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

PROGRAMME RESULTS 2018-2019

Introduction

This summary provides an overview of the activities carried out by the Committee of Experts on the Classification of Medicines as regards their Supply (CD-P-PH/PHO) during its 2018-2019 Terms of Reference (ToR) (expiry date: 31 December 2019).

Background

The availability of medicines with or without a medical prescription has implications on patient safety, accessibility of medicines to patients and responsible management of healthcare expenditure.

The decision on prescription status and related supply conditions is a core competency of national health regulatory authorities. The conditions of the supply of medicines vary considerably in Council of Europe member states, due to the fact that the provisions are differently interpreted and implemented by the member states, and that important additional classification criteria are not harmonised.

A pioneer in this field, the Council of Europe[1] (which is distinct from the European Union (EU)) has been concerned since 1961 with issues relating to the classification of medicines into prescription and non-prescription medicines and has inspired relevant EU legislation.

The classification criteria set out in the Council of Europe resolutions have been supplanted by Directives 92/26/EC and 2001/83/EC (art. 70-75). Directive 2001/83/EC refers to the Council of Europe in its Whereas 32: *"It is therefore appropriate, as an initial step, to harmonise the basic principles applicable to the classification for the supply of medicinal products in the Community or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe*[2]".

The Committee of Ministers Resolution CM/Res(2018)1 on the classification of medicines as regards their supply (which supersedes the previous Resolution ResAP(2007)1) helps to remedy the considerable remaining variations in medicines' supply conditions which exist in the Council of Europe member states parties to the Convention on the Elaboration of a European Pharmacopoeia (Ph. Eur. Convention).

The Committee of Experts on the Classification of Medicines as regards their Supply (CD-PPH/PHO)[3] is co-ordinated by the European Directorate for the Quality of Medicines and HealthCare (EDQM, Council of Europe) and its working programme is based on the above Resolution CM/Res(2018)1.

[1] www.coe.int
[2] http://goo.gl/Uy22V1
[3] https://go.edqm.eu/PHO

The CD-P-PH/PHO issues twice a year recommendations to health authorities of the Council of Europe member states parties to the Ph. Eur. Convention on the classification of medicines and establishes good classification practices.

In its work, the CD-P-PH/PHO focuses on public health promotion and uses scientific approaches, taking account of the national assessments of direct and indirect risks which may occur under normal treatment conditions and under medical surveillance, as well as from foreseeable misuse or abuse of medicines.

Programme Results (2018-2019)

22 Member States: Austria, Belgium, Bosnia and Herzegovina, Croatia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Lithuania, North Macedonia Poland, Portugal, Romania, Serbia, Spain, Switzerland, Turkey, United Kingdom.

3 Observers: Armenia, Georgia, Russian Federation.

This overview aims to fulfil the specific task "*Assess the impact of the results of its work programme, such as Committee of Ministers Resolution CM/Res(2018)1 and its biannually revised appendices in the member states parties to the Ph. Eur. Convention, for example through statistics on the implementation of the appendices and the use of the database on the classification of medicines hosted by the EDQM*" that is included in the CD-P-PH/PHO's ToR.

In particular, the current overview covers the CD-P-PH/PHO's tasks that are reported in the section "Main Tasks" of its ToR:

i. Carry out biannual revisions of the appendices to Committee of Ministers Resolution CM/Res(2018)1 on the classification of medicines as regards their supply

Biannual revisions of the above appendices were carried out during the CD-P-PH/PHO's 2018-2019 biannual meetings (spring and autumn).

In 2018 a total of 142 recommendations on the classification of medicines as regards their supply were issued by the CD-P-PH/PHO.

In 2019 a total of 184 recommendations on the classification of medicines as regards their supply were issued by the CD-P-PH/PHO.

ii. Carry out evidence-based classification reviews of medicines, underlying rationale and national requirements for medicines of specific interest or concerns for public health and promote harmonisation of the classification of medicines across Europe

The classification status of the therapeutic classes of medicines reported below was reviewed. These medicines are relevant for public health, but not harmonised as regards their classification and, therefore, might pose concerns for public health.

