in the first Member State, of a requirement to have at his disposal on its territory premises for storage and technical equipment when the importer complies with the conditions laid down in that regard by the law of the Member State in which his headquarters are situated constitutes a measure having an effect equivalent to a quantitative restriction on imports prohibited by Article 30 of the Treaty and is not justified on the ground of the protection of public health within the meaning of Article 36.

OPINION OF MR ADVOCATE GENERAL MANCINI
delivered on 22 April 1986 *

Mr President,
Members of the Court,

1. In two interlocutory judgments of 26 March 1985 the Conseil d'Etat [State Council], Luxembourg, asked the Court to interpret several aspects of the Community rules governing the marketing of proprietary medicinal products.

On 19 October 1984, two Belgian companies, Legia of Liège and Gyselinx-Cophalux of Namur, were refused an authorization to engage in the wholesale supply of medicinal products in the Grand Duchy of Luxembourg by the Minister for Health of that country. As the reasons for his decision, the Minister stated that the applicants had neither their registered office in Luxembourg nor premises for the storage of goods there, as required by the Grand Ducal Order of 12 July 1927 and the Law of 4 August 1975. He also informed them that if they wished to continue their activities in the Grand Duchy, they would have to make use of the services 'of a wholesaler or importer established there'.

Legia and Gyselinx challenged that decision before the Conseil d'Etat, which considered that, in order to resolve the dispute, it was necessary to ask the Court of Justice to rule on the following question:

'Do Article 30 of the EEC Treaty and Articles 17 (b) and 19 (d) of 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 (Official Journal 1975, L 147, p. 13) permit the competent authority of the importing Member State to impose on an importer of medicinal products whose headquarters are situated in another Member State, in addition to the obligation to obtain authorization from the competent authority of the importing Member State, the obligation to maintain in the importing Member State premises and technical equipment which comply with the legal requirements laid down by the importing Member State and to which the inspection agents of that State have access at any time, when the importer is the holder, in the State in which his headquarters are situated, of the administrative authorization required by the laws of that State and in particular has at his disposal there suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements

* Translated from the Italian.

which the Member State in which his headquarters are situated lays down as regards both production and control and the storage of the products?'

2. Let me first say a brief word about the Community rules. The special nature of the sector under consideration, in which the requirements of the common market often conflict with the equally important duty to protect health, led the Council of the Communities to proceed in stages, by way of harmonizing rules, towards the removal of the many obstacles which the Member States had set in the way of trade in medicinal products. The four directives so far adopted affect only administrative intervention and supervision by the competent national authorities of the two phases preceding the distribution of such products, namely manufacture and marketing. With respect to them, Directives 65/65 (Official Journal, English Special Edition 1965-1966, p. 20) and 75/319 (Official Journal 1975, L 147, p. 13) provide for two separate authorizations.

With regard to the second authorization, let me point out that 'no proprietary medicinal product may be placed on the market in a Member State unless an authorization has been issued by the competent authority of that Member State' (Article 3 of Directive 65/65). The first authorization is issued by the authorities of the State in which the products are manufactured and, in regard to proprietary medicinal products manufactured in non-member countries, is replaced by an authorization to import (Article 16 of Directive 75/319). In other words, in the present state of Community law:

(a) Only medicinal products coming from non-member countries are subject to a specific authorization, whereas a Community trader wishing to export to another Member State medicinal products which have been produced in the Community or imported is merely required to obtain a marketing authorization in respect of each product from the authorities of that State;

(b) Apart from the requirement that an authorization must be obtained in every case, the rules governing distribution remain under the control of the national legislatures, though, of course, the limits laid down in Articles 30 *et seq.* of the Treaty must be respected.

In the light of those facts, I would observe that the reference by the Conseil d'Etat to Articles 17 and 19 of Directive 75/319 is clearly mistaken. Those provisions merely lay down the conditions which must be complied with in order to obtain the authorization to manufacture and, in regard to products originating in non-member countries, the authorization to import. Therefore they do not deal with the problem under consideration, which concerns the movement of medicinal products from Member States of the Community.

3. The Luxembourg rules are much more complex. Let me say first that the *manufacture* and *importation* of medicinal products are governed by the Law of 4 August 1975 and by the Order of 12 November 1975 implementing it. According to Article 6 of the Law, 'the importation of medicinal products for commercial purposes shall be subject to prior authorization by the Minister for Health. Such authorization may be granted only for medicinal products in respect of which marketing authorization has been obtained . . . '. By virtue of Articles 8 and 13 of the Order, the applicant must also have at his disposal adequately qualified staff, premises, industrial plant and scientific apparatus suitable for the scale and variety of the business to be carried on and

of the verifications required to be carried out.

