



COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Committee of Ministers
Comité des Ministres

**Resolution ResAP(2007)1
on the classification of medicines as regards their supply
(superseding Resolution ResAP(2000)1 on the classification of medicines
which are obtainable only on medical prescription)**

*(Adopted by the Committee of Ministers on 12 April 2007
at the 993rd meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the representatives of Austria, Belgium, Bulgaria, Cyprus, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom, member states of the Partial Agreement in the Social and Public Health Field,

Recalling Resolution (59) 23 of 16 November 1959, on the extension of the activities of the Council of Europe in the social and cultural fields;

Having regard to Resolution (96) 35 of 2 October 1996 revising the above-mentioned Partial Agreement, whereby it revised the structures of the Partial Agreement and resolved to continue, on the basis of revised rules replacing those set out in Resolution (59) 23, the activities hitherto carried out and developed by virtue of that resolution, these being aimed in particular at:

- a. raising the level of health protection of consumers in its widest sense, including the making of a constant contribution to harmonising – in the field of products having a direct or indirect impact on the human food chain as well as in the fields of pesticides, pharmaceuticals and cosmetics – legislation, regulations and practices governing, on the one hand, quality, efficiency and safety controls for products, and, on the other hand, the safe use of toxic or noxious products;
- b. integrating people with disabilities into the community; defining and contributing to the implementation, at a European level, of a model of coherent policy for people with disabilities, which takes account simultaneously of the principles of full citizenship and independent living; contributing to the elimination of barriers to people's integration whatever their nature, whether psychological, educational, family-related, cultural, social, professional, financial or architectural;

Having regard to the action carried out for several years for the purpose of harmonising the legislation of the States members of the Partial Agreement in the public health field and, in particular, in the pharmacy sector;

Considering further that the lack of uniform legislation on the supply of medicines has created problems in the field of public health and still raises difficulties at international level;

Considering new possibilities and means of access to medicines due to new technologies, namely communication technologies, and the need to ensure patients' access to safe medicines in safe conditions whilst fighting tendencies to over-medication and inappropriate medication;

Considering the broader accessibility of medicines through new technologies, it is necessary to introduce harmonised provisions and conditions favouring the safe use of prescription and non-prescription medicines;

Considering that it is more and more important to move towards greater harmonisation of national legislation as regards the supply of medicines;

Considering, moreover, that it is important that prescriptions contain certain minimum information so that they can be authenticated and to ensure that the medicine prescribed is correctly supplied and properly used;

Considering that it is also important to harmonise this information, particularly in view of the increase in international travel;

Bearing in mind the results of the comparative study on the requirements to which prescriptions are subject in the member states of this Partial Agreement,

1. Recommends to the governments of the member states of the Partial Agreement in the Social and Public Health Field that they supply information on the national legal classification of medicines as regards their supply on a regular basis;
2. Recommends to the same governments that they apply the general provisions and the classification of active substances depending on the supply conditions of the medicines which contain them, as set out in the appendices;¹
3. Recommends to the same governments that they adopt the general provisions set out below, relating to minimum information to be included in prescriptions;
4. Invites the same governments to accept amendments which may be made to the appendices¹ to this resolution by the Public Health Committee (Partial Agreement) (CD-P-SP), which shall carry out, either itself or through subordinate bodies, an annual revision of the appended lists of active substances classified according to the conditions of supply of medicines which contain them in the light of the general provisions set out hereafter and of national information.

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 only active substances affected by the recommended provisions are those contained in medicines for human use.
2. Narcotic drugs are not referred to when they are already covered by special common provisions concerning the rules governing their supply.
3. This resolution does not apply to homeopathic preparations or to other similar non-allopathic, minute-dose preparations available on the market in the member states. Sale and supply of these preparations are governed by legal provisions in force in each member state.
4. 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 if they are used in accordance with the 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:
 - a. their acute and chronic toxicity;
 - b. clinical experience in use (adverse reactions, precautions for use, interactions, etc.);

¹ In Resolution ResAP(2000)1 on the legal classification of medicines which are obtainable only on medical prescription preceding Resolution ResAP(2007)1 on the classification of medicines as regards their supply, the Committee of Ministers, in its composition restricted to the representatives of the member states of the Partial Agreement in the Social and Public Health Field, delegated to the Public Health Committee (Partial Agreement) (CD-P-SP) the responsibility for carrying out the annual revisions of the lists of active substances and their classification according to the conditions of supply of the medicines which contain them in the appendices of the above-mentioned resolutions. Thus, the appendices I, II and III in their current edition are not subject to adoption by the Committee of Ministers in its composition restricted to the representatives of the member states of the Partial Agreement in the Social and Public Health Field.

Appendix I: Alphabetical list of active substances and their classification according to the conditions of supply of the prescription medicines which contain them.

