II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 92/25/EEC

of 31 March 1992

on the wholesale distribution 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 it is important to adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992; 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 wholesale distribution of medicinal products is at present subject to different provisions in the various Member States; whereas many operations involving the wholesale distribution of medicinal products for human use may cover several Member States simultaneously;

Whereas it is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions; whereas the requirements which must be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products;

Whereas any person involved in the wholesale distribution of medicinal products should be in possession of a special authorization; whereas pharmacists and persons authorized to supply medicinal products directly to the public, and who confine themselves to this activity, should be exempt from obtaining this authorization; whereas it is however necessary, in order to control the complete chain of distribution of medicinal products, that pharmacists and persons authorized to supply medicinal products to the public keep records showing transactions in products received;

Whereas authorization must be subject to certain essential conditions and it is the responsibility of the Member State concerned to ensure that such conditions are met; whereas each Member State must recognize authorizations granted by other Member States;

Whereas certain Member States impose on wholesalers who supply medicinal products to pharmacists and on persons authorized to supply medicinal products to the public certain public service obligations; whereas those Member States must be able to continue to impose those obligations on wholesalers established within their territory; whereas they must also be able to impose them on wholesalers in other Member States on condition that they do not impose any obligation more stringent than those which they impose on their own wholesalers and provided that such obligations may be regarded as

(1) OJ No C 58, 8. 3. 1990, p. 16 and OJ No C 207, 8. 8. 1991, p. 11.
(2) OJ No C 183, 15. 7. 1991, p. 139, and OJ No C 67, 16. 3. 1992.
(3) OJ No C 269, 14. 10. 1991, p. 84.

warranted on grounds of public health protection and are proportionate in relation to the objective of such protection,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive covers the wholesale distribution in the Community of medicinal products for human use to which Chapters II to V 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 [1] apply.

2. For the purposes of this Directive:

— *wholesale distribution of medicinal products* shall mean all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public; such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned,

— *public service obligation* shall mean the obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.

Article 2

Without prejudice to Article 3 of Directive 65/65/EEC, Member States shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorization has been granted in accordance with Community law are distributed on their territory.

Article 3

1. Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorization to engage in activity as a wholesaler in medicinal products, stating the place for which it is valid.

2. Where persons authorized or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the authorization provided for in paragraph 1.

3. Possession of an authorization, as mentioned in Article 16 of 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 [2], shall include authorization to distribute by wholesale the medicinal products covered by that authorization. Possession of an authorization to engage in activity as a wholesaler in medicinal products shall not give dispensation from the obligation to possess a manufacturing authorization and to comply with the conditions set out in that respect, even where the manufacturing or import business is secondary.

4. At the request of the Commission or any Member State, Member States shall supply all appropriate information concerning the individual authorizations which they have granted under paragraph 1.

5. Checks on the persons and establishments authorized to engage in the activity of wholesaler in medicinal products and the inspection of their premises shall be carried out under the responsibility of the Member State which granted the authorization.

6. The Member State which granted the authorization referred to in paragraph 1 shall suspend or revoke that authorization if the conditions of authorization cease to be met. It shall forthwith inform the other Member States and the Commission thereof.

7. Should a Member State consider that, in respect of a person holding an authorization granted by another Member State under the terms of paragraph 1, the conditions of authorization are not, or are no longer, met, it shall forthwith inform the Commission and the other Member State involved. The latter shall take the measures necessary and shall inform the Commission and the first Member State of the decisions taken and the reasons for those decisions.

Article 4

1. Member States shall ensure that the time taken for the procedure for examining the application for the authorization referred to in Article 3 (1) does not exceed 90 days from the day on which the competent authority of the Member State concerned receives the application.

The competent authority may, if need be, require the applicant to supply all necessary information concerning the conditions of authorization. Where the authority exercises this option, the period laid down in this

(1) OJ No 22, 9. 2. 1965, p. 369/65. Directive last amended by Directive 89/341/EEC (OJ No L 142, 25. 5. 1989, p. 11).

