JUDGMENT OF THE COURT (Fifth Chamber)
27 May 1986 *

In Joined Cases 87 and 88/85

REFERENCES to the Court under Article 177 of the EEC Treaty by the Conseil d'Etat du grand-duché de Luxembourg, comité du contentieux [Contentious Proceedings Division of the State Council of the Grand Duchy of Luxembourg] for a preliminary ruling in the proceedings pending before that court between

Société coopérative des laboratoires de pharmacie Legia, Liège (Belgium)

and

Louis Gyselinx et fils — Cophalux, Namur (Belgium)

and

Minister for Health, Luxembourg

on the interpretation of Article 30 of the Treaty and certain provisions of Directive 75/319/EEC of 20 May on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (Official Journal L 147, p. 13) for the purpose of assessing the compatibility with Community law of national rules governing the importation and marketing of medicinal products,

THE COURT (Fifth Chamber)

composed of: U. Everling, President of Chamber, R. Joliet, O. Due, Y. Galmot and C. Kakouris, Judges,

Advocate General: G. F. Mancini
Registrar: P. Heim

* Language of the Case: French.

after considering the observations submitted on behalf of

Société coopérative des laboratoires de pharmacie Legia and Louis Gyselinx et fils — Cophalux, by G. Margue, avocat, assisted by G. Baudinet,

Minister for Health, Luxembourg, by Raymond Mousty, conseiller du gouvernment, acting as Agent, and Nicolas Decker, avocat,

the Commission of the European Communities, by Michel van Ackere, acting as Agent,

the Italian Government, by Marcello Conti, avvocato dello Stato,

after hearing the Opinion of the Advocate General delivered at the sitting on 22 April 1986,

gives the following

JUDGMENT

(The account of the facts and issues which is contained in the complete text of the judgment is not reproduced)

Decision

1 By two interlocutory judgments of 26 March 1985, the Conseil d'Etat du grand-duchy de Luxembourg, comité du contentieux, referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty two questions on the interpretation of Article 30 of the Treaty and of certain provisions 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 for the purpose of assessing the compatibility with Community law of national rules governing the importation and marketing of medicinal products. Those questions are drafted in identical terms.

2 The questions arose in proceedings between two companies subject to Belgian law, Société coopérative des laboratoires de pharmacie Legia, whose registered office is in Liège, and Louis Gyselinx et fils — Cophalux, whose registered office is in Namur, and the Luxembourg Minister for Health. On 17 February 1983 and 23 December 1982 respectively, the two companies applied to the Luxembourg Minister for Health for authorization to import medicinal products and sell them wholesale to pharmacists established in the Grand Duchy of Luxembourg.

3 Their applications were refused by ministerial decisions of 19 October 1984 on the ground that, contrary to Luxembourg law, the applicants' registered office was not situated in Luxembourg and they did not even have at their disposal there premises for the storage of medicinal preparations.

4 The Belgian companies concerned challenged those decisions before the Conseil d'Etat and claimed that the Luxembourg rules which were relied on against them were incompatible with Community law. Since it considered that a question concerning the interpretation of Community law had arisen, the Conseil d'Etat stayed the proceedings and referred to the Court of Justice 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 which the Member State in which his headquarters are situated lays down as regards both protection and control and the storage of the products?'

5 In order to achieve the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, the Council adopted, in particular, two directives — Directive 65/65 of 26 January 1965 (Official Journal, English Special Edition 1965-1966, p. 20) and Directive 75/319 of 20 May 1975 (Official Journal L 147, p. 13) — which were amended by Directive 83/570 of 26 October 1983 (Official Journal L 332, p. 1).

6 Those directives make provision for two administrative authorizations. They provide first for an authorization to manufacture, which is issued by the Member State in which manufacture takes place and is replaced by an authorization to import where manufacture takes place in a non-member country. Article 17 (b) of Directive 75/319, cited in the order for reference, provides that in order to obtain such an authorization, the applicant must have at his disposal for the manufacture or importation from non-member countries of proprietary medicinal products suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements which the Member State concerned lays down. Article 19 (d) of the same directive, also cited in the order for reference, provides that the holder of an authorization to manufacture or import from a non-member country must allow the agents of the competent authority of the Member State concerned access to his premises at any time. Secondly, the directives provide for an authorization to place proprietary medicinal products on the market, issued by each Member State in regard to its own market and in respect of each proprietary medicinal product, on the application of the manufacturer or the person responsible for placing the product on the market in the Member State concerned. That authorization may be refused only on the grounds set out in the directive.

7 An examination of the directives shows that although they effected a detailed harmonization of the rules governing, in particular, the manufacture of proprietary medicinal products, their importation from non-member countries, authorization to place such products on the market and the free movement within the Community which was their objective, they did not approximate the rules governing the marketing of medicinal products within each Member State. Those rules are therefore still determined by the Member States, subject to compliance with the provisions of the Treaty.