Appendix II: Anatomical Therapeutic Chemical (ATC) Classification of prescription medicines containing the active substances in the alphabetical list in Appendix I.

Appendix III: Supply conditions of medicines exempt from the obligation to obtain a prescription containing certain active substances listed in Appendices I and II.

- c. 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.

5. A medicine should be supplied on a medical prescription when one or more of the following conditions apply:

a. it contains an active substance not previously used for medical purposes. In such a case, a revision of any restrictions should be carried out within a period of not less than three years from the first date of marketing authorisation in one of the member states of the Partial Agreement;

b. it is used parenterally;²

c. the medicine contains one or more active substances classified in List I or II³ in Appendix I, to which the following criteria apply:

i. List I

The supply of a medicine containing one of the substances in this list may only be repeated if the prescriber so specifies on the prescription.

ii. List II

The supply of a medicine containing one of the substances in this list may be repeated without the prescriber having so specified, provided that he did not explicitly forbid such repetition and that the amount supplied at renewals (and their frequency) be consistent with medical and pharmaceutical data (such as the prescribed daily dose, the duration of treatment, the degree of medical supervision required by the condition, etc.).

iii. Exemptions from Lists I and II

– For certain substances, exemptions from the “prescription only” requirement may appear in Lists I and II and their conditions of supply are indicated in Appendix III:¹

- in respect of a low dosage or concentration of the active substances and/or 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 content of the medicine per container.

– List of active substances classified according to the conditions of supply of the medicines which contain them, when supplied without prescription (over-the-counter (OTC) medicines) and their conditions of supply (Appendix III¹).

See “Medicines not subject to prescription (OTC medicines)” below.

General criteria for classification in the lists

1. List I

² Parenteral use refers to, in particular, epidural, extra-amniotic, intra-amniotic, intra-arterial, intra-articular, intrabursal, intracardiac, intracavernous, intracervical, intracisternal, intracoronary, intracutaneous, intradiscal, intralymphatic, intramuscular, intra-ocular, intraperitoneal, intrapleural, intraspinal, intrasternal, intrathecal, intratracheal, intravenous, peri-articular, perineural, subconjunctival and subcutaneous use.

³ The differentiation in the two lists applies only to the countries which divide prescription medicines into two categories based on whether or not the supply may be repeated.

- a. 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;
 - b. Active substances of medicines administered for diagnostic purposes;
 - c. Active substances with a new pharmacological mechanism of action.
2. List II

Active substances of 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.

3. List of OTC medicines

See below.

Medicines not subject to prescription (OTC medicines)

Active substances of medicines which are classified as not subject to prescription according to the criteria listed in item 4 of the General Provisions above will be classified in the list "Medicines not subject to prescription (OTC medicines)".

For the purpose of this resolution, OTC medicines are understood as having a valid marketing authorisation issued by a competent authority.

It is possible that active substances which are contained in OTC medicines can exist in medicines of the same ATC (Anatomical Therapeutic Chemical Classification), but subject to prescription, because of particular conditions of use of the medicines in question.

General provisions relating to minimum information to be included in prescriptions

1. The information given in prescriptions should be clear and legible.
2. Prescriptions should include the following minimum information:
 - name, address and, where appropriate, identification number of the prescriber;
 - professional qualification of the prescriber;
 - date of the prescription;
 - hand-written or electronic signature of the prescriber as set-out in specific national or European legislation;
 - first and second name of the patient;
 - age of the patient and, where necessary, details of height and weight;
 - name, dosage and pharmaceutical form of the medicine;
 - amount to be supplied;
 - instructions for use stating, for example, dosage and length of treatment.

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

1. The governments are free to apply stricter rules as regards the recommended classification of medicines in any given case.
2. Active substances are classified on the basis of the World Health Organisation (WHO) ATC codes of the medicines which contain them, if available.
3. Active substances not included in the lists have either not been studied or a medicine containing them has not been authorised in at least three member states.
4. Nomenclature

Wherever possible, the nomenclature used for an active substance is that of the International Non-Proprietary Names (INN) of the WHO.

5. Revisions

Annual revisions will deal with:

- classification of new active substances entering into the composition of medicines newly authorised in the states members of the Partial Agreement;
- classification of substances referred to in item 2 of this preamble;
- proposals for adding or deleting active substances;
- proposals for adding or deleting derogations;
- proposals for modifying exemption conditions or the classification in the list of OTC medicines.

Proposals for revision of classification will be submitted according to the annual sessions of the entrusted bodies of the Council of Europe to be adopted and published after their last annual session. In urgent cases, proposals for revision may be submitted at any time.

6. Date of adoption

The published list will indicate in each case the year of adoption by the Public Health Committee (Partial Agreement) (CD-P-SP) or the subordinate bodies it may entrust.