OPINION OF MR ADVOCATE GENERAL CAPOTORTI DELIVERED ON 29 OCTOBER 1980 [1]

Mr President,
Members of the Court,

1. This case again brings up for your consideration the issue of the conformity with Community law of national provisions which have or may have a restrictive effect on the importation of pharmaceutical products and in particular on what are know as parallel imports. I would recall that in the judgment delivered on 20 May 1976 in Case 104/75 *De Peijper* [1976] ECR 613 the Court held that national rules which made permission to market pharmaceutical products dependent on the production of documents not usually available to the national importer were unlawful. On that occasion the Court observed that national rules of that kind have effects equivalent to those of a quantitative restriction on imports since they enable a manufacturer and his exclusive dealers to enjoy a monopoly of importing and marketing the products simply by refusing to produce the documents in question.

In this case it is necessary to consider another aspect of the problem, namely the pecuniary charges relating to a national system of registration of imported medicinal products, in order to establish whether such charges are compatible with the Treaty and, if so, whether they are subject to any restrictions having regard to the criteria governing their amount and payment.

I shall now briefly summarize the facts of the case.

Mr Kortmann, a trader in medicinal products in the Netherlands, was charged with contravening the provisions in force in that country by having in his possession for sale and marketing in the course of 1978 pharmaceutical products which had been imported in parallel from other Member States of the EEC and which had not been registered. The court of first instance in Venlo acquitted him of that charge in a judgment of 8 March 1979 but the public prosecutor lodged an appeal and Mr Kortmann became subject to further proceedings before the Arrondissementsrechtbank [District Court], Roermond. In the course of those proceedings the court referred the following question to the Court of Justice for a preliminary ruling:

"Given that:

(a) certain pharmaceutical products are lawfully in free circulation in one or more Member States in the sense that the permits required under national law for those pharmaceutical products have been issued to the manufacturers or, where appropriate, to those who are responsible for putting the pharmaceutical

1 — Translated from the Italian.

products into circulation in each of the Member States; and

(b) third parties may be aware that such permits have been granted in each of the Member States because the fact has been officially published or has become generally known by some other means; and

(c) a (parallel) importer of medicinal products established in one of the Member States imports into the Member State in which he is established the pharmaceutical products which are in circulation as described above,

do the exceptions to the rules relating to the free movement of goods within the EEC, particularly Article 36 of the EEC Treaty in so far as it relates to the protection of health and life of humans, justify the authorities of the importing Member State permitting imports of those pharmaceutical products only on payment of a registration charge, and if so, what standards should be applied to the amount and frequency of the payments and the system governing payments?"

2. Although the question is formulated in general terms and thus appears formally to accord with the requirements of Article 177 of the EEC Treaty, it is in fact concerned with whether or not that part of the Netherlands legislation governing trade in medicinal products which deals with the fees payable on the registration of products which have been imported in parallel is in accordance with Community law. It follows that the Court is once again required to resolve within the framework of proceedings for a preliminary ruling a question which could have been considered in greater depth if the Commission had instituted a direct action under Article 169 of the EEC Treaty. There are thus grounds for fearing that it will not be easy to provide the national court, through the reply to a hypothetical question referred to the Court of Justice by the court seised of the main action, with the particular information which it requires and which relates to specific aspects of the relevant Netherlands legislation.

That said, it seems appropriate to give a broad outline of the provisions of that legislation.

The Law of 28 July 1958 relating to the supply of medicinal products [Wet op de Geneesmiddelenvoorziening] lays down as a condition for the production and marketing of proprietary medicinal products and pharmaceutical preparations that they should first be registered by a board of experts which is required to approve them and authorize their use. An Order of 8 September 1977 governs the procedure for such registration, establishing different legal arrangements for official importers and for parallel importers: the former receive the same treatment as domestic manufacturers whilst special provisions apply to the latter.

According to Article 23 of the said Order of 8 September 1977, any person wishing to effect a parallel importation into the Netherlands of a pharmaceutical product which has already been registered (obviously by a person, who may, for convenience, be referred to as the "official importer") must also register the product so that it may be checked whether its characteristics conform to those recorded through the earlier registration. However the administrative procedure in question is simplified since regard is had to the fact that the product in question has already been examined at the request of the

official importer (who will be the same manufacturer or an authorized distributor).

