COMMITTEE OF MINISTERS
COMITÉ DES MINISTRES

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

MINISTERS' DEPUTIES Resolutions CM/Res(2018)1 10 April 2018

Resolution CM/Res(2018)1 on the classification of medicines as regards their supply (superseding Resolution ResAP(2007)1 on the classification of medicines as regards their supply)

(Adopted by the Committee of Ministers on 10 April 2018 at the 1313th meeting of the Ministers' Deputies)

The Committee of Ministers, in its composition restricted to the representatives of States Parties[1] to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50),

Considering that the aim of the Council of Europe is to achieve greater unity between its member States and that this aim may be pursued, *inter alia*, by common action in the health field;

Having regard to the Council of Europe's actions carried out over several years for the purpose of harmonising the legislation of the States members of the Partial Agreement in the Social and Public Health Field[2] and, in particular, in the pharmaceutical sector;

Considering the broader accessibility of medicines through new technologies and the necessity to introduce harmonised legal provisions and conditions favouring the safe use of prescription and non-prescription medicines;

Considering the importance of moving towards greater harmonisation of national legal classifications as regards the supply of medicines for the benefit of patients;

Bearing in mind the impact of the classification of medicines on patient safety, the accessibility of medicines and the responsible management of health care expenditure;

Considering the importance of providing information on classification, particularly in view of the increase in international travel and cross-border trade;

Considering the importance of monitoring the impact of new and emerging issues related to safety in the classification of medicines;

Having regard to the work carried out by the Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO) whose 2016-2017 terms of reference included, among other primary responsibilities, the preparation of proposals for the revision of Resolution ResAP(2007)1 on the classification of medicines as regards their supply, with a view to adapting it to changes in the social, regulatory and scientific context of the classification of medicines,

Adopts the current resolution which shall replace Resolution ResAP(2007)1, adopted on 12 April 2007,

Recommends that the governments of States Parties to the Convention on the Elaboration of a European Pharmacopoeia:

[1] States concerned: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine and United Kingdom.
[2] Res(59)23 of 16 November 1959 extending the activities of the Council of Europe in the Social and Public Health field on the basis of a Partial Agreement, and Resolution Res(96)34 and Res(96)35 of 2 October 1996 revising the rules of the Partial Agreement.

1. provide information on a regular basis on the national legal classification of medicines as regards their supply for inclusion in the Melclass database;[3]

2. implement the recommendations for the classification of active substances depending on the supply conditions of the medicines which contain them, as listed in the Melclass database;

3. align their regulations and practices in accordance with the general provisions set out below. These general provisions should not prevent governments from maintaining or adopting more specific rules on the classification of medicines as regards their supply.

General provisions governing the drawing-up and periodical revision of the list of active substances classified according to the conditions of supply of the medicines which contain them

1. The recommended provisions apply only to active substances contained in medicines for human use.

2. Narcotic drugs are not referred to as they are already covered by special common legal provisions concerning the rules governing their supply.

3. Active substances in therapeutic groups Antihemorrhagics (Anatomical Therapeutic Chemical (ATC) group: B02), Immune Sera and Immunoglobulins (ATC group: J06) and Vaccines (ATC group: J07) are not affected by the recommended provisions (medicines containing these active substances are always supplied on prescription and are therefore classified in List I).

4. This resolution does not apply to homeopathic preparations and/or other forms of complementary or alternative medicines.

5. The lists of active substances classified according to the conditions of supply of the medicines which contain them are drawn up with reference to all the risks, direct or indirect, which they may represent to human health whether they are used in accordance with the product information leaflet or not. In particular, the lists of active substances and the conditions of supply of the medicines in which they are contained are drawn up according to:

- their acute and chronic toxicity;

- clinical experience in use (adverse reactions, precautions for use, interactions, etc.);

- their intended actions and therapeutic indications.

For the purpose of this resolution, salts, esters and salts of esters are subject to the same classification as the active substances from which they are derived unless otherwise specified in the lists.

In cases where several substances are present in a medicine, the classification will take account of the phenomena of synergy or of antagonism.

6. Medicinal products should be subject to medical prescription where they:

- are likely to present a danger either directly or indirectly if utilised without medical supervision, even when used correctly; or

- are, frequently and to a very large extent, used incorrectly, and as a result are likely to present a direct or indirect danger to human health; or

- contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation; or

- are normally prescribed by a medical doctor for parenteral administration;[4] or

[3] The Melclass database is hosted by the European Directorate for the Quality of Medicines and HealthCare (EDQM) (Council of Europe) and is supervised by the CD-P-PH/PHO, which is a subordinate body of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH).

[4] Parenteral use refers to, in particular, epidural, extra-amniotic, intra-amniotic, intra-arterial, intra-articular, intrabursal, intracardiac, intracavernous, intracervical, intracisternal, intracoronary, intradermal, intradiscal, intralymphatic, intramuscular, intra-ocular, intraperitoneal, intrapleural, intrasternal, intrathecal, intravenous, periarticular, perineural, subconjunctival and subcutaneous use.

- contain one or more active substances classified in List I or List II in the Melclass database.

General criteria for classification in the lists

The differentiation in the two prescription lists (List I and List II) applies only to the countries which classify prescription medicines into two categories based on whether the prescription can be renewed or not.

1. Active substances in medicines subject to prescription

A. List I

The supply of a medicine containing one of the substances in this list should not be renewed without the prescriber having so specified.

This classification should apply to active substances of medicines indicated for conditions calling for short-term treatment and/or for which continuous medical supervision is necessary, either because of potential undesirable effects or to check the efficacy of treatment; or active substances of medicines administered for diagnostic purposes; or active substances with a new pharmacological mechanism of action.

B. List II

The supply of a medicine containing one of the substances in this list can be renewed.

This classification should apply to active substances in medicines indicated for conditions for which the patient may continue the regular or intermittent treatment without new medical advice, and for which well-known undesirable effects do not call for frequent clinical examination.

C. Exemptions from Lists I and II under certain circumstances

Depending on the conditions of use of the medicine, active substances contained in prescription medicines may also be contained in medicines classified under the same ATC code but which are not subject to prescription.

Under certain circumstances, exemptions from the prescription requirement may be set out in the Melclass database:

- in respect of a low dosage or concentration of the active substances and/or the therapeutic indications of medicines in which they are contained;

- according to the route of administration and the composition of the medicine;

- according to the total amount of the medicine per container.

2. List of active substances in medicines not subject to prescription: active substances in medicines which are not classified as subject to prescription in Lists I or II.

Information about the list of active substances classified according to the conditions of supply of medicines which contain them

1. Classification system: active substances are classified on the basis of the World Health Organisation (WHO) ATC classification system.

2. Nomenclature: wherever possible, the nomenclature used for an active substance is that of WHO's International Non-Proprietary Names (INN) system.

3. Issuance of recommendations: a classification of an active substance should not be recommended unless there are entries in the Melclass database from at least three member States where a marketing authorisation exists.

4. Periodical revisions: biannual revisions will deal with:

- proposals for the classification of new active substances entering into the composition of medicines newly authorised in the States Parties to the Convention on the Elaboration of a European Pharmacopoeia;

- proposals for modification of the classification of substances listed in the Melclass database;

- proposals for removing active substances from the Melclass database.

Proposals for the revision of a classification will be submitted to the biannual sessions of the relevant bodies of the Council of Europe, to be adopted and subsequently published in the Melclass database. In urgent cases, proposals for revision may be submitted at any time.