On the other hand, *placing on the market* is governed by the Law of 11 April 1983 (which supersedes the Law of 4 August 1975, to which reference is made in the judgments of the national court). Article 3 of the new law, which is intended to give effect to the principles laid down in Directives 65/65 and 75/319, provides that: 'The marketing of any proprietary pharmaceutical product or ready-prepared medicinal product shall be subject to prior authorization by the Minister for Health.' *Wholesale trading* and *distribution* are governed by the Grand Ducal Order of 12 July 1927. That Order provides that any person who wishes to engage in wholesale trading in medicinal preparations must obtain an authorization from the competent Minister, indicating the name of the pharmacist with whom he proposes to associate for the purposes of that activity and the location of the premises in which the goods are to be stored. The goods may be sold only through Luxembourg pharmacies and chemists (Articles 1, 2 and 7).

It is also clear from the national court's judgments that in a circular of 15 October 1984 sent to wholesalers, importers and pharmacists resident in Luxembourg, the Head of the Pharmacy and Medicinal Preparations Division (Health Directorate) gave the following clarification of the legislation in force:

(1) Only wholesalers who are authorized by the Minister for Health and are established in Luxembourg are entitled to supply pharmacies in Luxembourg;

(2) Authorized importers are entitled to supply only authorized wholesalers;

(3) Dispensing pharmacists are required to obtain their supplies only from authorized wholesalers.

Finally, with regard to the scope *ratione personae* of the system just described, the Conseil d'Etat stated in the grounds for its judgments that 'the term "importer" must be construed as meaning a wholesaler or pharmacist established in Luxembourg who obtains his supplies from a foreign supplier. [Therefore] the provisions of that Law (the Law of 4 August 1975 on the importation of medicinal preparations) do not apply to foreign suppliers who undertake the exportation of medicinal preparations (to Luxembourg)'. By contrast, the provisions of the Order of 12 July 1927 governing wholesale trading are addressed to all persons intending to pursue that activity in the Grand Duchy.

To sum up, Luxembourg law imposes the following obligations on all three types of undertakings dealing in medicinal products (importers, wholesalers, foreign suppliers), in addition to the marketing authorization which is always required:

(a) *Importers* are required to have an import licence, which is issued on condition that the importer has suitable premises and equipment in Luxembourg. They may only supply wholesalers (Articles 6 and 7 of the Law of 4 August 1975 and Point 2 of the Circular of 15 October 1984);

(b) *Wholesalers*, even if they are not Luxembourg nationals, are required to obtain an authorization to engage in wholesale trading and, in order to pursue that activity, must obtain the assistance of a Luxembourg pharmacist holding the appropriate diploma. The premises used for storage and the equipment necessary for the business must be located in Luxembourg and must be approved by the local health authorities. Medicinal products may be sold only to pharmacies in the Grand Duchy (Articles 1, 2 and 7 of the Order of 12 July 1971 and Point 1 of the aforementioned circular);

(c) *Foreign suppliers* who supply only wholesalers in Luxembourg are not

required to apply for an authorization or to have at their disposal suitable premises and equipment in the Grand Duchy. However, if they wish to supply Luxembourg pharmacies without dealing with a local wholesaler, they must comply with all the conditions necessary to obtain an authorization to engage in wholesale trading and, in particular, the obligation to acquire appropriate premises for storage in Luxembourg (Articles 1, 2 and 7 of the Order of 12 July 1927). That is precisely the situation in which the plaintiffs in the main proceedings find themselves.

From my explanation and as a result of the clarification obtained during the hearing, the question to be answered by the Court is therefore clearer and may be reformulated as follows: since, on the basis of the existing Community rules, a Member State cannot prevent the marketing on its own territory of medicinal products which comply with the requirements concerning manufacture and placing on the market laid down in the Council directive but remains free to regulate distribution and sale, can it be argued that Articles 30 *et seq.* of the Treaty permit the authorities of that State to require a supplier residing in another Member State who wishes to supply directly pharmacies in the first State to maintain on the territory of that State premises and equipment which comply with the requirements of that State and to which the inspection agents at that State have access at any time, when he already has at his disposal in the State in which his headquarters are situated premises and equipment complying with the requirements which that State lays down as regards the protection, control and storage of goods?

