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

PROGRAMME RESULTS 2016-2017

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 2016-2017 Terms of Reference (expiry date: 31 December 2017).

Field of Activities

The supply of medicines with or without a medical prescription under specific related supply conditions (e.g. pack sizes, strength, repeated supply per prescription) has important implications for patient safety, the accessibility of medicines to patients and the responsible management of healthcare expenditure.

The decision on prescription status and related supply conditions is a core competency of national health regulatory authorities.

The *Council of Europe Committee of Ministers Resolution ResAP(2007)1 on the Classification of Medicines as Regards their Supply*[1] aims to harmonise basic and additional classification criteria and supply conditions of medicines.

For many years, the Council of Europe[2] (which is distinct from the European Union) has been concerned with the supply conditions of medicines for human use and the harmonisation of national legal provisions from the perspective of patient safety and public health protection.

The classification criteria set out in the Council of Europe resolutions have been included in European Union legislation, such as Directive 92/26/EC and Directive 2001/83/EC (art. 70-75). In the preamble of Directive 2001/83/EC (see point 32), reference is made to the Council of Europe: "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[3]".

Resolution *ResAP(2007)1* helps to remedy the considerable remaining variations in medicines' supply conditions which exist due to differing interpretations and implementation of European and national legislation in

[1] https://go.edqm.eu/ResAP20071
[2] www.coe.int
[3] http://goo.gl/Uy22V1

member states of the Council of Europe, and the different use of important additional classification criteria.

Among others, Resolution *ResAP(2007)1* requires:

- annual revision of the recommendations for the classification and supply of medicines appended to the resolution;

- the establishment of good classification practices which is ensured by the Committee of Experts CD-P-PH/PHO[4].

The European Directorate for the Quality of Medicines and HealthCare (EDQM) is the secretariat of the Committee of Experts CD-P-PH/PHO in the framework of the Partial Agreement of the European Pharmacopoeia.

Programme Results (2016-2017)

19 Member States: Austria, Belgium, Bosnia and Herzegovina, Croatia, Finland, "the former Yugoslav Republic of Macedonia", France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Poland, Portugal, Romania, Serbia, Switzerland, United Kingdom.

2 Observers: Armenia, Russian Federation.

This overview aims to fulfil specific task viii): "Assess the impact of the results of its work programme, such as Resolution *ResAP(2007)1* and its annually revised appendices in the States Parties of the Convention on the Elaboration of a European Pharmacopoeia, 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" included in the Terms of Reference of the CD-P-PH/PHO.

The current overview covers tasks i) to vii) of the CD-P-PH/PHO's Terms of Reference:

i) "Carry out an annual revision of the appendices to Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1 on the Classification of Medicines as Regards their Supply"

Annual revisions of the above appendices were carried out during the CD-P-PH/PHO's 2016-2017 biannual meetings (spring and autumn).

In 2016 a total of 59 recommendations on the classification of medicines as regards their supply were issued by the CD-P-PH/PHO.

In 2017 a total of 95 recommendations on the classification of medicines as regards their supply were issued by the CD-P-PH/PHO.

[4] https://go.edqm.eu/PHO

ii) "Carry out reviews on classification practices, underlying rationale and national requirements for medicines of specific interest or concerns for public health and develop, communicate and promote good classification practices"

The classification status of the therapeutic classes of medicines detailed 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 Anatomical Therapeutic Chemical (ATC) group G01AF (Imidazole derivatives)

- Medicines containing active ingredients belonging to ATC group M01 (Anti-inflammatory and anti-rheumatic products)

- Medicines containing Promethazine (ATC: R06AD02)

iii) "Monitor trends in and the impact of the classification of medicines on medicines' 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 referring in its stipulations to the authorised conditions of sale or distribution of medicines being subject to mail order trade, and with relevant provisions in European legislation, such as the Falsified Medicines Directive"

In 2016 the Committee of Experts CD-P-PH/PHO completed a study focusing on possible public health issues and risks that small markets may experience when supplied with medicines with packaging information in non-domestic languages, and possible solutions to address the identified issues. Among others, the survey also explored the potential impact of the classification of medicines on the supply of medicines labelled and packaged with languages other than the local language.

In 2017 the Committee of Experts CD-P-PH/PHO started work on a follow-up survey to a 2011 study focusing on new trends as regards the supply modes of medicines and their impact on classification practices (results expected in 2018).

iv) "Follow up the national implementation of the appendices to the above-mentioned Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1"

2016-2017: 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) "Prepare proposals for the revision of the text of the above-mentioned Resolution ResAP(2007)1, with a view to adapting it to changes in the social, regulatory and scientific context of classification of medicines"

A draft revision of the text of Resolution *ResAP(2007)1* was prepared and submitted to the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) (Steering body) in 2017. The revised text of the above resolution will be sent for adoption by the Council of Europe Committee of Ministers in 2018.

vi) "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"

Cooperation was established in 2017 with the Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh) Non-prescription Medicinal Products Task Force.

The European Medicines Agency (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 European Union via the centralised procedure for marketing authorisation, and ATC alterations and new ATC codes covering the years 2016-2017.

vii) "Develop further and co-ordinate the updates of a web published database presenting the classification status of medicines in the member States and the above-mentioned Resolution ResAP(2007)1 and its annually revised appendices"

In 2016 the Melclass database was upgraded and migrated to a web application with a responsive design using state-of-the-art technologies.

Content of Melclass database: 2319 recommendations of classification of medicines; 21459 entries, national classification information on a medicine.

Committee of Ministers (Partial Agreement) Resolution *ResAP(2007)1* appendices were revised (ongoing process) and recommendations (2016-2017) were published in the Melclass[5] database.

Overall Conclusions (2016-2017)

The Committee of Experts 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);

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

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

d) making available its expertise to European and national 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 Convention on the Elaboration of a European Pharmacopoeia;

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