3. The first of the issues raised by the Netherlands court is whether, having regard to Community rules on the free movement of goods, it is lawful for a Member State to require parallel importers of pharmaceutical products to pay a registration fee.

Having regard to the way in which the question has been drafted by the court seised of the main action, the aspect of the Netherlands legislation with which this case is concerned is that of payment of the fees relating to the registration procedure. In fact, according to the legislation, a parallel importer is required to pay two kinds of fee *on each proprietary medicinal product imported*, namely a single fee which is paid initially and another fee which is paid annually. The single fee is fixed at HFL 667 for a parallel importer and at HFL 2 668 for an official importer (see Article 4 of the Order of 8 September as amended by Article 6 of the Order of 15 April 1977). Nevertheless, whilst it is provided that in the case of an official importer the Minister for Health and the Environment may grant partial exemption from the fee in special circumstances (see Article 4 (3) of the Order of 8 September 1977) no such power is given in the case of a parallel importer. The annual fee is fixed at a uniform rate (HFL 890 for each proprietary medicinal product) for both an official importer and a parallel importer (see Article 15 (1) of the Order of 8 September 1977 and Article 9 (1) of the Order of 15 December 1977). Nevertheless in certain special circumstances the competent minister may grant either importer a partial exemption. The scope of that exemption is clarified in the recitals to the Order of 1977 in which it is stated that the exemption may be granted principally where a product has a limited market in view of the rarity of the illness which it is used to treat.

It should be emphasized that the lawfulness of the system of mandatory registration of medicinal products which are imported in parallel has not thereby been called in question. I have already had occasion to mention the judgment of the Court of 25 May 1976 in the *De Peijper* case which is concerned with a particular aspect of the national procedure designed to ensure the registration of products imported in parallel. I shall merely point out now that that judgment did not consider the lawfulness of registration as a form of precautionary check in the interests of health, its lawfulness being evidently taken for granted. Instead it considered a specific aspect of the authorization procedure (whether the parallel importer may be obliged to produce documents concerning the imported product). In general terms the Court held in its interpretation of Articles 30 and 36 of the Treaty that "national rules or practices which restrict imports of pharmaceutical products or are capable of doing so are only compatible with the Treaty to the extent to which they are necessary for the effective protection of health and life of humans". If the system of mandatory registration of pharmaceutical products is viewed from that standpoint, it appears to me possible to state without hesitation that, whilst such a system constitutes an obstacle to imports which may come under the prohibition in Article 30 of the EEC

Treaty, it is lawful pursuant to Article 36 in that it is necessary for the purpose of the protection of health. I should add that there are no grounds for restricting such recognition to the registration of products which constitute "official" importations. The objective need for registration, for the purposes indicated above, exists even when the medicinal products in question are imported in parallel and accordingly even in that case Article 36 justifies the conclusion that the system is lawful. In short, therefore, the Netherlands court was correct not to raise doubts on that point even though it is worth observing that the express reference to Article 36 would have appeared truly relevant only if the question had been thus extended.

In confirmation of the considerations which are based on the provisions of the Treaty on the free movement of goods I would observe that, with a view to harmonizing national rules on the marketing of pharmaceutical products, secondary Community law itself provides that in the case of both proprietary medicinal products produced by domestic manufacturers and imported products the placing of such products on the market is conditional upon the issue of an administrative authorization by the competent authority of the Member State where the products are to be marketed. The matter is governed essentially by Council Directive 65/65/EEC of 26 January 1965 (Official Journal, English Special Edition 1965-1966, p. 20) and by Council Directive 75/319/EEC of 20 May 1975 (Official Journal 1975, L 147, p. 13) which, in making provision for the grant of permission to place products on the market, do not distinguish between the principal importer and the parallel importer. In this connexion it is also significant that the Proposal for a Council Directive amending Directives 65/65/EEC and 75/319/EEC submitted by the Commission to the Council on 2 June 1980 (Official Journal 1980, C 143, p. 8) is expressly concerned *inter alia* precisely with the registration of parallel imports, the procedures for which are laid down in Article 10 (a) of that proposal. It is worth recalling that in the third recital of the preamble to that proposal it is stated that "... it is consequently necessary to supplement the provisions of Directive 65/65/EEC to allow the registration of parallel importers as persons responsible for marketing, which is necessary for the proper supervision of the market by the competent authorities".

