OPINION OF MRS ADVOCATE GENERAL ROZÈS DELIVERED ON 11 MAY 1983 [1]

Mr President,
Members of the Court

This reference for a preliminary ruling comes to the Court by way of a judgment given by the President of the Arondissementsrechtbank [District Court], The Hague, on 4 July 1982 in interlocutory proceedings between Roussel Laboratoria BV and Others, on the one hand, and the Netherlands, on the other.

I — I think it would be useful to begin by giving a brief outline of the rules in the Netherlands relating to pharmaceutical products.

Such products may not be marketed in the Netherlands until they have been registered by the College ter Beoordeling van Geneesmiddelen [Board responsible for the approval of medicines], a body established by the Wet op de Geneesmidelen-Voorziening [Law on the Supply of Medicines].

As in the case of other goods and services and irrespective of their origin (whether domestic or imported), their prices are determined by a decree of 29 December 1981 adopted pursuant to Article 2 (1) of the Prijzenwet [Prices Law] of 24 March 1961. Article 2 (1) authorizes the competent ministers to fix maximum prices — if necessary — each year by decree.

A decree of 8 June 1982 which entered into force on 18 June 1982 and introduced a dual pricing system applies *exclusively* to the prices of *imported* registered medicines, whilst the prices of medicines manufactured in the Netherlands continue to be governed by the general decree of 29 December 1981, mentioned earlier.

I should point out at this juncture that the expression "manufactured" in the Netherlands includes not only medicines which are produced in that country but also proprietary medicinal products imported from abroad provided that they are packed or wrapped in the Netherlands.

Thus, in the case of medicines "produced" in the Netherlands, the general decree fixes the maximum price for traders as the purchase price of the goods increased by 105% of the profit margin applied before 28 November 1981 for identical goods, in a similar case, increased by value-add tax.

In the case of "imported" medicines, however, the maximum price is the manufacturer's basic price last applicable in a similar case before 15 May 1982, increased by any direct costs (transport and so on), by the profit margin and by value added tax.

Thus, where for an "imported" proprietary medicinal product which is already packed there is an equivalent, original product in a so-called "cheap" foreign country, the selling price of the former product excluding value added tax in the Netherlands may not exceed the selling price, also excluding value-added tax, charged by the producer in the country of origin of that product. [2] A Netherlands wholesaler who sells a product of that kind retains his profit margin in absolute terms, although he is

1 — Translated from the French.

2 — Article 2 (3) of the Prices Decree.

bound by the purchase price of the proprietary medicinal product before 15 May 1982. [1] Finally, the application of the contested Prices Decree entails either the alignment of the export price with the level of domestic prices in the exporting State or a reduction in the importer's profit margin.

A number of pharmaceutical undertakings, which are all subsidiaries or exclusive representatives of multinational groups or are licensed to use patents belonging to the latter, instituted interlocutory proceedings against the Netherlands for an order suspending the operation of the decree of 8 June 1982.

The President of the Arrondissementsrechtbank, The Hague, has referred the following five questions to the Court for a preliminary ruling:

"1. In the light of the argument put forward by the Netherlands, a Member State of the Community, is the Prices of Registered Medicines Decree 1982 to be regarded as:

A measure having an effect equivalent to a quantitative restriction on imports, prohibited by Article 30 of the EEC Treaty?

A form of discrimination prohibited by Article 7 of the EEC Treaty?

2. Do Articles 3 (f) and 5, in conjunction with Articles 85 and 86 of the EEC Treaty, have direct effect?

3. If Question 2 is answered in the affirmative, has the Netherlands by adopting the Prices of Registered Medicines Decree infringed those articles?

4. Do the principles of equality, proportionality, legal certainty and proper and exact preparation have direct effect in a case such as this?

5. If Question 4 is answered in the affirmative, has the Netherlands by adopting the Prices of Registered Medicines Decree contravened one or more of those principles?"

II — Before the substantive issues which have been raised are considered, some preliminary remarks are called for.

1. The first question

(a) First part

By requesting the Court to determine whether the Netherlands decree constitutes a measure having an effect equivalent to a quantitative restriction on imports under Article 30 of the EEC Treaty, the national court seeks to ascertain whether the Netherlands legislation is consistent with the provisions of the Treaty.

The Court does not have jurisdiction under Article 177 of the Treaty to resolve questions which come within the scope of the proceedings under Article 169 for failure to fulfil an obligation under the Treaty. Moreover, it should be observed, as emphasized by the various plaintiff undertakings, that the facts on which the Netherlands relies to justify the measures adopted have not been established objectively and supported by reasons following a proper adversary procedure which would have enabled the trade circles concerned to express their views.