8 By virtue of the provisions laid down in Luxembourg by law, regulation or administrative action relating to the marketing of medicinal products, as they have been set out in the order for reference and further elucidated at the hearing by the representatives of the Luxembourg Government, the following rules apply in the Grand Duchy of Luxembourg:

(i) Wholesalers established on the territory of the Grand Duchy, whether or not they are of Luxembourg nationality, are required to obtain an authorization in order to carry on their activities and must, in particular, have at their disposal in Luxembourg premises and technical equipment authorized by the

local health authorities and subject to control by them. No other wholesalers are authorized to supply pharmacies in the Grand Duchy;

(ii) Suppliers in other Member States, who are regarded as exporters, are exempt from the obligation to obtain a special authorization permitting them to supply medicinal products in Luxembourg and to have at their disposal in the Grand Duchy suitable premises and technical equipment, on condition that they supply only authorized wholesalers;

(iii) However, if such suppliers wish to supply Luxembourg pharmacies directly, without dealing with a local wholesaler, they must meet all the above-mentioned requirements applicable to wholesalers and, in particular, must have at their disposal in Luxembourg premises suitable for the storage of medicinal products. For that purpose, they are required to obtain the 'authorization to import' provided for by Article 6 of the Law of 4 August 1975, as amended, which, according to the information supplied by the Luxembourg Government, is not in the nature of an import licence for each consignment of medicinal products but is in fact a general authorization to carry on the business of a wholesaler - importer.

9 That is precisely the position in which the plaintiffs in the main proceedings find themselves, since they have at their disposal storage facilities in Belgium and wish to export and sell medicinal products directly to pharmacies in Luxembourg without storing the products.

10 Two preliminary remarks must be made: first, Articles 17 (b) and 19 (d) of Directive 75/319 of 20 May 1975, to which the national court refers, do not apply since they refer solely to medicinal products imported from non-member countries; secondly, the discussion which took place before the Court on the compatibility with Community law of a system of import licences for medicinal products is of no interest in the light of the explanations provided at the hearing as to the scope of the authorization to import mentioned above.

11 Consequently, the question raised by the national court asks essentially whether Articles 30 *et seq.* of the Treaty permit a Member State to impose on an importer of medicinal products who resides in another Member State and wishes to supply directly pharmacies in the first Member State an obligation to have at his disposal

on its territory premises and equipment which comply with its law, when he already has at his disposal, in the Member State in which he resides, premises and equipment complying with the requirements of that State's law.

12 Under Article 30 of the Treaty, quantitative restrictions on imports and all measures having equivalent effect are prohibited in trade between the Member States. The Court has consistently held that all trading rules enacted by the Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade must be regarded as measures having an effect equivalent to quantitative restrictions.

13 The plaintiffs in the main proceedings, the Government of the Italian Republic and the Commission rely on the judgment of the Court of 28 February 1984 in Case 247/81 (*Commission* v *Federal Republic of Germany* [1984] ECR 1111) in support of the proposition that the requirement that suppliers of proprietary medicinal products established in a Member State should maintain in another Member State premises and technical equipment complying with the legal requirements of that State in order to be able to supply pharmacies there constitutes a measure having an effect equivalent to a quantitative restriction on imports, contrary to Article 30 of the Treaty. They claim that such a requirement is likely to involve additional costs for the importers and make access to the market in the importing Member State difficult or even impossible.

14 On the other hand, the Luxembourg Government contends that such a requirement is not contrary to Article 30 of the Treaty since it is applied without distinction to all wholesalers, whether or not they are of Luxembourg nationality, and, in contradistinction to the case decided in the aforementioned judgment of the Court of 28 February 1984, does not require wholesalers to establish their headquarters on Luxembourg territory or to have a representative there.

15 It must be pointed out that, in a situation such as that concerned here, in which a supplier established in one Member State does not wish to carry on a wholesale business in another Member State but merely wishes to supply directly and without intermediate storage pharmacies located in the latter State, legislation whose purpose or effect is to apply to him the rules governing wholesale trading, by

requiring him, in particular, to have at his disposal premises in the importing Member State even though he already has such premises at his disposal in the State in which his headquarters are situated, renders him liable to additional costs.

16 Moreover, although such an obligation apparently applies without distinction, it in fact penalizes traders who are nationals of other Member States inasmuch as it requires them to maintain premises for storage in more than one Member State. Accordingly, Article 30 of the Treaty does not permit the imposition of an obligation such as the one at issue in this case, which constitutes a measure having an effect equivalent to a quantitative restriction.

