authorities of the Member State into which the first product has been imported altready possess the documents relating to the method of preparation and also to the quantitative and qualitative composition, since these documents were produced to them previously by the manufacturer or his duly appointed importer in support of an application for authorization to place them on the market;

national rules or practices which make it possible for a manufacturer of the pharmaceutical product in question and his duly appointed representative, simply by refusing to produce the documents relating to the medicinal preparation in general or to a specific batch of that preparation, to enjoy a monopoly of the importing and marketing of the product, must be regarded as being unnecessarily restrictive and cannot therefore come within the exception specified in Article 36 of the Treaty, unless it is clearly proved that any other rules or practices would obviously be beyond the means which can be reasonably expected of an administration operating in a normal manner.

It is only if the information or documents to be produced by the manufacturer or his duly appointed importer show that there are several variants of the medicinal preparation and that the differences between these variants have a therapeutic effect that there would be any justification for trating the variants as different medicinal preparations, for the purpose of authorizing them to be placed on the market and as regards producing the relevant documents, it being understood that the answer to the first question remains valid as regards each of the authorization procedures which have become necessary.

In Case 104/75

Reference to the Court under Article 177 of the EEC Treaty by the Kantongerecht Rotterdam for a preliminary ruling in the criminal proceedings pending before that court against

ADRIAAN DE PEIJPER managing director of Centrafarm BV,

on the interpretation of Article 36 of the EEC Treaty,

THE COURT

composed of: R. Lecourt, President, H. Kutscher and A. O'Keeffe, Presidents of Chambers, A. M. Donner, J. Mertens de Wilmars, M. Sørensen and Lord Mackenzie Stuart, Judges,

Advocate-General: H. Mayras
Registrar: A. Van Houtte

gives the following

JUDGMENT

Facts

The order making the reference, the procedure and the written observations submitted under Article 20 of the Protocol on the Statute of the Court of Justice of the EEC may be summarized as follows:

I — Facts and procedure

1. The 'Besluit farmaceutische Preparaten' (the Decree on Pharmaceutical Preparations) adopted by the Netherlands Secretary of State for Social Security and Public Health on 22 January 1970 (Staatscourant No 22) and hereinafter called 'the BFP' — in the version in force when the proceedings in the main action were instituted — contains *inter alia* the following provisions:

Article 1

For the purposes of this Decree,

(e) 'importer' shall mean any person who imports pharmaceutical preparations and supplies them on a large scale.

Article 3 (1)

The manufacturer and importer shall not, without the consent of the Chief Public Health Inspector, supply a pharmaceutical packaging of a pharmaceutical preparation, whatever its quantitative composition may be.

Article 4

1. An application for the grant of the consent referred to in Article 3 (1) shall be made on a form prescribed by the Chief Public Health Inspector and sent to him by registered letter; this application shall contain the following particulars (gegevens):
   (a) the name and address of the manufacturer or importer;
   (b) the pharmaceutical packaging of the preparation;
   (c) full particulars concerning the quantitative and qualitative composition of the preparation, or, if this proves to be impossible, full particulars of the basic constituents and of the processing (bewerkingen) which the latter have undergone giving in each case particulars of the active ingredients (werkzame bestanddelen).
2. For a period of six weeks after the date when he receives the application the Chief Public Health Inspector may, with reference to the preparation in question, by a registered letter addressed to the applicant, require him to produce all the reports, publications and other scientific data relating to the results of every analysis and observation, of which he has a knowledge, as well as, in duplicate, one of the files referred to, as the case may be, in Article 5 (1) or in Article 6 (1); Article 5 (2) and (4), or as the case may be, Article 6 (2), shall apply to the file in so far as signing and endorsing the particulars 'seen and approved' (de ondertekening van de gegevens voor 'gezien en akkoord') is concerned.

3.—6. .....

Article 5

1. The manufacturer shall ensure that there is (aanwezig is) at the place or places where the manufacture is carried out a file for each pharmaceutical packaging of a pharmaceutical preparation and, if

this packaging is offered in several quantitative compositions, for each composition. Each file, compiled in accordance with the model prepared by the Chief Public Health Inspector must contain the following particulars (gegevens):

(a) (similar wording to that of Article 4 (1) (c))

(b) the manufacturing formula (bereidingsvoorschrift) of the preparation including:
  (1) a brief description of the processes undergone by the constituents before completion of the finished product and of the packing operations;
  (2) particulars of the amounts of the constituents referred to in subparagraph (1) above which have to be used for the preparation of a given quantity of the end product;
  (3) particulars of the checks carried out during manufacture in order to be able to guarantee the exact composition of the end product;

(c) details of the rules for checking the preparation and the substance of which it is made up including:
  (1) the quality requirements for all the constituents used;
  (2) the rules for identifying in the end product all the active ingredients and colourings used;
  (3) the rules for the quantitative determination of all the active ingredients of the end product;
  (4) the permitted margin of the amount of active ingredients in the end product;
  (5) so far as the following pharmaceutical packagings are concerned the rules relating to the data mentioned in them [a detailed list of them follows]:

(d) particulars of the period during which the preparation can be kept including:
  .....