It will, however, be relatively easy to identify the issues concerning the

1 — Article 3 of the Prices Decree.

interpretation of Community law *stricto sensu* in order to provide the national court with the information it requires to decide the case before it.

(b) Second part

Article 7 of the EEC Treaty, which prohibits discrimination on grounds of nationality, refers to the special provisions contained in the Treaty. The interpretation of that article therefore merges with that of Article 30 and it is unnecessary to consider it separately.

2. Third question

Article 3 (f) of the Treaty mentions, amongst the measures which are appropriate for the attainment of the objectives of the EEC Treaty set out in Article 2, "the institution of a system ensuring that competition in the common market is not distorted".

That provision is given concrete expression by Articles 85 and 86 of the EEC Treaty. Accordingly, it has no independent significance and may be relied upon only in conjunction with other articles of the Treaty, in which connection I would refer to the opinion of Mr Advocate General Reischl in the *Sacchi* case. [1]

According to the second paragraph of Article 5 of the EEC Treaty, the Member States "shall abstain from any measure which could jeopardize the attainment of the objectives of this Treaty". According to the case-law of the Court, that provision "lays down a general duty for the Member States, the actual tenor of which depends in each individual case on the provisions of the Treaty or on the rules derived from its general scheme". [2]

The national court may be assumed to be referring, in the first place, to contractual or financial relations between the Netherlands importer, buyer or wholesaler on the one hand and his foreign supplier on the other, or to the fact that part of the sum resulting from the resale of the goods accrues, either directly or indirectly, to the seller or to any other natural or legal person associated with him. In that case, the situation would come within the scope of Article 85 of the EEC Treaty.

In a previous judgment, the Court held as follows:

"Article 85 is not concerned with agreements or concerted practices between undertakings belonging to the same concern and having the status of parent company and subsidiary, if the undertakings form an economic unit within which the subsidiary has no real freedom to determine its course of action on the market, and if the agreements or practices are concerned merely with the internal allocation of tasks as between the undertakings." [3]

Furthermore, the abuse of a dominant position in the pharmaceutical sector may well come within Article 86 of the EEC Treaty. However, like Article 85, that provision refers to the conduct of *undertakings*. In the words of the Court, "with a view to safeguarding the principles and attaining the objectives set out in Articles 2 and 3 of the Treaty, Articles 85 to 90 have laid down general rules applicable *to undertakings*." [4]

1 — Case 155/73 [1974] ECR 409 at pp. 435-436.

2 — Judgment of 8 June 1971 in Case 78/70 *Deutsche Grammophon* [1971] ECR 487 at p. 499, paragraph 5 of the decision.

3 — Judgment of 31 October 1974 in Case 16/74 *Centrafarm* [1974] ECR 1183 at pp. 1199-1200.

4 — Judgment of 21 February 1973 in case 6/72 *Europemballage* [1973] ECR 215 at p. 244, paragraph 25 of the decision

However, measures adopted *by the Member States* come within Article 30 et seq. The contested decree does not constitute an agreement between undertakings, nor has it come into being as a result of a concerted practice within the meaning of Article 85.

The national court may have had in mind the dominant position occupied by sickness insurance schemes responsible for the reimbursement of sums paid for pharmaceutical products. However, those schemes are entrusted with the operation of a service of general economic interest. The sole restriction on the performance, in law or in fact, of the task assigned to them is that "the development of trade must not be affected to such an extent as would be contrary to the interests of the Community"; that would bring them within the scope of Article 90 of the EEC Treaty.

It is quite clear that the Member States may not adopt any measures encouraging or requiring undertakings to circumvent the prohibitions laid down by Articles 85 to 94 of the EEC Treaty but the fact that a deterioration in "normal" competition is brought about or given impetus by national legislation does not have the effect of bringing such legislation within the scope of those provisions where there is neither an agreement, decision or concerted practice nor an abuse of a dominant position.

In any event, even if the provisions of Articles 3 (f) and 5 (in particular, the second paragraph thereof) in conjunction with those of Articles 85 and 86 may be relied upon before the national court, it is first and foremost for the Commission to adopt any general or specific measure for their implementation and to ascertain whether the conduct of undertakings is not to be traced to the provisions of national laws or regulations.

3. Fourth and fifth questions

These questions are concerned with the "direct effect" of certain general legal principles, in particular, the principle of "proper and careful preparation". Since the Court has already recognized the direct effect of certain general principles of Community law, the plaintiff undertakings considered it normal to apply them where the national legislation of a Member State comes into conflict with the principles of Community law.

