COMMITTEE OF EXPERTS ON THE CLASSIFICATION OF MEDICINES AS REGARDS THEIR SUPPLY (CD-P-PH/PHO)

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

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)

MAIN TASKS

Under the authority of the CD-P-PH, the CD-P-PH/PHO will:

i. fulfil the tasks set out in the Committee of Ministers Resolution CM/Res(2018)1 on the classification of medicines as regards their supply (Partial Agreement) (superseding Resolution ResAP(2007)1 on the classification of medicines as regards their supply);

ii. maintain and co-ordinate the updates of the Melclass database presenting the classification status of medicines in the Council of Europe member states and the CD-P-PHO's recommendations on the classification of medicines and their supply conditions;

iii. monitor medication safety issues and their potential impact on the classification status of medicines;

iv. monitor and evaluate the impact of its work programme at national level;

v. maintain and develop links with national and European authorities, and international institutions and organisations active in the area of the classification of medicines as regards their supply;

vi. promote the harmonisation of the classification of medicines with a view to ensuring patient safety and accessibility of medicines in Europe.

SPECIFIC TASKS

Under the authority of the CD-P-PH, in 2020 and 2021 the CD-P-PH/PHO will pursue the following activities:

- review the national legal supply status of medicinal products for human use and issue recommendations on the classification of medicines and their supply conditions to health authorities of the Council of Europe member states which are parties to the Convention on the Elaboration of a European Pharmacopoeia (Ph. Eur. Convention)[1] (i.e. biannual revisions of the appendices to Committee of Ministers Resolution CM/Res(2018)1);

- compile evidence-based classification reviews focusing on therapeutic classes of medicines authorised via decentralised, mutual recognition and national marketing authorisation procedures, relevant for public health but not harmonised in terms of classification status;

- ensure that the Melclass database is up-to-date and enhance the database overall data quality and completeness;

- examine medication safety signals arising at national and European level as well as recommendations following signal assessments, and assess the need for a revision of the recommendations on the classification status of the medicines of interest;

- assess the extent to which its programme results are implemented in the Council of Europe member states parties to the Ph. Eur. Convention, for example through statistics on the implementation at national level of its recommendations on the classification of medicines or the use of the Melclass database;

- consolidate the co-operation with relevant competent authorities at national and European level, for example through attending or sending contribution to relevant meetings and/or identifying opportunities for collaboration and synergies;

[1] Note: the classification status of medicines authorised in Europe remains a core competency of the member states and the general provisions of the classification reported in the Committee of Ministers Resolution CM/Res(2018)1 are not legally binding "eo ipso".

- promote among relevant stakeholders its mission, work programme and results, for example through the organisation of an ad hoc event, participation in scientific conferences, publication of scientific articles, with a view to strengthening its role in the European context and enhancing the harmonisation of the classification of medicines in Europe.

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 public health authorities. The representatives may include experts responsible for the preparation and follow-up of national policies in the field of the classification of medicines as regards their supply. Each member of the CD-P-PH/PHO 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/PHO. The travel and subsistence expenses of the Chair for participating in the meetings of the CD-P-PH/PHO 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/PHO.

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:
38 members, 2 meetings in 2020, 2 days
38 members, 2 meetings in 2021, 2 days

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).

The CD-P-PH/PHO will hold regular meetings and carry out its programme of activities using scientific and public health oriented approaches, structured and systematic approaches for proposals for new projects and for carrying out repeated activities such as surveys.

The rules of procedure of the CD-P-PH/PHO 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 enabling multidisciplinary working methods, the CD-P-PH/PHO may arrange consultations, 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/PHO may entrust a limited number of its members with a specific task.

Whenever appropriate, the CD-P-PH/PHO will prioritise environmentally sound working methods, such as virtual meetings facilitated by information technology and written consultations.