17 It remains to be considered whether, as the Government of the Grand Duchy of Luxembourg contends, Article 36 of the Treaty may be interpreted as justifying such an obligation on grounds of public health. It has been argued that the obligation at issue constitutes a measure which is essential for the protection of the health and life of persons residing in the Grand Duchy. The measure is said to be essential if the Luxembourg health authorities are to be in a position to check whether medicinal products are in a good condition, to withdraw consignments which do not comply with the conditions laid down in the marketing authorization, to ensure regular supplies to the market, to detect illegal sales of toxic substances and, lastly, to supervise the granting of any discounts or other advantages on wholesale transactions.

18 The plaintiffs in the main proceedings, the Government of the Italian Republic and the Commission claimed, above all at the hearing, that none of the above five grounds put forward by the Luxembourg Government could justify the contested decision. They argued that the same result could be achieved by less restrictive measures, such as cooperation between the Member States and the extension of certain specific checks at frontiers or in pharmacies. The contested requirement was therefore out of proportion to the objective which it was intended to achieve.

19 The principle underlying the arguments put forward by the Luxembourg Government cannot be contested. In the absence of a sufficient degree of harmonization at Community level, every Member State is entitled to adopt appropriate

measures in order to ensure the protection of public health on its territory. However, such measures are justified only if it can be shown that they are necessary for the attainment of that objective, referred to in Article 36 of the Treaty, and that such objective cannot be attained by measures which are less restrictive of intra-Community trade.

20 With regard to the first argument, concerning the need to check that the medicinal products are in a good condition, it must be pointed out that where a supplier in one Member State supplies pharmacies in another Member State directly, the authorities in the latter State have several opportunities of checking that the medicinal products are in a good condition without requiring the supplier to have at his disposal premises and equipment in the importing Member State. To that end, cooperation and exchange of information between the authorities of the two Member States will make it possible to ensure that the products at issue are in a good condition before their importation. In accordance with Article 26 of Directive 75/319, the inspectors of the importing Member State can also check the condition of medicinal products stocked in pharmacies in that State. The pharmacies in the importing Member State must themselves ensure that the expiry date, which under Article 13 of Directive 65/65 must appear on containers and outer packages of proprietary medicinal products, is respected.

21 With regard to the argument to the effect that, without the contested requirement, the health authorities would be unable to withdraw consignments which did not comply with the conditions under which the marketing authorization was granted, it must be pointed out that that argument has no more foundation than the preceding one. Under Directive 65/65, the competent authorities in the Member States may not issue an authorization to place a medicinal product on the market unless the constituents of the product are clearly stated and must refuse, suspend or revoke such authorizations where the product proves to be harmful in the normal conditions of use, where its therapeutic efficiency is lacking or where its qualitative and quantitative composition is not as declared. According to Articles 30 and 33 of Directive 75/391, Member States must also communicate to each other such information as is appropriate to guarantee that the requirements for the authorization to place medicinal products on the market are fulfilled and any other relevant information concerning decisions authorizing marketing or refusing or revoking a marketing authorization.

22 With regard to the argument to the effect that the contested requirement is merely intended to ensure regular supplies to the market, it must be pointed out that a Member State is certainly entitled, for the protection of public health, to require wholesalers established on its territory to have at their disposal stocks of medicinal products, particularly those of foreign origin, so that they will at all times be able to meet the demand for such products. However, that objective may be attained without its being necessary to require suppliers based in other Member States who wish to supply pharmacies and who are also able to meet orders placed by wholesalers, themselves to have at their disposal premises for storage in the importing Member State.

23 With regard to the argument to the effect that the contested requirement provides the only means of detecting illegal sales of narcotic drugs and toxic substances, it must be pointed out that checks carried out by the competent authorities both at customs posts and in pharmacies would also enable that legitimate objective to be attained.

24 Lastly, as regards the contention that it is necessary to supervise the granting of any discounts or other advantages on wholesale transactions, it is sufficient to point out that that argument has no connection with the need to protect public health.

25 Consequently, Article 36 of the Treaty cannot be interpreted as justifying an obligation such as that at issue in the main proceedings.

26 The reply to the national court must therefore be that Articles 30 *et seq.* of the Treaty do not permit the authorities of a Member State to require an importer of medicinal products whose headquarters are situated in another Member State and who wishes to supply directly pharmacies in the first Member State 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.

Costs

27 The costs incurred by the Government of the Italian Republic and by the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. As these proceedings are, so far as the parties to the main proceedings are concerned, in the nature of a step in the actions pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Fifth Chamber),

in answer to the question referred to it by the Conseil d'Etat du grand-duché de Luxembourg, comité du contentieux, by judgments of 26 March 1985, hereby rules:

Articles 30 *et seq. of the Treaty do not permit the authorities of a Member State to* require an importer of medicinal products whose headquarters are situated in another Member State and who wishes to supply directly pharmacies in the first Member State 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.

Everling Joliet

Due Galmot Kakouris

Delivered in open court in Luxembourg on 27 May 1986.

P. Heim
Registrar

U. Everling
President of the Fifth Chamber