the accessibility of medicines to patients and the responsible use of medicines through promoting the annual revisions of the appendices of Committee of Ministers' (Partial Agreement) Resolution ResAP(2007)1 on the classification of medicines as regards their supply, supporting good classification practices taking into account scientific, regulatory and social aspects of the supply conditions of medicines, and evaluating the impact of the above resolution taking account of trends in demography, use of medicines in society and medicines' supply modes.

(ii) Further promote at European and global level, within the limits of the available resources, the implementation of the Medicrime Convention with special attention to:

- training and multidisciplinary co-operation among competent health, police and customs authorities through the network of Single Points of Contact (SPOC) specified in Articles 17 and 22 of the Medicrime Convention, in co-operation with European institutions and international organisations active in the field, in particular the World Health Organization (WHO) and the Heads of Medicines Agencies (HMA), and with other relevant Council of Europe bodies, in particular the European Committee on Crime Problems (CDPC);
- building up of expertise through an enlarged use by the SPOC Network of the Know-X database as an inventory of investigated cases of falsified medical products and testing of analytical methods;
- supporting the future Committee of the Parties.

(iii) Further promote the rational and safe use of medicines through:

- the elaboration of a Council of Europe Resolution defining pharmaceutical care and promoting its implementation and the evaluation of the quality of pharmaceutical care practices;
- the promotion of the Committee of Ministers' Resolution CM/Res(2016)2 on good reconstitution practices in health care establishments;
- the monitoring of the implementation of Committee of Ministers' Resolution CM/Res(2016)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients;
- the harmonisation of standards and approaches to automated dose dispensing (ADD) – defined as dispensing, by a method involving an automated process, one or more different medicinal products into an ADD container or pouch for a patient to take at a particular date and time.

COMPOSITION

Members:

Governments of the States Parties to the *Convention on the Elaboration of a European Pharmacopoeia* are invited to designate a representative of the highest possible rank, such as the Chief Pharmaceutical Officer. 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 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. The travel and subsistence expenses of the Chair for participating in the meetings of the CD-P-PH will be borne by the specific budgetary appropriations of the CD-P-PH.

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 (i), 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 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 cooperation activities;
- International professional societies, intergovernmental organisations (IGOs), and non-governmental organisations (NGOs) working on topics related to the tasks of the Committee.

WORKING METHODS

Meetings:

Plenary Meetings:

38 members, 1 meeting in 2018, 2 days

38 members, 1 meeting in 2019, 2 days

Representatives taking part in the Committee and its subordinate bodies shall complete a declaration of interest and confidentiality undertaking form (EDQM Form/226).

Extraordinary meetings of the CD-P-PH can be convened upon motivated request by the Chairperson.

The Committee will also appoint a Gender Equality Rapporteur from amongst its members.

The rules of procedure of the Committee 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 and to enable multidisciplinary working methods, the CD-P-PH may, in derogation of CM/Res(2011)24 and within the limit of budgetary attributions, create subordinate bodies.

BUDGETARY INFORMATION*

2018

Meetings per year	Number of days	Members	Plenary €	Bureau €	Subordinate structures / Working groups	Secretariat (A, B)
1	2	38	7 200	-	-	1 A; 1 B

2019

Meetings per year	Number of days	Members	Plenary €	Bureau €	Subordinate structures / Working groups	Secretariat (A, B)
1	2	38	7 200	-	-	1 A; 1 B

*The costs presented above take into consideration the per diem, travel, interpretation, translation and document printing. Costs calculated on the basis of the per diem and recharged services costs at their 2018 level.

APPENDIX 1 - RELEVANT DECISION OF THE COMMITTEE OF MINISTERS AND LIST OF CONVENTIONS

CM/Del/Dec(2013)1168/10.2 (Review of Council of Europe conventions)

9. [The Deputies] instructed the steering and ad hoc committees to carry out, at regular intervals, within the limits of the available resources and bearing in mind the priorities of each committee, an examination of some or all of the conventions for which they have been given responsibility, in co-operation, where appropriate, with the relevant convention-based bodies, in order to:

- propose ways of improving the visibility, impact and efficiency of some or all of the conventions for which they have been given responsibility;
- draw the attention of member States to the relevant conventions;
- where necessary, identify any operational problems or obstacles to ratification of the relevant conventions, and draw the attention of member States to reservations which impact substantively on the effectiveness of their implementation;

- encourage States to regularly examine the possibility and/or desirability of becoming a Party to new Council of Europe conventions;
- assess the necessity or advisability of drafting amendments or additional protocols to the conventions for which they have been given responsibility or drafting supplementary conventions;
- and to report back to the Committee of Ministers.

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CD-P-PH	
33	Agreement on the Temporary Importation, free of duty, of Medical, Surgical and Laboratory Equipment for use on free loan in Hospitals and other Medical Institutions for purposes of Diagnosis or Treatment
38	European Agreement on Mutual Assistance in the matter of Special Medical Treatments and Climatic Facilities
50	Convention on the Elaboration of a European Pharmacopoeia
134	Protocol to the Convention on the Elaboration of a European Pharmacopoeia