Better patient safety, access to medicines and responsible management of healthcare resources : Good practices to establish prescription status & supply conditions for medicines

INTRODUCTION

This summary provides an evaluation of the impact 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 terms of reference (**2011-2013**) expiring on 31 December 2013.

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 to harmonise 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 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;

[1] https://wcd.coe.int/wcd/ViewDoc.jsp?Ref=ResAP(2007)1&Language=lanEnglish&Ver=original&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383

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

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

EVALUATION (2011-2013)

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

Specific tasks (Terms of Reference, item 4)	Achievements	Impact
a) carry out reviews on the classification practice, underlying rationale and national requirements for medicines of specific interest or concerns for public health and **develop good classification practices**	**A07XA04:** Racecadotril **D06:** Aciclovir, amikacin, bacitracin, chloramphenicol, chlortetracycline, demeclocycline, docosanol, edoxudine, fusidic acid, gentamycin, ibacitabine, idoxuridine, imiquimod, inosine, lysozyme, mafenide, metronidazole, mupriocin, neomycin, oxytetracycline, pencyclovir, podophyllotoxin, retapamulin, rifaximin, sincechatechins, silver sulfadiazine, sulfamerazine, sulfamethizole, sulfanilamide, sulfathiazole, tetracycline, tromantadine, tyrothricine, virginiamycin **D07:** Bacitracin combination products for cutaneous use	The current classification practice relating to 36 medicines was reviewed: these medicines are relevant for public health, but not harmonised as regards their classification, which poses concerns for public health. The review established scientifically-based good practices, taking account of the societal perspective of the classification of medicines on the basis of national and European legislation. The review is being prepared for publication on the EDQM website for authorities, stakeholders and the general public. This follows up the series of reviews (2008-2010) published on the EDQM website and provides value for the promotion of public health[3]
b) monitor the impact of and trends in the classification of medicines on medicines' safety and accessibility to patients		"Impact of new modes of medicines supply on good medicines classification practice": Survey and Report (2011), prepared by the Portuguese delegation CD-P-PH/PHO. **Good classification practices: see Conclusions Expert Workshop 2011**[4]
c) follow up the national implementation of the appendices for the above-mentioned Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1		2011-2013: 6 meetings (bi-annual) – every participating authority: 6 reports about national modifications of the classification of medicines (6-month reporting interval)
d) prepare proposals for the		Draft of a revision of Committee

[2] http://www.edqm.eu/en/Classification-of-Medicines-as-Regards-their-Supply-1241.html

[3] http://www.edqm.eu/en/classification-of-medicines-1241.html: go to programme results (middle column) - **Evidence-based reviews**

[4] http://www.edqm.eu/en/classification-of-medicines-1241.html: go to events (right column) – **Expert WS 2011 Proceedings pg 74-86**

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		of Ministers Resolution ResAP (2007)1 items supply conditions taking account of new modes of the supply of medicines (draft submitted for adoption to CD-P-PH/PHO): 55th meeting (October 2013)
e) maintain and develop links with national, European and international institutions and organisations active in the sphere of the classification of medicines as regards their supply	Press communication on the EDQM website increasing awareness on the role and working programme on the occasion of 50th meeting Expert Workshop "Good practices for the classification of medicines as regards their supply which protect public health and promote the accessibility of medicines in Europe" November 2012 Presentations of Chair, Dr Macolic Sarinic in 2011, 2012 to: Prescription Commission, Croatia; January 2013, Dublin: AESGP Meeting Delegate of Macedonia: 5th Congress of Pharmacy of Macedonia, presentation: "The classification of medicines as regards their supply, a prerequisite for public health protection". Publication (2013) (Pharmaceutical information: summary of the Expert Workshop) Informal joint CHMP, CMDh and PRAC meeting, Dublin, May 2013 - proposal of additional HMA group on prescription/non-prescription medicines: it was accepted in the conclusion to have CD-P-PH/PHO as part of this new group of the HMA	A representative number of 30 participants from authorities (DRA, national healthcare funds) from 17 member states; relevant numbers of speakers from European Institutions (EMA), stakeholder organisations AESGP, professional associations (FIP) which enabled comprehensive expert workshop conclusions (published on the EDQM website), outlining good classification practices, giving directions for the committee's future role and working programme. Scope and modes of information on a medicine by pharmaceutical industry supporting the review of individual recommendation(s) by the CD-P-PH/PHO were agreed by the committee of experts.

f) develop further and co-ordinate the updates of a web published database[5] presenting the classification status of medicines in the member states and the above-mentioned Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1 and its annually revised appendices		Melclass database (April 2013): 2 408 entries, recommendations of classification of medicines; 18 004 entries, national classification information on a medicine. Committee of Ministers (Partial Agreement) Resolution ResAP(2007)1 appendices were revised (ongoing) and three recommendations of 2010, 2011, 2012 published on the EDQM website / hard copies
g) assess the impact of the results of its work programme, such as the Committee of Ministers (Partial Agreement) 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		See Overall Evaluation (2011-2013)

OVERALL EVALUATION (2011-2013)

- The use and implementation of the results of the working programme of the Committee of Experts CD-P-PH/PHO was promoted and its role and function in the European context strengthened. This promotes patient safety and – where appropriate – access to medicines without a prescription across Europe, and fosters public health and responsible management of healthcare resources.

- Through the expert workshop (2011) the differences, needs and expectations of different national healthcare systems and other stakeholders of medicines' classification were better understood.

- It was confirmed that the Committee of Experts provides a multisectorial and multidisciplinary platform for the discussion of the societal, scientific, and regulatory dimension of the classification of medicines as regards their supply and is competent for establishing good medicines' classification practices taking into account the above-mentioned dimension.

- The Committee of Experts has status as a source of expertise through:
    - providing a platform for member states to work collectively towards harmonised standards for the classification of active substances for a given therapeutic use
    - providing reviews and advice on classification practices in selected therapeutic areas and in relation to new modes of medicines' supply
    - comparing benefits to risks in changes of classification status

[5] http://www.edqm.eu/melclass/; Password for national (restricted) information : « melclasscoe2005 »

- making available its expertise to national and European authorities, for example through consultation
- improving the quality and comprehensiveness of the database on the classification of medicines by adding more data through targeted studies
- seeking and taking account of stakeholders' specific views

- Informal joint CHMP, CMDh and PRAC Dublin, May 2013: in the conclusions, the CD-P-PH/PHO was accepted as member of this new group of the HMA focusing on prescription/non-prescription medicines.