

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

(PARTIAL AGREEMENT IN THE SOCIAL AND PUBLIC HEALTH FIELD)

RESOLUTION AP (90) 1

ON PATIENT PACKAGE INFORMATION PROVIDED WITH MEDICINES

(superseding Resolution AP (84) 2)

*(Adopted by the Committee of Ministers on 25 April 1990
at the 438th meeting of the Ministers' Deputies)*

The Representatives on the Committee of Ministers of Belgium, France, the Federal Republic of Germany, Italy, Luxembourg, the Netherlands and the United Kingdom of Great Britain and Northern Ireland, these states being parties to the Partial Agreement in the Social and Public Health Field, and the Representatives of Austria, Denmark, Ireland, Spain and Switzerland, states which have participated in the public health activities carried out within the above-mentioned Partial Agreement since 1 October 1974, 2 April 1968, 23 September 1969, 21 April 1988 and 5 May 1964 respectively,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members and that this aim may be pursued, amongst others, by common action in the social and public health fields ;

Having regard to the provisions of the Brussels Treaty, signed on 17 March 1948, by virtue of which Belgium, France, Luxembourg, the Netherlands and the United Kingdom of Great Britain and Northern Ireland declared themselves resolved to strengthen the social ties by which they were already united ;

Having regard to the protocol modifying and completing the Brussels Treaty, signed on 23 October 1954 by the signatory states of the Brussels Treaty, on the one hand, and the Federal Republic of Germany and Italy, on the other hand ;

Observing that the seven states parties to the Partial Agreement, which have resumed, within the Council of Europe, the social work hitherto undertaken by the Brussels Treaty Organisation and then by Western European Union, which derived from the Brussels Treaty as modified by the protocol mentioned in the fourth paragraph above, as well as Austria, Denmark, Ireland, Spain and Switzerland, who participate in Partial Agreement activities in the field of public health, have always endeavoured to be in the forefront of progress in social matters and also in the associated field of public health, and have for many years undertaken action towards harmonisation of their legislation ;

Being aware of the need to maximise the benefit and minimise the risk to patients of using medicines ;

Having regard to the need, in the interest of public health, to supply users with clear and comprehensive information on proper use and storage of medicines placed on the market,

Recommend that the governments of the seven states parties to the Partial Agreement, as well as the governments of Austria, Denmark, Ireland, Spain and Switzerland, bring their national laws into conformity with the provisions set out hereafter :

I. Provisions governing patient package information provided with medicines

1. Unless the information set out in item II hereafter is provided on the package, it should be contained in a package leaflet (hereafter referred to as "leaflet").
2. The content of the leaflet is not intended to replace the primary professional advice given at the time of prescribing, dispensing or sale, but needs to be adequate to answer key relevant questions for the patient without further recourse to a health professional.
3. Only information of direct relevance to the patient should be included in the leaflet.
4. The leaflet should be written at a level and in a style intelligible to the patient and which ensures that the patient takes the right course of action.
5. The arrangement of the text and the size of the print should be adequate to be legible particularly to the elderly and should not give undue emphasis to either the advantages or disadvantages of the product.
6. The text included in the leaflet is to be compatible with the terms of licence approval.
7. Generally, there will be a common approach to all medicines, but it is recognised that there may be a need for differences in the expression of the recommended dosages for medicines available without prescription and prescription only medicines. For certain conditions, there could also be a need for differences in the expression of the therapeutic indications.
8. Unless necessary for safety reasons, specific reference should not generally be made to another product.
9. The information shall not enable patients to draw conclusions about the seriousness of illnesses being treated with a prescribed medicine ; it should not arouse fears about the patient's condition ; and should not include any recommendations or testimonials from health professionals.

II. Information to be included on the leaflet

1. Name of the product.
2. - INN (if available) or the usual common name for the active constituent(s) ;
- pharmaco-therapeutic category (i.e. mode of action of the medicament in its therapeutic category) (if necessary) and chemical group (if necessary).
3. Therapeutic indications as approved (expressed in terms consistent with the licence approval).
4. Contra-indications :
- priority given to absolute contra-indications.
5. Precautions, including :
- anticipated or confirmed pregnancy ;
- breast-feeding ;
- children/elderly people ;
- co-existing illnesses ;
- relevant allergies ;
- others.

6. Interactions :
 - other medicines ;
 - food ;
 - alcohol ;
 - others.
7. Doses and mode of administration (expressed in terms consistent with the licence approval):
 - usual dosage ;
 - complete and unambiguous instructions for administration including avoidance of incompatibilities ;
 - Maximum dose not to be exceeded.
8. Side effects :
 - priority in listing according to incidence and/or severity ;
 - expressed as symptoms recognisable and detectable to the patient ;
 - guidance on action to be taken when present.
9. Effect on performance :
 - ability to drive or operate machinery ;
 - others.
10. Storage conditions (if applicable):
 - definition of necessary temperature and humidity controls ;
 - need for protection from sunlight.
11. Composition :
 - qualitative and quantitative composition in terms of the active ingredients ;
 - mention of excipients.
12. Dose form — presentation — legal route of supply.
13. Keep medicines out of reach of children.
14. This medicine may be unsuitable for administration to other people (when it is a prescription only medicine).
15. Do not use after any stated expiry date.
16. Name and address of licence holder of product.