

COUNCIL DIRECTIVE 92/27/EEC

of 31 March 1992

on the labelling of medicinal products for human use and on package leaflets

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas measures aimed at progressively establishing the internal market over a period expiring on 31 December 1992 need to be taken; whereas the internal market is to comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulations or administrative action relating to medicinal products (4), as last amended by Directive 89/343/EEC (5), establishes a list of particulars to be given on the immediate packaging and the outer packaging of medicinal products for human use; whereas this list should be supplemented and details given of how labelling is to be presented;

Whereas Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (6), as last amended by Directive 89/381/EEC (7), establishes a non-exhaustive list of particulars to be included in package leaflets; whereas this list should be supplemented and details given of how such leaflets are to be presented;

Whereas the provisions on labelling and on package leaflets should be brought together in a single text;

Whereas the provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information;

Whereas the marketing of medicinal products whose labelling and package leaflets comply with this Directive should not be prohibited or impeded on grounds connected with the labelling or package leaflet,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope and definitions

Article 1

1. This Directive deals with the labelling of medicinal products for human use and leaflets inserted in packages of such products, to which Chapters II, III, IV and V of Directive 65/65/EEC apply.

2. For the purposes of this Directive:

- *name of the medicinal product* means the name given to a medicinal product, which may be either an invented name or a common or scientific name, together with a trade mark or the name of the manufacturer; the invented name shall not be liable to confusion with the common name,
- *common name* means the international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name,
- *strength of the medicinal product* means the content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form,
- *immediate packaging* means the container or other form of packaging immediately in contact with the medicinal product,
- *outer packaging* means the packaging into which is placed the immediate packaging,

(1) OJ No C 58, 8. 3. 1990, p. 21.

(2) OJ No C 183, 15. 7. 1991, p. 213.

(3) OJ No C 225, 10. 9. 1990, p. 24.

(4) OJ No 22, 9. 2. 1965, p. 369/65.

(5) OJ No L 142, 25. 5. 1989, p. 14.

(6) OJ No L 147, 9. 6. 1975, p. 13.

(7) OJ No L 81, 28. 6. 1989, p. 44.

- *labelling* means information on the immediate or outer packaging,
- *package leaflet* means a leaflet containing information for the user which accompanies the medicinal product,
- *manufacturer* means the holder of the authorization referred to in Article 16 of Directive 75/319/EEC on behalf of whom the qualified person has performed the specific obligations laid down in Article 22 of that Directive.

CHAPTER II

Labelling of medicinal products

Article 2

1. The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:

- (a) the name of the medicinal product followed by the common name where the product contains only one active ingredient and if its name is an invented name; where a medicinal product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and/or the strength (baby, child or adult as appropriate) must be included in the name of the medicinal product;
- (b) a statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;
- (c) the pharmaceutical form and the contents by weight, by volume or by number of doses of the product;
- (d) a list of those excipients known to have a recognized action or effect and included in the guidelines published pursuant to Article 12. However, if the product is injectable, or a topical or eye preparation, all excipients must be stated;
- (e) the method and, if necessary, the route of administration;
- (f) a special warning that the medicinal product must be stored out of reach of children;
- (g) a special warning, if this is necessary for the medicinal product concerned;
- (h) the expiry date in clear terms (month/year);
- (i) special storage precautions, if any;
- (j) special precautions for disposal of unused medicinal products or waste materials derived from such products, if appropriate;

- (k) the name and address of the holder of the authorization for placing the medicinal product on the market;
- (l) the number of the authorization for placing the medicinal product on the market;
- (m) the manufacturer's batch number;
- (n) in the case of self-medication, instructions on the use of the medicinal products.

2. The outer packaging may include symbols or pictograms designed to clarify certain information mentioned in paragraph 1 and other information compatible with the summary of the product characteristics which is useful for health education, to the exclusion of any element of a promotional nature.

Article 3

1. The particulars laid down in Article 2 shall appear on immediate packagings other than those referred to in paragraphs 2 and 3.

2. The following particulars at least shall appear on immediate packagings which take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Article 2:

- the name of the medicinal product as laid down in Article 2 (a),
- the name of the holder of the authorization for placing the product on the market,
- the expiry date,
- the batch number.

3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Article 2 cannot be displayed:

- the name of the medicinal product and, if necessary, the strength and the route of administration,
- the method of administration,
- the expiry date,
- the batch number,
- the contents by weight, by volume or by unit.

Article 4

1. The particulars referred to in Articles 2 and 3 shall be easily legible, clearly comprehensible and indelible.

2. The particulars listed in Article 2 shall appear in the official language or languages of the Member State where the product is placed on the market. This provision shall not prevent these particulars from being indicated in several languages, provided that the same particulars appear in all the languages used.

Article 5

1. Member States may not prohibit or impede the placing on the market of medicinal products within their territory on grounds connected with labelling where such labelling complies with the requirements of this Chapter.

2. Notwithstanding paragraph 1, Member States may require the use of certain forms of labelling making it possible to indicate:

- the price of the medicinal product,
- the reimbursement conditions of social security organizations,
- the legal status for supply to the patient, in accordance with Directive 92/26/EEC ⁽¹⁾,
- identification and authenticity.

CHAPTER III

User package leaflet

Article 6

The inclusion in the packaging of all medicinal products of a package leaflet for the information of users shall be obligatory unless all the information required by Article 7 is directly conveyed on the outer packaging or on the immediate packaging.