(e) a description of the contents of every commercial package, and to the extent to which the packages concerned are of a standard type, the label on the packages, as well as a specimen of the packages and a description of their composition (hoedanigheid).

2. The particulars referred to in the first paragraph must be signed by the pharmacist referred to in Article 9 (1) or, as the case may be, by the person referred to in the second paragraph of that Article (signature) certifying that the particulars were 'seen and approved' (... moeten door de apotheker ... 'voor gezien en akkoord' zijn getekend).

3. The files referred to in the first paragraph must at all times be available to the Chief Public Health Inspector and the Inspectors so that they may examine them.

4.—6. .....

Article 6

1. The importer shall ensure that there is (aanwezig is) a file ... for every pharmaceutical packaging of a pharmaceutical preparation which he imports, and, if this packaging which is imported covers several quantitative compositions, for each composition. The file, which must be kept in accordance with the model provided by the Chief Public Health Inspector, must contain the particulars referred to in Article 5 (1). The file must also contain a declaration in writing by a government authority of the country where the manufacture took place, considered by the Chief Public Health Inspector 'to be empowered for this purpose, and certifying that in that country the preparation was manufactured in accordance with the provisions in force and may be marketed, and, if the Chief Public Health Inspector considers it to be necessary, the text of those provisions, all of which must be in a language acceptable to the Chief Public Health Inspector.

2. Article 5 (2) to (6) shall apply by analogy to an imported with the further promise that ther particulars referred to in the second paragraph of thes article must be signed by a person responsible for the manufacture abroad, (the signature) certifying that the particulars have been 'seen and approved' (... voor 'gezien en akkoord' moeten zijn getekend ...) ...

Article 7

1. The manufacturer and the importer must, at the request of the Chief Public Health Inspector, forward to him in duplicate, the file referred to according to the circumstances in Article 5 or Article 6 for the purpose of certification (waarmerking).
2. The Chief Public Health Inspector shall certify a file when:
   (a)—(c) .....
   After the Chief Public Health Inspector has certified the file he returns it to the manufacturer or importer, as the case may be.

3.—7. .....

Article 14

1. The importer must ensure that when he supplies a pharmaceutical preparation which he has imported:
   (a) there are (aanwezig zijn) dated record relating to this preparation disclosing that the latter has in fact been manufactured and checked in accordance with the manufacturing formula and the rules for carrying out checks referred to in Article 5 (1) (b) and (c);
   (b)—(d) .....

2.—3. .....

2. A — In 1973 the Centrafarm company purchased from a wholesale business house in the UK various quantities of valium tablets of doses of 5 and 10 mg and imported them into the Netherlands as valium coming from the British factory belonging to the Hoffmann-La Roche group, under its original trade-mark. It then packed the tablets in packages bearing its name and marked 'Diazepam', the generic name of the preparation in question, and distributed them to several pharmacies in the Netherlands.

The Officier van Justitie for the district of Rotterdam instituted criminal proceedings based on these facts in the Cantonal court (Kantongerecht) of Rotterdam against Mr De Peijper, a director of Centrafarm. The charges include *inter alia* the following allegations:

Centrafarm is said to have engaged in 'parallel importation' by purchasing, *inter alia* in the United Kingdom, not from manufacturers of medicinal preparations of a particular brand but from wholesalers — in packages bearing the original trade-mark. For the purpose of resale it then apparently packed the products in new packages bearing the generic name of the medicinal preparation, Centrafarm's label and reference number and marked 'original product' ('origineel fabrikaat'). When carrying out these operations Centrafarm is alleged to have committed the following offences under Netherlands law for which Mr De Peijper is alleged to be responsible and which he is said to have in fact admitted:

— The company effected the above-mentioned deliveries without having obtained the consent provided for by Article 3 of the BFP.
— It did not have available the documents referred to in Article 6 (2) of the BFP.
— It did not have in its possession the records referred to in Article 14 of the BFP, since the foreign manufacturer had not placed such records at its disposal.

Contrary to the objections raised by Mr De Peijper the Netherlands provisions in question, which apply to domestic as

well as foreign products, are compatible with Article 36 of the EEC Treaty because they are 'justified on grounds of ... the protection of health and life of humans' and do not constitute 'a means of arbitrary discrimination or a disguised restriction on trade between Member States'. Nor do they run counter to Commission Directive No 70/50/EEC of 22 December 1969 on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty (OJ English Special Edition 1970 (1), p. 17) and more particularly against Article 3 (2) thereof which provides that the said directive also covers:

'measures governing the marketing of products ... where the restrictive effect of such measures on the free movement of goods exceeds the effects intrinsic to trade rules', in particular where

(1) 'they are out of all proportion to their purpose', or

(2) 'the same objective can be attained by other means which are less of a hindrance to trade'.

So far as subparagraph (1) is concerned the provisions in question are necessary in order to guarantee the identity and the quantitative and qualitative composition of the product which is a very important factor in determining its therapeutic efficacy and ensuring that it is not dangerous.