4. During the written procedure, observations were submitted by the plaintiffs in the main proceedings, the Commission of the European Communities, the Italian Government and the Luxembourg Government. All except the latter concluded that the requirement laid down in the Law of 4 August 1975 that an import licence should be obtained in respect of products originating in other Member States was incompatible with Community law. For pharmaceutical products, Directives 65/65 and 75/319 provide only for authorizations for the manufacture and placing on the market of such products. Nor could it be otherwise since in intra-Community trade the need to protect public health has already been met by the supervision of the manufacturers by the authorities of the place in which manufacture takes place and of the traders who place the product on the market by the authorities of the State concerned. Moreover, since the rules in question have been harmonized by a directive, the exceptions laid down in Article 36 of the Treaty may no longer be relied on (judgment of 5 April 1979 in Case 148/78 *Pubblico Ministerio* v *Ratti* [1979] ECR 1629).

I regard those remarks as justified. Moreover, they are not the only grounds on which the Luxembourg system may be criticized. There is also, for example, the rule prohibiting local importers and wholesalers from exporting and selling medicinal products in other Member States. Such restrictions are of their very nature contrary to the provisions of the aforementioned directives, the purpose of which, at least in regard to authorizations, is to remove all obstacles to intra-Community trade. Although it cannot be denied that they do not expressly prohibit restrictive national measures, the Court has decided that their 'silence may not be interpreted as authorizing Member States to introduce or

maintain' such restrictions (judgment of 28 February 1984 in Case 247/81 *Commission* v *Federal Republic of Germany* [1984] ECR 1111).

However, the importance of the foregoing is relative. The plaintiffs in the main proceedings are in fact two Belgian undertakings who wish to export and sell medicinal products in Luxembourg. According to the national court, the rules contained in the Law of 4 August 1975 on the importation of such products are not applicable in this case. Furthermore, in reply to a question from the Court, the Luxembourg Government states that that Law does not require suppliers residing in another Member State who wish to supply only wholesalers in the Grand Duchy to obtain an import licence and to have premises and equipment in Luxembourg. The real core of the question on which the Court is asked to give a preliminary ruling is thus not the lawfulness of that authorization but the compatibility with Community law of the rule which makes the right to supply Luxembourg pharmacists directly subject to the possession of storage facilities and suitable equipment on the territory of the Grand Duchy. It seems to me that it follows that in order to reply to the national court, the only provisions on which the Court can base its decision are those contained in Articles 30 *et seq.* of the Treaty. As I have already said, the four directives so far adopted have not harmonized the rules governing wholesale trading in medicinal products. They therefore cannot be of any assistance in resolving the problem referred to the Court.

5. Let me repeat that the Luxembourg rules concerning the distribution of medicinal products require wholesalers residing in another Member State who wish to supply Luxembourg pharmacies directly to comply with two separate requirements:

(a) they must have at their disposal in the Grand Duchy suitable storage facilities for such products and adequate technical equipment; and

(b) they must arrange for their premises to be accessible to the health authorities at all times.

The Luxembourg Government contends that such an obligation does not constitute a measure having equivalent effect within the meaning of Article 30 because it applies to all wholesalers, whether they reside in Luxembourg or abroad, who supply pharmacies in Luxembourg. Furthermore, it does not imply that foreign suppliers must have their registered office in Luxembourg or maintain a representative there. The present case therefore cannot be assimilated to the one on which the Court ruled in Case 247/81, cited above.

However, in putting forward this argument, the Luxembourg Government is confusing two different situations: wholesale trading in medicinal products and exportation of such products to Luxembourg by a wholesaler residing in another Member State. It is clear that Member States are entitled to require any person who wishes to pursue the first of those activities on its territory to obtain an administrative authorization in order to meet public interests. However, the foreign supplier in this case is not in fact seeking to trade as a wholesaler in the Grand Duchy. He merely wishes to supply local pharmacies directly. Indeed, if he sells the same consignment of goods to a Luxembourg wholesaler, he does not need either a licence or storage facilities in the Grand Duchy. Thus to extend to him the rules governing wholesale trading and to require him to maintain premises in Luxembourg even though he already has

such premises at his disposal in the State in which his headquarters are situated imposes on him additional costs and so obstructs his access to the market in the importing State, or even renders such access impossible.