It must be pointed out that such principles are applicable only if they are embodied in a Treaty provision which needs to be interpreted or if they come within the scope of a provision of "secondary" Community legislation. Article 30 does not contain any direct or indirect reference to the principles mentioned by the national court and no provision of secondary Community legislation is at issue.

III — Those observations bring me to the fundamental issue raised by this case: does the concept of a measure having an effect equivalent to quantitative restrictions, contained in Article 30 — or rather in Article 31 — of the Treaty, apply to the legislation on prices which was adopted in this case?

1. The Treaty does not provide for the establishment of a common organization of markets accompanied by a common system of prices in the sector of proprietary medicinal products and, without prejudice to Articles 85 to 90, it

does not prohibit the charging, in respect of a single product, of different prices on different markets. Therefore, whilst under an obligation to comply with existing provisions of Community law, the Member States retain the power to regulate the prices of such products.

The Treaty thus empowers the Community institutions to ensure the approximation of national laws on prices where they directly affect the establishment or functioning of the common market (Article 100) or where the differences between national laws distort the conditions of competition in the common market and the resultant distortion needs to be eliminated (Article 101). The Court's judgment in the *Centrafarm* case, which I have already cited, throws considerable light on the meaning of those conditions. The Court held that

"it is part of the Community authorities' task to eliminate factors likely to distort competition within Member States, in particular by the harmonization of national measures for the control of prices and by the prohibition of aids which are incompatible with the common market, in addition to the exercise of their powers in the field of competition" (paragraph 16 of the decision);

and that

"the existence of factors such as these in a Member State ... cannot justify the maintenance or introduction by another Member State of measures which are incompatible with the rules concerning the free movement of goods, *in particular in the field of industrial and commercial property*" (paragraph 17 of the decision).

2. In its judgment of 24 January 1978 in the *Van Tiggele* case, [1] the Court clarified the position further still by pointing out that

"Article 30 of the Treaty prohibits in trade between Member States all measures having an effect equivalent to quantitative restrictions" (paragraph 11 of the decision),

and that

"for the purpose of this prohibition it is sufficient that the measures in question are likely to hinder, directly or indirectly, actually or potentially, imports between Member States (paragraph 12 of the decision),

and finally that

"whilst national price-control rules applicable *without distinction* to domestic products and imported products cannot in general produce such an effect they may do so in certain specific cases" (paragraph 13 of the decision).

Therefore national price-control rules which apply *specifically* to imported products will produce such an effect. If account is taken of the origin of the goods — that is to say the country in which they were produced — and of the manufacturer's basic price normally charged on the market in that country, a measure such as that laid down by the contested prices decree reconstructs, as it were, "the value for customs purposes" of the imported goods and their "reference price".

The common organization of agricultural markets shows that freedom of movement is not incompatible with the approximation or harmonization of prices. However, a disparity in prices increases the flow of trade from "cheap" countries to "expensive" countries, if only as as result of parallel imports which, according to the case-law of the Court, prevent the importation and marketing of a product from being monopolized by the manufacturer and his authorized representatives.

1 — Case 82/77 [1978] ECR 25 at p. 39.

3. The Netherlands Government states that approximately 80% of the medicines consumed in the Netherlands are imported from abroad, for the most part from the other Member States. Consequently, the general decree of 1981 affects no more that approximately 20% of domestic consumption.

In those circumstances, the Netherlands Government found it necessary to adopt the 1982 decree in order to *step up* its intervention in the formation of prices for *imported* medicines.

The Netherlands Government observes that discrimination arises only where equivalent situations are treated dissimilarly, that is to say where legislation on prices for domestic products and legislation on prices for imported products are concerned with similar situations. In its view, different situations are involved. Manufacturers of pharmaceutical products established in countries whose authorities keep prices artificially low seek to compensate for the low profit margin imposed upon them by raising their export prices, to the detriment either of consumers in the importing country or of the importing country itself.

The Netherlands Government contends that the "dual pricing" system applied by multinational undertakings, that is to say the charging of prices which vary arbitrarily from one Member State to another and which are not justified by normal factors (transport costs and so on), has as its purpose to exploit each national market to the limit of "what it can bear" and leads to a partitioning of the common market which is incompatible with the principle of the free movement of goods within the meaning of the EEC Treaty.

It also contends that trade between Member States is not restricted where the effect of a measure adopted by the public authorities is to frequent an artificial partitioning of the common market and that, consequently, there is no breach of Article 30 of the EEC Treaty.

