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**I

# R E P O R T

of the Committee on the Environment, Public Health and Consumer Protection

on the Commission proposal for a Council directive on the wholesale distribution of medicinal products for human use

(COM(89) 607 final - C3-0048/90 - SYN 229)

Rapporteur: Mrs Adriana CECI

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Or. FR.

*A Series: Reports - B Series: Motions for Resolutions, Oral Questions - C Series: Documents received from other Institutions (e.g. Consultations)*

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| * | = *Consultation procedure requiring a single reading* | **II | = *Cooperation procedure (second reading) which requires the votes of a majority of the current Members of Parliament for rejection or amendment* |
| **I | = *Cooperation procedure (first reading)* | *** | = *Parliamentary assent which requires the votes of a majority of the current Members of Parliament* |

## C O N T E N T S

By letter of 13 February 1990 the Council consulted the European Parliament, pursuant to Article 100a of the EEC Treaty, on the Commission proposal for a Council directive on the wholesale distribution of medicinal products for human use.

At the sitting of 12 March 1990 the President of Parliament announced that he had referred this proposal to the Committee on the Environment, Public Health and Consumer Protection as the committee responsible and to the Committee on Economic and Monetary Affairs and Industrial Policy and the Committee on Budgets for their opinions.

At its meeting of 23 March 1990 the Committee on the Environment, Public Health and Consumer Protection appointed Mrs Ceci rapporteur.

At its meetings of 9 November and 18 December 1990 and of 31 January and 25 April 1991 it considered the Commission proposal and draft report.

At the last meeting it adopted the draft legislative resolution by 29 votes to 2 with 2 abstentions.

The following were present for the vote: Collins, Chairman; Schleicher, vice-chairman; Ceci, rapporteur; Alavanos, Alber, Amendola, Banotti, Bertens, Bjørnvig, Bombard, Bowe, Canavarro, Chanterie, Diez de Rivera Icaza, Di Rupo, Florenz, Green, Guidolin, Hadjigeorgiou (for Douste-Blazy), Jensen, Kuhn, Llorca Vilaplana, Monnier-Besombes, Oomen-Ruijten, Partsch, Pollack, Roth-Behrendt, Schwartzenberg, Simmonds, Llewellyn Smith, Valverde Lopez, Veil, Vernier, Vertemati and Vittinghoff.

The opinions of the Committee on Economic and Monetary Affairs and Industrial Policy and the Committee on Budgets are attached.

The report was tabled on 30 April 1991.

The deadline for tabling amendments will appear on the draft agenda for the part-session at which the report is to be considered.

A

Commission proposal for a Council directive
on the wholesale distribution of medicinal products for human use

| Commission text[1] | Amendments |
|---|---|
| | (Amendment No. 1)<br>First recital a (new) |
| | Whereas, according to Article 100a, the completion of the internal market must be based on the highest possible level of environmental, public health and consumer protection; |
| | (Amendment No. 2)<br>Second recital |
| Whereas the wholesale distribution of medicinal products for human use is at present subject to different provisions in the various Member States; whereas many operations involving the wholesale distribution of medicinal products may cover simultaneously several Member States; | Whereas the wholesale distribution of medicinal products for human use is at present subject to different provisions in the various Member States; whereas many operations involving the wholesale distribution of medicinal products cover and will increasingly cover simultaneously several Member States; |
| | (Amendment No. 3)<br>Third recital |
| 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 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 subject to all the stages in the distribution process, with a view to effective efforts against counterfeit products and to facilitating the prompt withdrawal of defective products from the market; |