(2) OJ No L 147, 9. 6. 1975, p. 13. Directive last amended by Directive 89/381/EEC (OJ No L 181, 28. 6. 1989, p. 44).

paragraph shall be suspended until the requisite additional data have been supplied.

2. All decisions to refuse, suspend or revoke the authorization referred to in Article 3 (1) shall state in detail the reasons on which they are based. A decision shall be notified to the party concerned, who shall at the same time be informed of the redress available to him under the laws in force and of the time limit allowed for access to such redress.

Article 5

In order to obtain the authorization referred to in Article 3 (1), applicants must fulfil the following minimum requirements:

(a) they must have suitable and adequate premises, installations and equipment so as to ensure proper conservation and distribution of the medicinal products;

(b) they must have staff, and in particular a qualified person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned;

(c) they must undertake to fulfil the obligations incumbent on them under the terms of Article 6.

Article 6

Holders of the authorization referred to in Article 3 (1) must fulfil the following minimum requirements:

(a) they must make the premises, installations and equipment referred to in Article 5 (a) accessible at all times to the persons responsible for inspecting them;

(b) they must obtain their supplies of medicinal products only from persons who are themselves in possession of the authorization referred to in Article 3 (1) or who are exempt from obtaining such authorization under the terms of Article 3 (3);

(c) they must supply medicinal products only to persons who are themselves in possession of the authorization referred to in Article 3 (1) or who are authorized or entitled to supply medicinal products to the public in the Member State concerned;

(d) they must have an emergency plan which ensures effective implementation of any recall from the market ordered by the competent authorities or carried out in cooperation with the manufacturer or holder of the marketing authorization for the product concerned;

(e) they must keep records either in the form of purchase/sales invoices, or on computer, or in any other form giving for any transaction in medicinal products received or dispatched at least the following information:

— date,

— name of the medicinal product,

— quantity received or supplied,

— name and address of the supplier or consignee, as appropriate;

(f) they must keep the records referred to under (e) available to the competent authorities, for inspection purposes, for a period of five years;

(g) they must comply with the principles and guidelines of good distribution practice for medicinal products as laid down in Article 10.

Article 7

With regard to the supply of medicinal products to pharmacists and persons authorized or entitled to supply medicinal products to the public, Member States shall not impose upon the holder of an authorization referred to in Article 3 (1) which has been granted by another Member State, any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorized to engage in equivalent activities.

The said obligations should, moreover, be justified, in keeping with the Treaty, on grounds of public health protection and be proportionate in relation to the objective of such protection.

Article 8

For all supplies of medicinal products to a person authorized or entitled to supply medicinal products to the public in the Member State concerned, the authorized wholesaler must enclose a document that makes it possible to ascertain:

— the date,

— the name and pharmaceutical form of the medicinal product,

— the quantity supplied,

— the name and address of the supplier and consignor.

Member States shall take all appropriate measures to ensure that persons authorized or entitled to supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product.

Article 9

The provisions of this Directive shall not prevent the application of more stringent requirements laid down by Member States in respect of the wholesale distribution of:

— narcotic or psychotropic substances within their territory,

— medicinal products derived from blood governed by Directive 89/381/EEC [1],

— immunological medicinal products governed by Directive 89/342/EEC [2],

— radiopharmaceuticals governed by Directive 89/343/ EEC [3].

Article 10

The Commission shall publish guidelines on good distribution practice. To this end it shall consult the Committee for Proprietary Medicinal Products and the Pharmaceutical Committee.

Article 11

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

2. When these measures are adopted by the Member States, 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 12

This Directive is addressed to the Member States.

Done at Brussels, 31 March 1992.

For the Council

The President

Vitor MARTINS

(1) OJ No L 181, 28. 6. 1989, p. 44.
(2) OJ No L 142, 25. 5. 1989, p. 14.
(3) OJ No L 142, 25. 5. 1989, p. 16.