Finally, any decline in patterns of trade does not constitute a restriction within the meaning of Article 30 where the decline concerns, as in the present case, situations which are fundamentally incompatible with the principle of freedom of movement.

4. Those arguments call for the following observations:

Even on the assumption that the legislation in question does not, in practice, create discrimination between domestic products and imported products, it leads to discrimination between products from so-called "cheap" countries and products from so-called "expensive" countries, in which prices are not regulated by legislation, and between proprietary medicinal products "imported" into the Netherlands and proprietary medicinal products "manufactured" in the Netherlands following importation in bulk into that country. Any increase in the domestic resale price for medicines imported from so-called "expensive" countries is prevented altogether by a provision such as Article 2 (3) of the contested decree. Accordingly, importers may no longer sell those medicines at such profitable prices on the domestic market. Moreover, the result is a freeze in the pattern of trade since, after the reference date of 15 May 1982, a change in the country of origin does not entail a change in the maximum price.

Furthermore, the Netherlands Government states that preference should be given to a *more restricted*, though "natural", pattern of trade, as opposed

to a *more extensive* pattern resulting from price discrimination practised by suppliers and from the defective functioning of the "market".

Along with technical barriers to the free movement of medicines which harmonization directives seek to remove by means of mutual recognition of marketing authorizations, the fact that a medicine does not qualify for reimbursement under the social security system (which covers 70% of consumers in the Netherlands) or that prices are fixed by the public authorities or by private undertakings may constitute obstacles which are just as considerable.

The plaintiff undertakings consider it of paramount importance that the legal protection afforded to "the citizen" should be effective *vis-à-vis* the public authorities. They contend that "to be sure legal protection of that kind may to some extent inhibit effective intervention by the national or Community authorities but ... a degree of inefficiency is inevitable if a State governed by the rule of law is to give the citizen the feeling that he too is not without redress against injustices committed by the authorities".

5. In that area, however, account must be taken, in particular, of the protection of health and life of humans (Article 36 of the EEC Treaty).

According to the case-law of the Court, that provision applies only to situations which are not of an economic nature. In point of fact, a medicine is unlike other products. Its distribution involves a manufacturer, a prescribing doctor, a dispensing chemist, a consumer and a social security institution. A medicine is an element in the course of treatment contributing to an improvement in a person's state of health and the assumption of responsibility by sickness insurance institutions — which also involves public and community financing — for payment of the cost of pharmaceutical products may affect the volume of sales by undertakings.

If the price to be paid by sickness insurance schemes or the share of the price to be borne by the insured for medicines prescribed by doctors were too high, and presumably the most effective medicines are prescribed, public health policy might be placed in jeopardy. The cost of health care and of sickness benefits which is borne by social security schemes forms an integral part of public health policy. [1] There is a risk that an excessive growth in costs may lead to selective medicine. Accordingly, it is insufficient to rely on the principle of the free movement of goods in order to reconcile such differing essential interests as:

the improvement of public health;

the vitality of the pharmaceutical sector;

the containment of public expenditure; and

compliance with the rules of competition laid down by the Treaty.

Moreover, that was the approach taken by the Court in the *De Peijper* judgment of 20 May 1976 [2] when it held that: "... the effective protection of health and life of humans also demands that medicinal preparations should be sold at reasonable prices". [3] Article 36, which in the matter of public health leaves residual powers, which are still substantial, to the Member

1 — Opinion of Mr Advocate General Mayras in Case 104/75 *De Peijper* [1976] ECR 613 at p. 650.

2 — [1976] ECR 613 at pp. 636 and 637.

3 — *De Peijper* judgment, paragraph 25 of the decision.

States, may be relied upon to justify legislation containing restrictions which are explained primarily by a concern to reduce public expenditure where, in the absence of such legislation, that expenditure would *clearly* exceed the limits of what can *reasonably* be required. [1]

It would be desirable if freedom of competition, parallel imports and the removal of technical barriers to trade were in themselves sufficient to bring about an ideal market. However, in this respect the strategy pursued by the large pharmaceutical groups must be reckoned with. Although many proprietary medicinal products are sold in numerous countries, the price of a given product varies considerably from one country to another. Differences in production costs, in research, in the amortization of investments, in currency fluctuations and in the rate of inflation are not sufficient in themselves to account for the disparity in prices. Accordingly, both the commercial policy pursued by those groups and national legislation on prices must also be taken into account.