[1] For full text see COM(89) 607 final - OJ No. C 58, 8.3.1990, p. 16

| Commission text | Amendments |
| --- | --- |
| | (Amendment No. 4)<br>Fourth recital |
| 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 always necessary in order to control the complete chain of distribution of medicinal products, that pharmacists and persons authorized to deliver medicinal products to the public keep records showing entry transactions; | Whereas any person involved in the wholesale distribution of medicinal products should be in possession of a specific authorization; whereas the definition of distribution does not cover dividing up, packaging and presentation operations referred to in Article 16 of Directive 75/319 and in the amendments thereto or operations linked to direct supply to the public; |
| | (Amendment No. 5)<br>Fourth recital a (new) |
| | Whereas it is necessary to lay down uniform rules applicable throughout the Community with a view to establishing the conditions for obtaining authorization, arrangements in connection with transport, personnel and premises, and the procedures for the checks to be carried out by the Member States; |

| Commission text | Amendments |
|---|---|
| | (Amendment No. 6)<br>Article 1(2) |
| 2. For the purposes of this Directive, the definition of "medicinal products" set out in Article 1 of Council Directive 65/65/EEC[1] shall apply. In addition "wholesale distribution of medicinal products" shall mean all activities consisting of procuring, holding, supplying, importing or exporting medicinal products. | 2. For the purposes of this directive the definition of medicinal products set out in Annex I of Council Directive 65/65/EEC[1] shall apply. In addition 'wholesale distribution of medicinal products' shall mean all activities consisting of procuring, holding, supplying to persons other than the final consumer, importing or exporting medicinal products. The import of medicinal products from third countries corresponds to marketing and shall therefore be deemed to be equivalent to the activities of manufacturers. |
| | (Amendment No. 7)<br>Article 1(2a)(new) |
| | 2a. For the purposes of this directive 'public service obligations' shall include the obligation for wholesalers to guarantee a constant range of medicinal products to meet the needs of a geographically determined territory and to ensure the supply at very short notice of the products requested throughout the territory in question. |
| | (Amendment No. 8)<br>Article 1(3)(new) |
| | A wholesale distributor of medicinal products shall be responsible for ensuring a full range of proprietary medicinal products and for making them available promptly on the territory for which he is responsible. |
| | (Amendment No. 9)<br>Article 3, title (new) |
| | Persons to be granted authorization |

| Commission text | Amendments |
|---|---|
| | (Amendment No. 10)<br>Article 3(3) |
| 3. The possession of an authorization to carry out the activity of a wholesaler of medicinal products shall not dispense from the obligation to possess a manufacturing authorization or an authorization for importation from third countries in accordance with Article 16 of Council Directive 75/319/EEC[2], and to comply with the conditions set out in that respect, even when the manufacturing activity is secondary. | 3. A manufacturer in possession of an authorization in accordance with Article 16 of Directive 75/319 who proposes to distribute a proprietary medicinal product directly may apply, to the relevant health authorities in the Member State in which he proposes to engage in distribution activities, and obtain an authorization restricted to that proprietary product. Manufacturers/importers wishing to supply their products to another holder of such authorization and/or a number of distributors must have authorization to engage in wholesale trade in their own products. |
| | (Amendment No. 11)<br>Article 5, title (new) |
| | Requirements for granting the authorization |
| | (Amendment No. 12)<br>Article 5(a) |
| (a) they must have suitable and adequate premises, such as to ensure good conservation of the medicinal products warehoused; | (a) they must have suitable and adequate premises, such as to ensure good conditions for conservation and handling, appropriate to the nature of the medicinal products warehoused as well as suitable arrangements for the proper handling and transport of medicinal products; |
| | (Amendment No. 13)<br>Article 5(aa) (new) |
| | (aa) they must ensure that the most stringent laboratory hygiene and safety rules are applied; |