4. I shall now endeavour to establish whether the provisions of the Treaty on the free movement of goods permit Member States to require payment of fees from parallel importers as a condition of their placing pharmaceutical products on the market.

In this action the Netherlands Government has maintained *in limine* that this question is irrelevant in that under Netherlands legislation failure to pay the fee does not prevent parallel importers from placing medicinal products on the market.

That argument must be rejected and first of all on grounds of principle. Whereas it is true that in exercising the jurisdiction conferred upon it by Article 177 of the EEC Treaty, the Court of Justice is required to interpret Community law and not a particular national law, there are even stronger grounds for holding that it may not infer from a given interpretation of the law of a Member State that a question submitted by a national court is irrelevant or superfluous. Furthermore,

in the present case the court making the reference has worded the question itself in general terms and with reference to Community law. Accordingly, I do not see how the Court of Justice may escape its own duty to provide a reply by making reference to the content of the national law of that court.

It must next be stated that, even if the objection on the basis of principle were to be disregarded, the argument of the Netherlands Government is so weak that it is impossible to accept. The documents which have been produced in fact appear to give the lie to the view that the registration of medicinal products in the Netherlands is independent of the payment of the fee and to show on the contrary that, according to the prevailing administrative practice, requests for registration cannot be processed if the initial fee is not paid. Of importance in this connexion is the letter dated 4 January 1979 from Dr Reijgeler, the Netherlands chief public health inspector of medicinal products, which is concerned precisely with the registration of pharmaceutical products which have been imported in parallel.

5. I have already noted that the question which has been submitted to the Court of Justice refers specifically to Article 36 of the EEC Treaty. This entails the notion that charging parallel importers fees for the registration of medicinal products may be considered a measure having an effect equivalent to quantitative restrictions which is nevertheless capable of qualifying for the exemption referred to in Article 36 as a restriction intended to protect health.

In my view the Commission and the Netherlands Government are correct in denying that the fees in question may be considered as measures having an effect equivalent to quantitative restrictions on imports. Classification in the category of the restrictions contemplated by Articles 30 to 36 of the EEC Treaty would be appropriate if the concern were with checks applied to imported pharmaceutical products through the registration system. I have however stated that the court making the reference has properly considered it pointless to raise doubts under this head and that this case is accordingly concerned only with the lawfulness in Community law of the imposition of pecuniary charges on importers on occasion of the registration of medicinal products.

In the question submitted by the national court there is a general reference to the compatibility of such pecuniary charges with the provisions of the Treaty on the free movement of goods. As is well known, the first of these provisions (in numerical order and also in order of importance) are those contained in Article 9 of the Treaty which lays down the prohibition between Member States of customs duties on imports and exports and of all charges having equivalent effect. Article 9 is to be taken in conjunction with the subsequent Article 12 which prohibits the introduction of "any new customs duties on imports or exports or any charges having equivalent effect". These are two provisions which in theory might apply to the situation described by the Netherlands court. In the abstract the requirement that an importer of pharmaceutical products pay sums of money as the registration fee for such products may come within the concept of a charge having an effect equivalent to a customs duty since it undoubtedly constitutes a pecuniary burden intended to have an incidence on

the price of the imported products and thus to have the same restrictive effect on trade-patterns as a customs duty.

Classification of the fees in question as measures prohibited by Articles 9 and 12 would have to be ruled out if such fees were regarded as the consideration for a service, the health inspection, rendered by the importing State to the importer. As is well known, according to the case-law of the Court all pecuniary charges which constitute the consideration for a service rendered by the administration may not be classified as a charge having an effect equivalent to a customs duty. The Court has repeatedly pronounced to that effect; I would recall the judgments of 1 July 1969 in Case 24/68 *Commission* v *Italian Republic* [1969] ECR 193 (in particular paragraph 11 of the decision), of 11 October 1973 in Case 39/73 *REWE* [1973] ECR 1039 (in particular paragraph 4 of the decision), of 5 February 1976 in Case 87/75 *Bresciani* [1976] ECR 129, of 25 January 1977 in Case 46/76 *Bauhuis* [1977] ECR 5 (in particular paragraphs 7 and 11 of the decision) and of 12 July 1976 in Case 89/76 *Commission* v *Netherlands* [1977] ECR 1355. However that case-law may not be relied upon in this case for the simple reason that the activity of the administration of the State intended to set up a system of health inspection in the general interest may not be considered as a service rendered to the trader subject to the inspection which is such as to justify, as a consideration therefor, the imposition of a pecuniary charge (cf. in this connexion the aforementioned judgments of 11 October 1973 in the case of *REWE* and of 5 February 1976 in the case of *Bresciani).*