Article 7

1. The package leaflet shall be drawn up in accordance with the summary of the product characteristics; it shall include, in the following order:

(a) for the identification of the medicinal product:

- the name of the medicinal product, followed by the common name if the product contains only one active ingredient and if its name is an invented name; where a medicinal product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and/or the strength (for example, baby, child, adult) must be included in the name of the medicinal product,
- a full statement of the active ingredients and excipients expressed qualitatively and a statement of the active ingredients expressed quantitatively, using their common names, in the case of each presentation of the product,
- the pharmaceutical form and the contents by weight, by volume or by number of doses of the product, in the case of each presentation of the product,

- the pharmaco-therapeutic group, or type of activity in terms easily comprehensible for the patient,
- the name and address of the holder of the authorization for placing the medicinal product on the market and of the manufacturer;

(b) the therapeutic indications;

(c) a list of information which is necessary before taking the medicinal product:

- contra-indications,
- appropriate precautions for use,
- forms of interaction with other medicinal products and other forms of interaction (for example, alcohol, tobacco, foodstuffs) which may affect the action of the medicinal product,
- special warnings.

this list must:

- take into account the particular condition of certain categories of users (e.g. children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions),
- mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery,
- detail those excipients, knowledge of which is important for the safe and effective use of the medicinal product and included in the guidelines published pursuant to Article 12;

(d) the necessary and usual instructions for proper use, in particular:

- the dosage,
- the method and, if necessary, route of administration,
- the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered,

and, as appropriate, depending on the nature of the product:

- the duration of treatment, where it should be limited,
- the action to be taken in the case of an overdose (for example, symptoms, emergency procedures),
- the course of action to take when one or more doses have not been taken,
- indication, if necessary, of the risk of withdrawal effects;

(e) a description of the undesirable effects which can occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case; the

⁽¹⁾ See page 5 of this Official Journal.

patient should be expressly invited to communicate any undesirable effect which is not mentioned in the leaflet to his doctor or to his pharmacist;

- (f) a reference to the expiry date indicated on the label, with:
- a warning against using the product after this date,
 - where appropriate, special storage precautions,
 - if necessary, a warning against certain visible signs of deterioration;
- (g) the date on which the package leaflet was last revised.

2. Notwithstanding paragraph 1 (b), the competent authorities may decide that certain therapeutic indications shall not be mentioned in the package leaflet, where the dissemination of such information might have serious disadvantages for the patient.

3. The package leaflet may include symbols or pictograms designed to clarify certain information mentioned in paragraph 1 and other information compatible with the summary of the product characteristics which is useful for health education, to the exclusion of any element of a promotional nature.

Article 8

The package leaflet must be written in clear and understandable terms for the patient and be clearly legible in the official language or languages of the Member State where the medicinal product is placed on the market. This provision does not prevent the package leaflet being printed in several languages, provided that the same information is given in all the languages used.

Article 9

Member States shall not prohibit or impede the marketing of medicinal products within their territory on grounds relating to the package leaflet if the latter complies with the requirements of this Chapter.

CHAPTER IV

General and final provisions

Article 10

1. One or more specimens or mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the authorities competent for authorizing marketing when the authorization for placing the medicinal product on the market is requested.

2. The competent authorities shall refuse the authorization for placing the medicinal product on the market if the labelling or the package leaflet do not comply with the provisions of this Directive or if they are not in accordance with the particulars listed in the summary of product characteristics referred to in Article 4b of Directive 65/65/EEC.

3. All proposed changes to an aspect of the labelling or the package leaflet covered by this Directive and not connected with the summary of characteristics shall be submitted to the authorities competent for authorizing marketing. If the competent authorities have not opposed a proposed change within 90 days following the introduction of the request, the applicant may put the change into effect.

4. The fact that the competent authorities do not refuse an authorization to place the medicinal product on the market pursuant to paragraph 2 or a change to the labelling or the package leaflet pursuant to paragraph 3 does not alter the general legal liability of the manufacturer or as appropriate the holder of the authorization to place the medicinal product on the market.

5. The competent authorities may exempt labels and package leaflets for specific medicinal products from the obligation that certain particulars shall appear and that the leaflet must be in the official language or languages of the Member State where the product is placed on the market, when the product is not intended to be delivered to the patient for self-administration.

Article 11

1. Where the provisions of this Directive are not complied with, and a notice served on the person concerned has remained without effect, the competent authorities of the Member States may suspend the authorization to place the medicinal product on the market, until the labelling and the package leaflet of the medicinal product in question have been made to comply with the requirements of this Directive.

2. All decisions taken pursuant to paragraph 1 shall state in detail the reasons on which they are based. They shall be notified to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force and of the time limit allowed for the exercise of such remedies.

Article 12

1. As necessary, the Commission shall publish guidelines concerning in particular:

- the formulation of certain special warnings for certain categories of medicinal products,
- the particular information needs relating to self-medication,

- the legibility of particulars on the labelling and package leaflet,
- methods for the identification and authentication of medicinal products,
- the list of excipients which must feature on the labelling of medicinal products and the way these excipients must be indicated.

2. These guidelines shall be adopted in the form of a Directive addressed to the Member States, in accordance with the procedure laid down in Article 2c of Directive 75/318/EEC.

Article 13

Articles 13 to 20 of Directive 65/65/EEC and Articles 6 and 7 of Directive 75/319/EEC are hereby repealed.

Article 14

Member States shall take the measures necessary to comply with this Directive before 1 January 1993. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

From 1 January 1994, Member States shall refuse an application for authorization to place a medicinal product on the market or for the renewal of an existing authorization, where the labelling and the package leaflet do not comply with the requirements of this Directive.

Article 15

This Directive is addressed to the Member States.

Done at Brussels, 31 March 1992.

For the Council

The President

Vitor MARTINS