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[2] OJ No. L 147, 9.6.1975, p. 13

| Commission text | Amendments |
|---|---|
| | (Amendment No. 14)<br>Article 5(b) |
| (b) they must have a qualified personnel meeting the conditions provided for by the legislation of the Member State concerned; | (b) They must have qualified personnel working under the responsibility of a pharmacist, meeting the conditions provided for by the legislation of the Member State concerned; |
| | (Amendment No. 15)<br>Article 5(c) |
| (c) they must undertake to fulfil the obligations incumbent on them under the terms of Article 6. | (c) they must undertake to comply with sound distribution practices and to establish that they have the requisite means at their disposal to apply them in practice. |
| | (Amendment No. 16)<br>Article 5(ca)(new) |
| | (ca) They must guarantee the presence of a pharmacist with the following responsibilities:<br>1. The administration and supervision of the technical services responsible for general hygiene in the pharmacies<br>2. Quality control and analysis of unpackaged products to ensure that they meet the required standards<br>3. Keeping and checking laboratory analysis report files<br>4. Stocktaking, ensuring suitable storage conditions in particular for narcotic and toxic substances in general and keeping a detailed inventory of the arrival and removal of stocks<br>5. Checking final dates for use<br>6. The withdrawal of products if necessary. |

| Commission text | Amendments |
|---|---|
| | (Amendment No. 17)<br>Article 6, title (new) |
| | Obligations incumbent on wholesale distributors of medicinal products |
| | (Amendment No. 18)<br>Article 6, first phrase |
| Holders of the authorization referred to in Article 3(1) shall be required: | Holders of the authorization referred to in Article 3(1) shall be obliged: |
| | (Amendment No. 19)<br>Article 6(a) |
| (a) to make the premises referred to in Article 5(a) accessible at all times to the persons responsible for inspecting them; | (a) to make the premises, facilities and procedures used accessible at all times to the persons from the competent authorities responsible for inspecting them. |
| | (Amendment No. 20)<br>Article 6(b) |
| (b) to obtain 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 this authorization under the terms of Article 3(2); | (b) to obtain medicinal products only from persons who hold an authorization as referred to in Article 16 et seq of Directive 75/319/EEC, or who are themselves in possession of the authorization referred to in Article 3(1) or who are exempt from obtaining this authorization under the terms of Article 3(2); |
| | (Amendment No. 21)<br>Article 6(c) |
| (c) to supply medicinal products only to persons who are themselves in possession of the authorization referred to in Article 3(1) or who are exempt from obtaining this authorization under the terms of Article 3(2); | (c) not to open or tamper in any way with the medicinal products distributed by them; |

| Commission text | Amendments |
|---|---|
| | (Amendment No. 22)<br>Article 6(d) |
| (d) to have an emergency plan which allows participation in any action of withdrawal from the market ordered by the competent authorities or initiated by the manufacturer of the medicinal product concerned; | (d) to accept an emergency plan which allows participation in any action of withdrawal from the market ordered by the competent authorities of the Member State or initiated by the manufacturer/importer of the medicinal product concerned;<br><br>The Commission shall entrust the European Community organization set up under Council Regulation No. (EEC) with the task of coordinating at Community level all emergency plans for the withdrawal of a medicinal product from the market. Pending the setting-up of this body, all dealers with information concerning the medicinal product being withdrawn from the market shall immediately inform their suppliers and customers. In addition all wholesalers and wholesale distributors shall check their stocks for the presence of the medicinal product and prevent it from entering the market. |
| | (Amendment No. 23)<br>Article 6(da)(new) |
| | (da) to be in a position normally to dispatch products requested within 12 hours of receiving a request, and within 24 hours where isolated areas are involved, and at all times to organize emergency deliveries in the event of a disaster; |

| Commission text | Amendments |
|---|---|
| | (Amendment No. 24)<br>Article 6(e) |
| (e) to keep detailed records, possibly computerized, stating for each transaction in medicinal products received or dispatched, the following information:<br>- date,<br>- name of the medicinal product,<br>- production batch number,<br>- quantity received or supplied,<br>- name and address of the supplier or consignee;<br><br>when the delivery is destined for a retailer, the production batch number is not required; | (e) to keep detailed computerized records stating for each transaction in medicinal products received or dispatched, the following information:<br>- date,<br>- name of the medicinal product,<br>- production batch number,<br>- quantity received and supplied,<br>- name and address of the supplier and consignee;<br><br>when the delivery is destined for a retailer, the production batch number is not required; |
| | (Amendment No. 25)<br>Article 6(ga)(new) |
| | (ga) to entrust the qualified member of staff referred to in Article 5(b) with the supervision and checking of the operations referred to in paragraphs (d), (e) and (g) of this Article; |
| | (Amendment No. 26)<br>Article 6(gb)(new) |
| | (gb) to have suitable facilities for the stroage and transport of products requiring special arrangements in respect of their conservation, human safety or environmental protection; |
| | (Amendment No. 27)<br>Article 6(gc)(new) |
| | (gc) to provide adequate guarantees for the continuation of the cold chain in the transport and storage of medicinal products which need to be kept at certain termperatures; |