Since such a measure is certainly contrary to the prohibition contained in Article 30 of the EEC Treaty, it is then necessary to ascertain whether the measure can be justified on the basis of Article 36 and, in particular, of the rule concerning the protection of health. On this question, the Luxembourg Government points out that the medicinal products sold in Luxembourg are nearly all imported and that, in the absence of the contested obligation, the local health authorities would have no opportunity of exercising effective control of the market. Such control is essential for reasons of public order to meet the following requirements:

(a) to check whether the products are in a good condition;

(b) to withdraw from the market consignments which do not comply with the legal requirements;

(c) to ensure regular supplies to the market;

(d) to detect unlawful sales of toxic substances; and,

(e) to supervise the granting of any discounts or other advantages on wholesale transactions.

Let me say at once that the last three requirements are of very little weight. The fifth appears to be motivated by concerns of a protectionist nature rather than by the need to protect health. The fourth (preventing the sale of narcotic drugs) can be achieved by other methods which are both more effective and more consistent with Community law, such as customs controls or inspections carried out in the individual pharmacies. With regard to the third (the regular supply of the Luxembourg market), it seems to me that it is mainly up to local suppliers and wholesalers to ensure such supplies. However, the other two requirements, concerning the quality of medicinal products placed on the market and their conformity with national requirements, deserve more detailed examination. As the representative of the Luxembourg Government observed on this point, there are medicinal products on the European markets which have identical names and packaging but have slightly different constituents. It is precisely in regard to such products, which appear identical to consumers but are substantially dissimilar, that periodical inspections must be carried out in the places from which pharmacies are directly supplied. Such inspections are possible only if those places are located on the national territory.

What can be said in regard to that argument? It seems to me that the problem to which it relates has already been largely resolved by Community law. Thus, according to Article 11 of Directive 65/65, the Member States may suspend or revoke an authorization to place a proprietary medicinal product on the market where that product proves to be harmful under normal conditions of use or where its qualitative and quantitative composition is not as declared. Furthermore, Article 13 provides that the outer packages of medicinal products must indicate the name of the product, the name and permanent address of the person responsible for placing it on the market and, where applicable, of the manufacturer, and the 'expiry date for proprietary products with a shelf-life of less than three years'. Finally, Article 30 of Directive 75/319 requires the Member States to take all appropriate measures to ensure that the competent authorities concerned communicate to each other such information as is appropriate to guarantee

that the requirements for the marketing of proprietary medicinal products are fulfilled.

However, that is not all. The Luxembourg legislature itself does not share its Government's concern, since it has recently amended the rules governing the marketing of medicinal products, which no longer require foreign suppliers to have storage facilities in Luxembourg and provide for inspections to be carried out prior to wholesale distribution and sale to the public. For example, Articles 4 and 13 of the Law of 11 April 1983 prohibit the sale and *importation* of medicinal products which are not covered by a marketing authorization issued by the Luxembourg authorities. Under Article 7, the holder of such an authorization, and hence also foreign suppliers who market their products in Luxembourg, must immediately transmit to the Minister for Health any new information which they obtain concerning the medicinal product and, in particular, any prohibitions and restrictions imposed by the authorities in the country of origin and in the countries in which the product is marketed. Furthermore, the authorization may be withdrawn, not only on the grounds laid down in the directives, but also when the name of the medicinal product:

(a) coincides with that of another product of different composition which is already on the market; or

(b) is likely to give rise to error or, because of the similarity of name, cause confusion as to its therapeutic effect (Article 11).

In my view, that is sufficient reason for the Court to decide that the dangers alleged by the Luxembourg Government are not substantial or, at least, are not such as to justify recourse to measures which obstruct intra-Community trade. That conclusion appears all the more reasonable because it is supported by a final and, as it were, practical argument: it is not clear for what purpose foreign suppliers should be required to have storage facilities in Luxembourg when the Luxembourg authorities are unable to require them to store a certain quantity of samples of each proprietary medicinal product there.

6. On the basis of the foregoing considerations, I propose that the Court should reply as follows to the question referred to it by the Luxembourg Conseil d'Etat by a judgment of 26 March 1985 in proceedings between Legia and Gyselinx-Cophalux and the Minister for Health:

Where an undertaking obtains in the Member State in which its headquarters are situated the administrative authorizations required by the legislation of that State for the marketing of proprietary medicinal preparations and where the products exported by it to another Member State are covered by a marketing authorization issued by the competent authorities of the latter State, Articles 30 *et seq.* of the EEC Treaty do not permit the competent authority of the importing Member State to impose on the undertaking concerned an obligation to maintain on its territory premises and technical equipment which comply with the legal requirements laid down by the importing Member State and to which the inspection agents of that State have access at any time.