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

PROGRAMME RESULTS 2020-2021

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 2020-2021 Terms of Reference (ToR) (expiry date: 31 December 2021).

Background

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

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] has taken charge since 1961 of 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].

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 differences in medicine 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.

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.

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[1] www.coe.int
[2] https://eur-lex.europa.eu/eli/dir/2001/83
[3] https://go.edqm.eu/PHO

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.

The information on the national assessments and the recommendations are collected and stored in a public database called Melclass[4].

Programme Results (2020-2021)

25 member States contributed to the work of the Committee: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Lithuania, Republic of Moldova, Montenegro, Poland, Portugal, North Macedonia, Romania, Serbia, Slovak Republic, Switzerland, Turkey, United Kingdom.

3 Observers: Armenia, Georgia, Russian Federation.

The current overview covers the CD-P-PH/PHO's tasks that are reported in the section "Specific Tasks" of the 2020-2021 Terms of Reference:

1. 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

Biannual revisions of the above appendices were carried out during the CD-P-PH/PHO's meetings that took place in 2020 and 2021.

In 2020, a total of 5 recommendations on the classification of medicines as regards their supply were issued by the CD-P-PH/PHO (note: the spring meeting was cancelled due to the COVID-19 pandemic).

In 2021, a total of 31 recommendations on the classification of medicines as regards their supply were issued by the CD-P-PH/PHO.

2. 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

Evidence-based classification reviews were prepared focusing on the therapeutic classes of medicines reported below. 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 Anatomical Therapeutic Chemical (ATC) group D04A (Antipruritics, incl. antihistamines, anaesthetics, etc.)

- Medicines containing active ingredients belonging to ATC group R05DA (Opium alkaloids and derivatives)

- Medicines containing active ingredients belonging to ATC group R05DB (Other cough suppressants)

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

- Medicines containing Doxylamine (ATC code: R06AA09)

3. Ensure that the Melclass database is up-to-date and enhance the database overall data quality and completeness

Throughout 2020 and 2021, the Melclass database was regularly updated with the recommendations from the CD-P-PH/PHO to national health authorities on the classification of medicines and their supply conditions. The database was also updated with national information about the legal status of newly authorised medicines through centralised, national, mutual recognition and decentralised procedures, reclassifications of the legal supply status of medicines (switches), and medicines withdrawn from the market (e.g. due to safety reasons).

Content of the Melclass database: 2261 recommendations on the classification of medicines as regards their supply and 44 970 entries concerning the national legal supply status of medicinal products.

The Melclass database is consulted by approximately 2400 users per year, including 700 non-European users (2020).

4. 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

The recommendations and referrals of the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) and Committee for Medicinal Products for Human Use (CHMP) were examined during the CD-P-PH/PHO's meetings and, whenever applicable, the classification status of the medicines of interest was revised accordingly.

Medication safety signals arising at national and international level were also taken into consideration in the evidence-based classification reviews focusing on selected therapeutic classes of medicines (for further details, see point no. 2).

5. 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

A survey was carried out in Q1-Q2 2021 among the members of the CD-P-PH/PHO, Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh)[5] and CMDh Non-Prescription Medicinal Products Task Force (CMDh Task Force). The aims of the survey were to better understand the actual use of Melclass in EU and Council of Europe member States, and to evaluate the need for a common and comprehensive database centralising national data on legal status of medicines in Europe. Forty-four respondents (out of 93 recipients) completed the survey. The results showed that the majority of the respondents know about the Melclass database and consult it on a regular basis. Melclass is mainly consulted to obtain information about national classification of medicines and CD-P-PH/PHO recommendations. Finally, the vast majority of the respondents agreed that it would be useful to have a common and comprehensive database centralising national data on the legal status of medicines in Europe.

[5] https://www.hma.eu/cmdh.htm

6. Consolidate the co-operation with relevant competent authorities at national and European level, for example through attending or sending contributions to relevant meetings and/or identifying opportunities for collaboration and synergies

The EMA 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 procedure for marketing authorisation, and ATC alterations and new ATC codes covering the years 2020-2021 (WHO Centre for Drug Statistics Methodology).

Dialogue was re-established in 2021 with the CMDh Task Force (to further explore synergies and areas for co-operation). In this context, a survey about the use of Melclass in the EU and Council of Europe member States was carried out in Q1-Q2 2021 (for further details, see point no. 5). The results of this survey were presented at the CMDh meeting held on 13 April 2021 under the Portuguese Presidency of the Council of the European Union and at the CMDh Task Force meeting held on 17 May 2021. Strengthening the collaboration with the CD-P-PH/PHO has been chosen by the CMDh Task Force as one of their priorities for 2021.

A survey was carried out in 2020-2021 among the members of the CD-P-PH/PHO. The aim of the survey was to gather information about national requirements for non-prescription medicines and reclassification of medicines in member and observer States. The survey outcomes will be published in due course on the EDQM website.

7. 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

The mission, mandate and work programme of the CD-P-PH/PHO were presented at the Association of the European Self-Medication Industry (AESGP) Regulatory Affairs Committee Meeting that was held on 17 March 2020. The meeting also provided the opportunity to exchange views about the possibility of industry stakeholders contributing to and discussing issues of common interest with the CD-P-PH/PHO.

The CD-P-PH/PHO activities, Melclass database and preliminary results of the survey on the use of Melclass in the EU and Council of Europe member States were presented at the CMDh meeting held on 13 April 2021 under the Portuguese Presidency of the Council of the European Union (for further details, see point no. 5).

The Melclass database was presented at the UNICOM community of expertise webinar on medicinal product dictionaries that was held on 29 April 2021 (note: UNICOM is an EU-funded project that focuses on the univocal identification of medicinal products (IDMP)).

Overall Conclusions (2020-2021)

The Committee of Experts CD-P-PH/PHO is recognised as a trustworthy 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, whenever applicable, 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.