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 a 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 include 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 procautions, 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.