| Commission text | Amendments |
| --- | --- |
| | (Amendment No. 28)<br>Article 6(gd)(new) |
| | (gd) not to supply products that are physically damaged, damaged as a result of variations in temperature or humidity or contaminated, or products reaching the end of their shelf life; |
| | (Amendment No. 29)<br>Article 6(ge)(new) |
| | (ge) to store damaged products separately and to dispose of them only as directed by the competent authorities; |
| | (Amendment No. 30)<br>Article 6(gf)(new) |
| | (gf) to dispatch products in such a way that they can be always identified; |
| | (Amendment No. 31)<br>Article 6(gg) (new) |
| | (gg) not to accept for redistribution products that have been returned if: |
| | they are not in their original, sealed and unopened packaging and are not in good condition; |
| | (Amendment No. 32)<br>Article 7, title (new) |
| | Qualifications and duties of personnel in charge |

| Commission text | Amendments |
|---|---|
| | (Amendment No. 33)<br>Article 7(1a)(new) |
| | 1a. The public service obligations imposed by certain Member States on wholesalers established in their territories shall not be affected by this directive. |
| | (Amendment No. 34)<br>Article 8 |
| 1. All pharmacists, as well as all persons authorized to supply medicinal products to the public, shall be required to keep accurate records, possibly computerized, giving the following details at least for each transaction of medicinal products received:<br>- date,<br>- name and pharmaceutical form of the medicinal product,<br>- quantity received,<br>- name and address of the supplier. | 1. All pharmacists, as well as all persons authorized to supply medicinal products to the public, shall be required to keep accurate records, possibly computerized, or a file of documents from suppliers, giving the following details at least for each transaction of medicinal products received or dispatched, such as to enable them to participate in any recall action which may take place:<br>- date,<br>- name and pharmaceutical form of the medicinal product,<br>- quantity received and supplied,<br>- name and address of the supplier and prescriber, |
| 2. The records referred to in paragraph 1 shall be kept available to the competent authorities, for inspection purposes, for a period of three years. | 2. The records or files of documents referred to in paragraph 1 shall be kept available to the competent authorities, for inspection purposes, period of three years. |
| | 3. If an emergency plan comes into effect, the pharmacist shall ascertain whether he has batches of the product or products concerned in stock. |

| Commission text | Amendments |
| --- | --- |
| | (Amendment No. 35)<br>Article 10 |
| If appropriate, the Commission shall publish guidelines on good distribution practices. In that case the pharmaceutical committee instituted by Council Decision 75/320/EEC[1] shall be consulted. | Within a period of two years from the date of adoption of this directive, the Commission shall publish guidelines on good distribution practices. It shall update this publication annually. It shall consult for this purpose the pharmaceutical committee instituted by Council Decision 75/320/EEC. |

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[1] OJ No. L 47, 9.6.1975, p. 23

A

**DRAFT LEGISLATIVE RESOLUTION**
(Cooperation procedure: first reading)

embodying the opinion of the European Parliament on the Commission proposal for a Council directive on the wholesale distribution of medicinal products for human use

The European Parliament,

- having regard to the Commission proposal to the Council (COM(89) 607 final - SYN 229)[2],

- having been consulted by the Council pursuant to Article 100a of the Treaty (C3-0113/91),