- Medicines containing active ingredients belonging to the Anatomical Therapeutic Chemical (ATC) group D07A (Corticosteroids, plain)

- Medicines containing active ingredients belonging to the ATC group N02B (Other analgesics and antipyretics)

- Medicines containing active ingredients belonging to the ATC group R01 (Nasal preparations)

- Medicines containing the following active ingredients: Roboflavin (Vit B12) (ATC code: A11HA04); Phenprocoumon (ATC code: B01AA04); Silver sulfadiazine (ATC: D06BA01); Benzocaine (ATC code: N01BA05); Amitriptyline (ATC code: N06AA09); Duloxetine (ATC code: N06AX21); Varenicline (ATC code: N07BA03); Cinnarizine, combinations (ATC code: N07CA52); Dimethyl Fumarate (ATC code: L04AX07); Ipratropium bromide (ATC code: R01AX03)

iii. Monitor trends in and the impact of the classification of medicines on medication safety and accessibility to the patient also with reference to Committee of Ministers (Partial Agreement) Resolution ResAP(2007)2 on good practices for trade in medicines by mail order which protect patient safety and the quality of the delivered medicine

In 2018-2019 the CD-P-PH/PHO completed a study aimed at gathering information about the sale of medicines with a valid marketing authorisation in establishments other than community pharmacies (i.e. all those stores that are not licensed retail pharmacies but are authorised to sell medications) and via internet pharmacies, and the impact that this may have on medicine classification practices. The survey outcomes will be published in due course on the EDQM website.

iv. Follow up the national implementation of the appendices to the Committee of Ministers Resolution CM/Res(2018)1

2018-2019: 4 reports were prepared about national modifications of the classification of medicines (biannual reports from national competent authorities) on the occasions of the biannual meetings.

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

The cooperation with the Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh) Non-prescription Medicinal Products Task Force was further discussed in 2018 and 2019. The Committee of Experts CD-P-PH/PHO is invited to attend the meetings of the Non-prescription Medicinal Products Task Force in its capacity as observer, and regular exchanges of information take place between the CD-P-PH/PHO and Task Force.

The European Medicines Agency (EMA), Federal Institute for Drugs and Medical Devices (BfArM) and World Health Organization (WHO) Centre for Drug Statistics Methodology regularly provided information about the classification and supply status of medicines authorised in the EU via the centralised, decentralised and mutual recognition procedures for marketing authorisation (EMA and BfArM), and ATC alterations and new ATC codes covering the years 2018-2019 (WHO Centre for Drug Statistics Methodology).

The article “European countries urged to help harmonize legal classification of medicines” was published in the Pink Sheet in June 2018 highlighting the role of the Committee of Ministers Resolution CM/Res(2018)1 and the CD-P-PH/PHO in harmonising the classification status of medicines and their related supply conditions in Europe.

A teleconference was held in November 2018 involving the representatives of the Association of the European Self-Medication Industry (AESGP), CD-P-PH/PHO's Vice-Chair and EDQM Secretariat. The teleconference aimed to share views on the mandate and working methods of the Committee of Experts CD-P-PH/PHO, and discuss the possibility of industry stakeholders contributing to and discussing issues of common interest with the CD-P-PH/PHO.

The Vice-Chair's presentation at the Sixth Croatian Congress on Pharmacy (Dubrovnik, 4-7 April 2019) highlighted the mission, mandate and work programme of the Committee of Experts CD-P-PH/PHO, and was well received.

vi. Develop further and co-ordinate the updates of a web published database (Melclass) presenting the classification status of medicines in the Member States and the biannually revised appendices of the above Resolution CM/Res(2018)1

Content of the Melclass[4] database: 2163 recommendations on the classification of medicines as regards their supply and 34834 entries concerning the national legal supply status of medicinal products.

The Committee of Ministers Resolution CM/Res(2018)1 appendices were revised (ongoing process) and the Committee of Experts' recommendations (2018-2019) were published in the Melclass database.

Overall Conclusions (2018-2019)

The Committee of Experts CD-P-PH/PHO is recognised as a reputed source of expertise through:

a) providing a platform for member states to work collaboratively towards the harmonisation of classification status in Europe through non-legally binding recommendations and additional classification criteria;

b) providing reviews and advice on classification practices in selected therapeutic areas (relevant for public health but not harmonised in terms of classification status);

c) comparing benefits to risks in changes of classification status;

d) making available its expertise to European and national competent authorities;

e) improving the quality and comprehensiveness of the *Melclass* database in regard to national information about the classification status and supply conditions of medicines in Council of Europe member states parties to the Ph. Eur. Convention;

f) its longstanding experience in classification of medicines involving delegates with different backgrounds, competences and expertise.

[4] https://melclass.edqm.eu/