6. The problem of controlling the cost of health care must, moreover, be seen in the wider context of "economic policy". The explanatory memorandum to the legislation in question, which formed part of the measures adopted to combat inflation, refers to the increase in prices and to the concern expressed by the Netherlands Government regarding the need to contain national health expenditure within certain limits. Thus, a measure of that kind, which is applicable for a limited period, is undeniably a short-term economic measure.

Conjunctural policy is the subject of a chapter in the EEC Treaty which contains only one provision, namely Article 103; paragraph (1) of that article provides as follows:

"Member States shall regard their conjunctural policies as a matter of common concern. They shall consult each other and the Commission on the measures to be taken in the light of the prevailing circumstances."

Furthermore, Article 104 of the EEC Treaty, which is included in the chapter on the balance of payments, imposes an obligation on the Member States to take care "to ensure ... a stable level of prices".

Although, according to the case-law of the Court, Article 103 does not relate to areas which are *already* subject to common rules, such as the common organization of agricultural markets, [2] it continues to apply in other areas.

Admittedly, a government which intends to adopt a measure of that kind must consult the other Member States and the Commission, but the absence of consultation cannot validly be relied upon by individuals before a national court.

The Council has acted under Article 103 on several occasions.

In a *resolution* adopted in 1973, [3] it stated in particular that as regards prices the Member States could have recourse, *inter alia*, to "strict surveillance of the conditions in which prices are fixed for goods and services, and possibly [to] *limiting profit margins*."

On 18 February 1974, the Council adopted a *directive* [4] which provides in Article 10 that, in so far as they deem it expedient, the Member States are to take "the measures necessary to enable them to impose, where necessary, without

1 — *De Peijper* judgment, paragraph 18 of the decision.

2 — Judgment of 29 June 1978 in Case 154/77 *Dechmann* [1978] ECR 1573 at p. 1584, paragraph 22 of the decision.

3 — Official Journal, C 116 of 29. 12. 1973, p. 22.

4 — Official Journal, L 63 of 5. 3. 1974, p. 19.

delay and temporarily, an overall or selective *restriction on the rise in prices* and incomes".

Finally, on 4 July 1974 the Council adopted a *decision* [1] which provides that the Member States are to pursue an economic policy which is in keeping with the guidelines laid down in an annex which, as regards the Netherlands, contains the following sentence: "... the imposition of *temporary controls on prices* and all incomes ... seems appropriate ...".

If the Community institutions are unable to decide upon the measures appropriate to the situation and to adopt the directives needed to give effect to the measures decided upon (Article 103 (2) and (3) of the EEC Treaty), a Member State is entitled to adopt legislation containing restrictions which are explained primarily by a concern to reduce public health expenditure where, in the absence of such legislation, that expenditure "clearly would exceed the limits of what can reasonably be required".

7. The question which arises is who is to set the limit beyond which what can reasonably be required is clearly exceeded.

For its part, the Commission states that "it is unable to confirm that the level of prices of pharmaceutical products in all the Member States is at present an accurate reflection at least of the actual cost price of those products". The Commission also states that it lacks sufficient information "to ascertain the extent to which price legislation relating to domestic products are concerned with similar situations". In its view, it is for the national court to resolve that question. I do not share that opinion.

In common with certain Advocates General of the Court, [2] I incline to the opposing view that the establishment of such a balance is not a matter for a national court giving judgment in interlocutory proceedings but is first and foremost a matter for the Commission acting in conjunction with the trade and with the competent authorities of the Member States.

IV — Although none of the "interveners" in this case has proposed a specific answer to the questions submitted by the national court, I am of the opinion that the Court should rule as follows:

Article 31 of the EEC Treaty must be interpreted as meaning that the establishment by the public authorities of a Member State of a system of maximum prices specifically for the retail sale of proprietary medicinal products registered in that State and imported from another Member State or a group of Member States constitutes a measure having an effect equivalent to a quantitative restriction.

1 — Official Journal, L 199 of 22. 7. 1974, p. 1

2 — Mr Advocate General Warner in Case 31/74 *Galli* [1975] ECR 47 at p. 70 et seq. and Mr Advocate General Mayras in Joined Cases 16 to 20/79 *Danis* [1979] ECR 3327 at pp. 3346-3348.

However, the provisions of Article 36 in conjunction with those of Article 103 of the EEC Treaty may justify the adoption of national legislation containing restrictions which are explained primarily by the objective of reducing public health expenditure, where, in the absence of such legislation, that expenditure would exceed the limits of what may reasonably be required.

It is for the Commission to determine whether, in the light of all the conditions governing the application of the provisions of Community law to which reference has been made, such an objective clearly exists.