COUNCIL DIRECTIVE 92/26/EEC

of 31 March 1992

concerning the classification for the supply of medicinal products for human use

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 the conditions for the supply of medicinal products for human use to the public vary appreciably from one Member State to another; whereas medicinal products sold without prescriptions in certain Member States can be obtained only on medical prescription in other Member States;

Whereas Directive 91/28/EEC (4) specifies what medicinal products may be advertized to the public; whereas, in view of the development of means of communication, the conditions governing the supply of medicinal products to the public should be harmonized.

Whereas, moreover, persons moving around within the Community have the right to carry a reasonable quantity of medicinal products lawfully obtained for their personal use; whereas it must also be possible for a person established in one Member State to receive from another Member State a reasonable quantity of medicinal products intended for his personal use; whereas it is important therefore to harmonize the conditions governing the supply of medicinal products to the public;

Whereas, in addition, under the new system of registration of medicinal products in the Community, certain medicinal products will be the subject of a Community marketing authorization; whereas, in this context, the classification for the supply of medicinal products covered by a Community marketing authorization needs to be established; whereas it is therefore important to set the criteria on the basis of which Community decisions will be taken;

Whereas it is therefore appropriate, as an initial step, to harmonize the basic principles applicable to the classification for the supply of medicinal products in the Community or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe as well as the work of harmonization completed within the framework of the United Nations, concerning narcotic and psychotropic substances;

Whereas this Directive is without prejudice to the national social security arrangements for reimbursement or payment for medicinal products on prescription,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns the classification for the supply of medicinal products for human use in the Community into:

— medicinal products subject to medical prescription,

— medicinal products not subject to medical prescription.

2. For the purposes of this Directive, the definition of 'medicinal product' in Article 1 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (5) as last amended by Directive 89/343/EEC (6), shall apply. In addition, 'medicinal prescription' shall mean any prescription issued by a professional person qualified to prescribe medicinal products.

Article 2

1. When a marketing authorization is granted, the competent authorities shall specify the classification of the medicinal product into:

— a medicinal product subject to medical prescription,

— a medicinal product not subject to medical prescription.

(1) OJ No C 58, 8. 3. 1990, p. 18.
(2) OJ No C 183, 15. 7. 1991, p. 178 and OJ No C 67, 16. 3. 1992.
(3) OJ No C 225, 10. 9. 1990, p. 21.
(4) See page 13 of this Official Journal.
(5) OJ No 22, 9. 6. 1965, p. 369/65.
(6) OJ No L 142, 25. 5. 1989, p. 14.

To this end, the criteria laid down in Article 3 (1) shall apply.

2. The competent authorities may fix sub-categories for medicinal products which are available on medical prescription only. In that case, they shall refer to the following classification:

(a) medicinal products on renewable or non-renewable medical prescription;

(b) medicinal products subject to special medical prescription;

(c) medicinal products on restricted medical prescription, reserved for use in certain specialized areas.

Article 3

1. Medicinal products shall be subject to medical prescription where they:

— are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or

— are frequently and to a very wide 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 side effects of which require further investigation, or

— are normally prescribed by a doctor to be administered parenterally.

2. Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors:

— the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions in force (United Nations Conventions of 1961 and 1971), or

— the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes, or

— the medicinal product contains a substance which, by reason of its novelty or properties, could be considered as belonging to that group as a precautionary measure.

3. Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors:

— the medicinal product, because of its pharmaceutical characteristics or novelty or in the interests of public health, is reserved for treatments which can only be followed in a hospital environment,

— the medicinal product is used in the treatment of conditions which must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere, or

— the medicinal product is intended for outpatients but its use may produce very serious side-effects requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.

4. A competent authority may waive application of paragraphs 1, 2 and 3 having regard to:

(a) the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; and/or

(b) other circumstances of use which it has specified.

5. If a competent authority does not designate medicinal products into sub-categories referred to in Article 2 (2), it shall nevertheless take into account the criteria referred to in paragraphs 2 and 3 of this Article in determining whether any medicinal product shall be classified as a prescription-only medicine.

Article 4

Medicinal products not subject to prescription shall be those which do not meet the criteria listed in Article 3.

Article 5

1. The competent authorities shall draw up a list of the medicinal products subject on their territory to medical prescription, specifying, if necessary, the category of classification. They shall update this list annually.

2. On the occasion of the five-yearly renewal of the marketing authorization or when new facts are brought to their notice, the competent authorities shall examine and, as appropriate, amend the classification of a medicinal product, by applying the criteria listed in Article 3.

Article 6

1. Within two years of adoption of this Directive, the Member States shall communicate the list referred to in Article 5 (1) to the Commission and to the other Member States, when requested by the latter.

2. Each year, Member States shall communicate to the Commission and to the other Member States the changes that have been made to the list referred to in paragraph 1.

3. Within four years of the adoption of this Directive, the Commission shall submit a report to the Council on the application of this Directive. This report will be accompanied, if necessary, by appropriate proposals.

Article 7

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993. They shall forthwith inform the Comission 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.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 31 March 1992.

For the Council

The President

Vitor MARTINS