Rather, it is on the basis of another and decisive circumstance that it is necessary to reject the classification of the fees in question as charges having an effect equivalent to customs duties. I have had occasion to recall that under the Netherlands legislation the registration fees are payable by both manufacturers and importers of medicinal products and we know that in framing its question the national court had particular regard to the rules of its national law. It is impossible to consider as a charge specifically burdening imports — and therefore as a charge having an effect equivalent to a customs duty — a fee which forms part of a domestic system of charges applicable to all products, domestic and imported, belonging to a certain category of goods and which arises in connexion with a formality prescribed equally for all products in that group. The Court of Justice has frequently upheld this principle; I would recall the judgments of 14 December 1972 in Case 29/72 *Marimex* [1972] ECR 1309, (in particular, paragraph 8 of the decision) of 11 October 1973 in the case of *REWE,* of 25 January 1977 in the case of *Bauhuis,* both cited above, of 29 June 1978 in Case 142/77 *Statens Kontrol med ædle Metaller* v *Preben Larsen* [1978] ECR 1543 and of 8 November 1979 in Case 251/78 *Denkavit* [1979] ECR 3369 (in particular, paragraph 11 of the decision). The question which has given rise to the present proceedings relates, by implication at least, to a type of fee which is payable by parallel importers, official importers and also domestic producers. It follows in my view that the reply to the question must be sought

within the application not of Articles 9 and 12 of the Treaty but rather of Article 95 which prohibits the imposition upon the products of other Member States of taxation in excess of that applied to the domestic products.

6. The conclusion which I have just reached remains valid even where certain differences exist between the treatment accorded to importers and that given to domestic producers provided that such differences are not so marked as to preclude their being regarded as features of substantially one single system.

I shall now proceed to take as a point of departure the situation created by the Netherlands legislation. In that legislation the differences in system to which I have referred may be summarized in essentially two points: the differing amounts of the single fee, which is less in the case of parallel importers, and the possibility of obtaining partial exemption from that fee, which is not provided for in the case of parallel importers.

With regard to the first matter I would observe that in fixing a lower fee for parallel importers the Netherlands legislature probably intended to relate (albeit by means of flat-rate arrangements) the amount of the fee to estimated turnover and thereby to align the charge with that imposed on other traders. It is in fact known that parallel importers tend to obtain a large number of products from different markets and under the Netherlands system, which calls for a fee for each imported proprietary medicinal product, such importers are thus required to pay very many single fees in relation to their total turnover. The situation is different in the case of official importers and domestic producers who market a smaller number of proprietary medicinal products, all in considerable quantities, and require in consequence to pay a smaller number of single fees in relation to their turnover. In these circumstances the fact that the Netherlands rules prescribe a single fee which is appreciably lower in the case of parallel importers is not only related to the lower cost of the checks which the State is obliged to carry out on the product before registration but appears also to be prompted by the intention of effecting a certain equalization in the tax burdens on parallel importers and other traders. I therefore consider that on that basis it may be accepted that the registration fee charges to parallel importers forms part of a general system of internal taxation which displays substantial homogeneity.

With regard then to the second point, that is, the possibility which is given only to domestic producers and official importers of obtaining a partial exemption from the single fee, the difference is of limited scope the more since the exemption does not take the form of a right enjoyed by the trader but is a power enjoyed by the administration in exceptional cases.