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection and the opinions of the Committee on Economic and Monetary Affairs and Industrial Policy and the Committee on Budgets (A3-.../..),

1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;

2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EEC Treaty;

3. Calls on the Council to incorporate Parliament's amendments in the common position that it adopts in accordance with Article 149(2)(a) of the EEC Treaty;

4. Instructs its President to forward this opinion to the Council and Commission.

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[2] OJ No. C 58, 8.3.1990, p. 16

B

## EXPLANATORY STATEMENT

Distribution is the intermediate stage when a medicinal product reaches the retailer from the manufacturer, during which product quality, safety and efficacy depend on optimum storage, transport, handling and knowledge of the physico-chemical and biological properties of the product concerned.

In economic terms, the distributive sector has become increasingly important, accounting for 8 to 13% of the sector's entire turnover and employing tens of thousands; it has been characterized in recent years by a major process of concentration, as has manufacturing.

As regards organizational setup in general, however, there are major differences in some Community countries in specific areas. In Spain, for example, cooperatives operate in the distributive sector, while, in Belgium, there are still small firms operating (39), 10 of which are pharmacists' cooperatives and account for 42% of the volume of pharmaceutical products distributed in the country.

Many countries have adopted specific rules, but the position at present is uncertain and lacks consistency. In particular:

- not all countries insist on an authorization;

- not all countries have laid down the requirements to be met by the person in charge of technical organization (in France, that person must be a member of the Pharmacists' Association);

- duties and responsibilities are not clearly defined;

- inspections are not comprehensive and are often not carried out.

To date, no Community legislation has applied specifically to the distributive sector. Inspections of manufacturing and commercial establishments are referred to only in Article 26 of Directive 75/319[3]; but this is because of the persistent failure to distinguish between manufacturing and imports and not because direct action was taken to deal with the specific problem in question.

Community action is all the more necessary, then, since it is precisely the area of trade between the Member States and between them and third countries which is the source of some of the more worrying distortions on, and damage to, the medicinal-products market.

The fact that there are parallel markets via which a sizeable proportion of production is withdrawn from the official distribution chain (manufacturer, distributor, retailer), and put through a further intermediate stage (manufacturer, distributor in one Member State, distributor in a second Member State, retailer), can most certainly be termed a distortion of the market.

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[3] OJ No. L 147, 9.6.1975

What usually happens during this intermediate stage is that products are improperly handled in a variety of ways with a view to obtaining an authorization to market the product concerned in a second Member State at a higher price than in the first Member State.

The problems in this regard are those of:

1. Legality;

2. Fair competition vis-à-vis firms operating in one Member State only;

3. Consumer safety, since the products are improperly handled in order simply to increase their commercial value rather than to enhance their medicinal value.

Furthermore, over the last few years, uncontrolled distribution activities have been a factor helping to establish a black market in medicinal products, which is a serious and dangerous development; this market exists side by side with the market in narcotic substances, albeit less prominent and less tangible. The preferred routes are to be found precisely in those areas where there are fewer checks; and these include the distribution chain for veterinary products.

The objectives behind the proposal for a directive (COM(89) 607 - SYN 229) therefore merit our wholehearted support.

We take the view, however, that the measures proposed are inadequate in that they:

(a) fail to make the entire distribution chain transparent;

(b) fail to delimit clearly the duties and responsibilities to be discharged at the various manufacturing, distribution and retail levels;

(c) fail to lay down sound distribution practices for the entire Community.

The amendments proposed are designed to respond to these points, with a view to making the proposal a more fitting and more effective vehicle for realizing the objective of a single market while fully taking heed of the safety and interests of the consumer including his economic interests.

# OPINION

(Rule 120 of the Rules of Procedure)

of the Committee on Economic and Monetary Affairs and Industrial Policy
for the Committee on the Environment, Public Health and Consumer Protection

Draftsman: Mr SISO CRUELLAS

At its meeting of 27 June 1990, the Committee on Economic and Monetary Affairs and Industrial Policy appointed Mr SISO CRUELLAS draftsman.

