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.