7. Once it has been established that the registration fee for medicinal products must be appraised in the light of Article 95 it remains to ascertain what deductions may be drawn from that provision with regard to the treatment of parallel importers. In seeking to do so, it is necessary also to broach the second issue raised by the national court, namely the standards which should be applied to the amount and frequency of the payments and the system governing the

payments. Nevertheless in this connexion I am bound to repeat what I pointed out at the outset: the reply to a question of this nature which is in abstract terms can only be general whilst taking into consideration the details of the specific case goes beyond the function of these proceedings.

Turning now to compare the taxation which the system in the Netherlands imposes upon parallel importers with that imposed upon official importers and national producers, it is easy to see that the single fee payable by a parallel importer is fixed at a flat rate for each imported pharmaceutical product and for each Member State from which it comes. If account is taken of the fact, which has already been emphasized, that parallel importers usually handle a larger range of medicinal products than that marketed by official importers and national manufacturers it is also necessary to find that there is a risk that tax arrangements such as those provided for in the Netherlands law may prove more burdensome for parallel importers than for national producers notwithstanding the correcting factor of the smaller amount of the fee payable by the former. The Court has already considered the case of a flat-rate tax in its judgment of 5 May 1970 in Case 77/69 *Commission* v *Kingdom of Belgium* [1970] ECR 237 and has held that a flat-rate duty which has the effect, *by reason of the different basis on which it is applied*, of taxing imported products more heavily than national products is of a discriminatory nature and is contrary to the first paragraph of Article 95 of the EEC Treaty. In view of the fact that in the present case such inequality may, and probably does, occur and having regard to the special features of international trade in pharmaceutical products, national legislation which fixes a fee without having regard to the basis on which the tax is applied appears discriminatory and contrary to Article 95. It might be argued against that view that it is practically impossible to determine the basis on which the tax is applied, namely the amount of the turnover, at the time when the importer requests the registration of a given product; that difficulty could however be overcome by making provision for *subsequent* payment or, better still, by abolishing the single fee leaving only a periodic charge measured on turnover.

With regard, then, to the *annual registration fee* laid down by Netherlands law, I have already stated that it is charged at the same rate for all manufactured or imported products. However, here too there is no link with turnover, that is to say with the quantity of products imported and marketed. The fee is in fact paid annually at a fixed rate for each product registered and marketed irrespective of the volume of the imports. The same kind of inequality in taxation which I have noted in the case of the single fee therefore occurs, again as a consequence of the fact that parallel importers deal in a very much larger number of products than national manufacturers and official importers. Nor do I consider that the possibility of obtaining a partial exemption (which is available to all traders) may correct this inequality. It is sufficient to note that the exemption may be granted only "if

special circumstances (which are not specified) justify it" and that it is for the competent minister to assess in individual cases whether such circumstances exist.

It therefore does not appear to me that the difference between the single fee and the annual fees affects the criterion whereby the lawfulness of the charge in question must be appraised within the framework of Article 95 of the EEC Treaty. With regard to both forms of the charges relating to the registration of medicinal products which I have examined it may be said that Article 95 requires that the principle of the uniformity of the basis on which the charge is applied must be respected both where the medicinal products in question are manufactured in the Member State and where they are imported officially or in parallel. Shortly stated, that principle implies that the charge must have the same incidence on the price of national and imported products.

8. On the basis of all the considerations which have been set out above I propose that the reply to be given to the question submitted to the Court of Justice by the Arrondissementsrechtbank Roermond, The Netherlands, by judgment of 4 November 1979 should be as follows:

1. Article 36 of the EEC Treaty justifies the application to imported pharmaceutical products of a national system of inspection and registration provided that the system is necessary for the effective protection of health and life of humans.

2. If fees relating to the registration of pharmaceutical products imported both officially and in parallel are also applied to national manufacturers of such products they do not fall within the prohibition of all charges having an effect equivalent to customs duties (Articles 9 and 12 of the EEC Treaty) but must be appraised in terms of the principle of equality of taxation of domestic products and products from other Member States (Article 95).

3. By virtue of the first paragraph of Article 95 of the EEC Treaty national authorities may make the parallel importation of pharmaceutical products (that is to say the importation of medicinal products for which authorization to place them on the market in the State of importation has already been granted at the request of another importer or producer) conditional on payment of a fee only if, by means of the criteria whereby its amount is calculated, the fee in question has the same incidence on the price of products imported in parallel and on that of products placed on the market by official importers and by domestic producers.