At its meetings of 26-28 June, 25 and 27 September and 15-16 October 1990, the committee considered the draft opinion. It adopted its conclusions by 20 votes to none, with one abstention.

The following took part in the vote: Beumer, chairman; Fuchs, vice-chairman; Siso Cruellas, draftsman; Cassidy, Cox, Ernst de la Graete, Herman, Lulling, Merz, Metten, Pinxten, Rogalla, Speciale, Amaral (for de Donnea), Martinez (for Megret), Nielsen (for Visentini), Peter (for Ford), Randzio-Plath (for Hoff), Titley (for Seal), Van der Waal (for Lataillade) and Navarro (for Gallenzi) pursuant to Rule 111(2).

## I. Proposal for a directive on the wholesale distribution of medicinal products for human use

### 1. Contents of the proposal

#### (a) The present situation

The distribution systems for pharmaceuticals have hitherto been organized along national lines, and cross-frontier distribution systems have been the exception. This situation will change in the future; from now on, it will be necessary to take account of parallel imports[4], and also of the EC Court of Justice ruling that a Member State may not prevent a wholesaler established in another Member State from directly supplying pharmacies in its territory. This process will be accelerated by the completion of the internal market.

It is now desirable to regulate the wholesale distribution of medicinal products in the Community, thus superseding the present multiplicity of national regulations.

#### (b) The proposed control measures

The objective of the Commission proposals is to ensure, in the context of the increasing internationalization of the wholesale distribution system in the Community, that medicinal products are stored, transported and handled in adequate conditions. The proposed measures also concern the safety of supplies and, in particular, the capacity of the distribution system to effect, as quickly as possible, the supply of medicinal products and, where necessary, their withdrawal from the market.

To this end, the directive proposes that a specific authorization should be issued for wholesale distribution (see Article 3). Such an authorization would be issued by the Member State in which the wholesaler's storage premises is situated and only on condition that a certain number of minimum requirements were met (suitable premises, qualified personnel and compatibility of the products distributed).

Should these conditions not be fulfilled, the Member State would be enabled to suspend or revoke the authorization.

The Commission would also, if appropriate, publish guidelines on good distribution practice (see Article 10).

### 2. Comments

The completion of the single market will probably lead to an increase in the cross-frontier circulation of pharmaceuticals. The proposal for a directive therefore corresponds to a specific need. However, the term 'wholesaler' should be more precisely defined (cf. Articles 1 and 3). It is also essential that the conditions of storage, preservation and handling should be subject to the strictest possible rules. In fact, many products are created by advanced technologies, and it is vital that they should reach the patient both rapidly

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[4] European Court reports: Cases 87 and 88/85, 27 May 1986

and undamaged. Further specifications to this end could be added to the text (see Articles 5 and 6).

The same applies to Article 9, which in practice only concerns dispensers (pharmacists and hospitals) and not the public.

It may also be asked whether it is desirable to include rules concerning pharmacists in this directive (see Articles 7 and 8), given that they are retailers.

## DRAFT AMENDMENTS

to the proposal for a directive on the wholesale distribution of medicinal products for human use

| Commission text | Amendments |
|---|---|
| | Amendment No. 1<br>Article 1(2) |
| 2. For the purposes of this Directive, the definition of 'medicinal product' set out in Article 1 of Council Directive 65/65/EEC[1] shall apply. In addition 'wholesale distribution of medicinal products' shall mean all activities consisting of procuring, holding, supplying, importing or exporting medicinal products. | 2. For the purposes of this Directive, the definition of 'medicinal product' set out in Article 1 of Council Directive 65/65/EEC[1] shall apply. In addition 'wholesale distribution of medicinal products' shall mean all activities consisting of procuring, holding, supplying, importing or exporting medicinal products undertaken with manufacturers, importers or other wholesale distributors or with pharmacists or persons expressly authorized to dispense medicinal products to the public. |

