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

PROGRAMME RESULTS 2014-2015

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 2014-2015 Terms of Reference (expiry date: 31 December 2015).

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, age limits) has important implications for patient safety, the accessibility of medicines to patients and the responsible management of health care expenditure.

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

Council of Europe Committee of Ministers Resolution ResAP(2007)1 on the Classification of Medicines as Regards their Supply[1] aims at harmonising basic and additional classification criteria and supply conditions of medicines.
Pioneers in this field, the Council of Europe bodies have been concerned since 1961 with the classification of medicines into prescription and non-prescription medicines. In the light of moves to make medicines more easily available without a prescription, the harmonisation of classification criteria and supply conditions are relevant for health and law enforcement authorities, pharmaceutical manufacturers, mail order trade in medicines ("e-pharmacies"), where such trade is legal, and the public. **The above resolution 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 member states of the Council of Europe, and the different use of important additional classification criteria**.

The classification criteria set out in Council of Europe resolutions in this field were taken over by the Council Directive 92/26/EEC of 31 March 1992 concerning the classification of the supply of medicinal products for human use and by the Directive 2001/83/EC (Art 70-75) of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. In the preamble of the latter directive (item 32) reference is made to the Council of Europe: "[…] it is therefore appropriate to harmonise the basic principles applicable to the supply of medicinal products in the Community of member states concerned, while taking as a starting point the principles already established on this subject by

[1] https://go.edqm.eu/ResAP20071

the Council of Europe". This was confirmed in Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Resolution *ResAP(2007)1* requires:

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

- the establishment good classification practices which is ensured by the Committee of Experts CD-P-PH/PHO[2].

The EDQM supports the Committee of Experts CD-P-PH/PHO in the framework of the Partial Agreement of the European Pharmacopoeia.

Programme Results (2014-2015)

20 Members: AUSTRIA, BELGIUM, BOSNIA AND HERZEGOVINA, CROATIA, CZECH REPUBLIC, FINLAND, FORMER YUGOSLAV REPUBLIC OF MACEDONIA, FRANCE, GERMANY, HUNGARY, IRELAND, ITALY, LITHUANIA, LUXEMBOURG, POLAND, PORTUGAL, REPUBLIC OF SERBIA (2015), ROMANIA, SWITZERLAND, UNITED KINGDOM; Participant: ARMENIA.

This overview aiming at fulfilling the 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) - 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 2014-2015 biannual meetings (spring and autumn).

In 2014 a total of 64 recommendations on the classification of medicines as regards their supply were issued by the CD-P-PH/PHO.

In 2015 a total of 59 recommendations on the classification of medicines as regards their supply were issued by the CD-P-PH/PHO.

[2] 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 good classification practices […]"

The current classification practice relating to 105 medicines was reviewed: these medicines are relevant for public health, but not harmonised as regards their classification and, therefore, might pose concerns for public health.

2014:

- **Corticosteroids, dermatological preparations** (ATC group: D07)

- **Medicines containing triamcinolone** (long-acting corticosteroid) (ATC codes: A01AC01, C05AA12, D07AB09, D07BB03, D07CB01, D07XB02, H02AB08, R01AD11, R03BA06, S01BA05, S02CA04)

2015:

- **Drugs for peptic ulcers and gastro-oesophageal reflux disease** (ATC groups: A02BA: H2-receptor antagonists and A02BC: Proton pump inhibitors)

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 […."

The Expert Workshop "OTC Medicines: The Role of Good Classification Practices in Promoting Medication Safety and Accessibility in Europe" was organised in November 2014 in Zagreb (Croatia). Inter alia, the workshop discussed new modes of medicinal products' distribution (with special attention to distant trade of medicinal products) and examined possible regulation of supply modes of OTC medicines into "Pharmacy-only medicines" and "General sales medicines".

Valuable information was gathered for a project aimed at identifying possible solutions for issues in small markets through supply with medicines labelled in foreign languages.

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

2014-2015: 4 reports were prepared about national modifications of the classification of medicines (6-month reporting period) on the occasion of the biannual meetings.

v) "[…] Prepare proposals for the revision of the text of the above-mentioned Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1, with a view to adapting it to changes in pharmaceutical care and practice […]"

A draft revision of the text of Resolution ResAP(2007)1 will be prepared and submitted to the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) in 2016.

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 […]"

- The Expert Workshop "OTC Medicines: The Role of Good Classification Practices in Promoting Medication Safety and Accessibility in Europe" co-organised by the EDQM and the Croatian Agency for Medicinal Products and Medical Devices (HALMED) in November 2014 in Zagreb (Croatia) served as a platform for open discussion.

- The Chairperson's presentation at the 75th meeting of the Heads of Medicines Agencies (HMA) (February 2014), the Expert Workshop of November 2014 and the Chairperson's presentation at the Develop Innovate Advance (DIA) 27th Euromeeting (April 2015) confirmed that the CD-P-PH/PHO plays an important role in harmonising the variations in medicines' supply conditions which exist due to differing interpretations and implementations of European and national legislation in the Council of Europe member states.

- The CD-P-PH/PHO Chairperson and Vice-Chairperson and the EDQM Secretariat met with industry stakeholders in September 2014 for an informative exchange of views of the respective contribution of authorities and stakeholders in the classification practices in Europe.

- The EDQM Secretariat's presentation at the 11th traditional annual symposium of the Serbian Medicines and Medical Devices Agency (ALIMS) (November 2015) highlighted the mission, organisation and work programme of the Committee of Experts CD-P-PH/PHO, and was very well received.

- Establishment of further cooperation with European authorities (EMA; EU Commission): European institutions, such as the European Medicines Agency (EMA), the Deutsches Institut für Medizinische Dokumentation und Information (DIMDI), 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, decentralised and mutual recognition procedures for marketing authorisation covering the years 2014-2015.

Support was received from the EMA also for the November 2014 Expert Workshop via an EMA representative, who attended the event and contributed to the discussions around patient involvement and education with respect to safe/appropriate use of OTC medications.

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 […]"

- Melclass database: 2637 entries, recommendations of classification of medicines; 16870 entries, national classification information on a medicine.

- Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1 appendices were revised (ongoing process) and 2 recommendations (2014-2015) were published on the EDQM website.

Overall Conclusions (2014-2015)

The Committee of Experts is recognised as reputed source of expertise through:

a) providing a platform for member states to work collaboratively towards harmonised standards for the classification of active substances for a given therapeutic use;

b) providing reviews and advice on classification practices in selected therapeutic areas and in relation to new modes of medicines' supply;

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

d) making available its expertise to national and European authorities (e.g. via targeted consultations);

e) improving the quality and comprehensiveness of the database on the classification of medicines by adding more data through targeted studies;

f) seeking and taking account of stakeholders' specific views (e.g. views on expanding the CD-P-PH/PHO's recommendations to pharmacy-only and general sale OTC medicines).