| Commission text | Amendments |
|---|---|
| | Amendment No. 2<br>Article 3(1) |
| 1. Member States shall take all appropriate measures to ensure that the distribution of medicinal products is subject to the possession of an authorization to engage in activity as a wholesaler in medicinal products. | 1. Member States shall take all appropriate measures to ensure that the distribution of medicinal products is subject to the possession of an authorization to engage in activity as a wholesaler in medicinal products, except where the distributer is the holder of the marketing authorization for the medicinal product being distributed. |
| | Amendment No. 3<br>Article 3(2) |
| 2. Pharmacists and persons expressly authorized to supply medicinal products to the public shall be exempt from obtaining the authorization referred to in paragraph 1, provided that they do not engage, principally or secondarily, in any activity as wholesaler of medicinal products. | 2. Pharmacists and persons expressly authorized to dispense medicinal products to the public shall not be obliged to obtain the authorization referred to in paragraph 1, provided that they do not engage, principally or secondarily, in any activity as wholesaler of medicinal products.<br><br>The following shall, for this purpose, not be classified as wholesale distribution activities: obtaining medicinal products from the manufacturers, importers or wholesale distributors for supply to the public and returning medicinal products acquired from them. |
| | Amendment No. 4<br>Article 5(a) |
| (a) they must have suitable and adequate premises, such as to ensure good conservation of the medicinal products warehoused; | (a) they must have suitable and adequate premises, such as to ensure good conservation of the medicinal products warehoused and adequate arrangements for the proper handling and transport of medicinal products; |

| Commission text | Amendments |
|---|---|
| | Amendment No. 5<br>Article 6, first line |
| Holders of the authorization referred to in Article 3(1) shall be required: | Holders of the authorization referred to in Article 3(1) shall be obliged: |
| | Amendment No. 6<br>Article 6(b) |
| (b) to obtain 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 this authorization under the terms of Article 3(2); | (b) to obtain medicinal products only from persons who are themselves in possession of a manufacturing authorization or the authorization referred to in Article 3(1) or who are exempt from obtaining this authorization under the terms of Article 3(2); |
| | Amendment No. 7<br>Article 6(c) |
| (c) to supply medicinal products only to persons who are themselves in possession of the authorization referred to in Article 3(1) or who are exempt from obtaining this authorization under the terms of Article 3(2); | (c) to supply medicinal products only to persons who are themselves in possession of the authorization referred to in Article 3(1) or who are exempt from obtaining this authorization under the terms of Article 3(2), or to other persons or entities authorized to dispense medicinal products to the public. |

## CONCLUSION

The three proposals for directives are aimed at rationalizing the distribution of medicinal products for human use in order to facilitate their circulation in conditions offering the highest possible security to the patient.

They are consequently in line with the objective of creating a large unified market in a sector which has hitherto been relatively compartmentalized.

- Proposal concerning the wholesale distribution of medicinal products for human use

The completion of the internal market by 1992 will lead to an increase in the cross-frontier movement of pharmaceuticals. In this context, the proposal for a directive on the wholesale distribution of medicinal products for human use lays down the arrangements governing the issue of specific authorizations for wholesale distribution in the Community.

The proposal is to be welcomed, but there is a need to ensure, in the interests of both patients and manufacturers, that all the necessary guarantees are present in respect of storage, preservation and handling.

# O P I N I O N

of the Committee on Budgets

on the proposals for Council Directives
on the rational use of medicinal products
(COM(89) 607 final)

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Dear Mr Collins,

At its meeting of 1 June 1990 the Committee on Budgets considered the above subject.

After considering the proposal itself and the financial implications thereof, the Committee on Budgets decided to deliver a favourable opinion.

Yours sincerely,

(sgd) Thomas von der VRING

The following were present: von der Vring, chairman; Arias Canete, Böge, Colajanni, Colom i Naval, Elles, Kellett-Bowman, Langes, Lo Giudice, McCartin (for Forte), Miranda da Silva, Pasty, Theato, Tomlinson and Wynn.