So far as subparagraph (2) is concerned there can be no question of requiring the imported product to be subject to less stringent rules than the domestic product as long as the laws of the Member States have not been harmonized. This applies in particular if the importer has not received the product direct from the foreign manufacturer, because in such a case there is no guarantee as to the identity and composition of the product.

The judgments of the Court of 31 October 1974 in Cases 15/74 *(Centrafarm BV and Adriaan de Peijper* v *Sterling Drug Inc,* [1974] ECR 1147) and 16/74 *(same plaintiffs* v *Winthrop BV* [1974] ECR 1183) do not lead to any other conclusions. Although the Court held in those cases that the behaviour of proprietors of patents or trade-marks in a particular way infringes Community law, it must be borne in mind that in this case much more important interests are at issue.

B — By order of 29 September 1975 the Kantongerecht decided to refer to the Court the following questions:

I — On the assumption that:

(a) a proprietary medicinal product prepared in accordance with a given (uniform) method of preparation and qualitative and quantitative composition is lawfully in circulation in one or more Member States, in the sense that, in pursuance of the national systems of legislation of the Member States, the requisite authorizations have been granted in relation to that proprietary medicinal product to the manufacturer or — as the case may be — the person responsible for putting the proprietary medicinal product in question on the market in each of those Member States;

(b) knowledge of the fact that such authorizations have been granted in each of those Member States is available to third parties by general notice being given by official publication or in some other way; and

(c) an importer of medicinal preprations established in one of those Member States purchases the proprietary medicinal product which, as mentioned above, is lawfully in circulation, in one of the Member States above referred to and imports it into the

Member State in which he is established; and

(d) the particulars with reference *inter alia* to the method of preparation and qualitative and quantitative composition of the proprietary medicinal product in the Member State into which importation takes place cannot in fact be obtained by that importer except from the manufacturer (with his collaboration) or, as the case may be, from the person who is responsible there for the marketing of the proprietary medicinal product (degene die aldaar voor het in de handel brengen van de farmaceutische specialiteit verantwoordelijk is);

In such circumstances do the exceptions to the rule relating to free circulation of goods within the Community, namely Article 36 of the Treaty, in so far as the protection of the health of humans is concerned, justify the authorities of the importing Member State in making the marketing there of the proprietary medicinal product dependent on the grant of an authorization to that importer in realtion to that proprietary medicinal product when for the grant or, as the case may be, the obtaining of that authorization by that importer the same particulars regarding *inter alia* the method of preparation and quantitative and qualitative composition of the prorpietary medicinal product are required as those which have already been supplied to those authorities in the context of the procedure for the grant of the authorization(s) already existing in that Member State in relation to that proprietary medicinal product?

II — Is it necessary to take a different view with regard to the foregoing if the proprietary medicinal product is in circulation in the exporting country following a different method of preparation or having a different qualitative and/or quantitative composition from those which characterize the product circulating in the importing country, but the difference(s) between the one and the other product is/are of such minor importance that it is likely that the manufacturer is applying or introducing this/these difference(s) with the conscious and exclusive intention of using these differences (within the framework of the respective national rules) in order to prevent or impede the possibility of parallel import of the proprietary medicinal product?

In the grounds of the order making the reference the Kantongerecht, after finding that the offences with which Mr De Peijper was charged had been proved, makes *inter alia*, the following observations.

The provisions of the BFP in force at that time did not expressly provide that the importation of pharmaceutical preparations may only be effected by an importer having his place of business in the Netherlands who must have in his possession, *inter alia,* documents dealing with the composition, the method of preparation etc., of the products to be imported and which are supplied to him by the foreign manufacturer. But Articles 3 (1), 4 (2) and 6 (2) of BFP had substantially the same effect.

In this case the Hoffmann-La Roche company refused to issue to Centrafarm the documents referred to in these provisions. Thus the said provisions in practice prevented Centrafarm from finding any outlets for the imported products in the Netherlands, so that there is a case for considering, having regard to Article 36 of the Treaty, whether the provisions in question, which are a hindrance to intra-Community trade, 'constitute a means of arbitrary discrimination and a disguised restriction on trade between Member States'.

Article 36 undoubtedly permits national legislatures to adopt provisions designed to guarantee that the quality, identity and composition of imported medical preparations are of the highest standard, such as those provisions in the BFP which provide for administrative checks from the time when productions commences up to the point of supply to the consumer. Nevertheless two questions must be raised: first whether the disputed provisions do not in fact create an export or import monopoly for the benefit of foreign manufacturers and the sole representatives which they have appointed in the Netherlands; secondly whether these provisions do not depart further from the principle of free movement of goods than is necessary for the purpose of protecting public health.

3. The order making the reference was registered at the Court of Justice on 2 October 1975.

In accordance with Article 20 of the Protocol on the Statute of the Court of Justice of the EEC written observations were lodged by the Officier van Justitie for the District of Rotterdam, the British, Danish and Netherlands Governments and by the Commission of the European Communities.

After hearing the report of the Judge-Rapporteur and the views of the Advocate-General the Court decided to open the oral procedure without any preparatory inquiry. Nevertheless, it invited the Netherlands Government and the Commission respectively to define their position during the hearing on certain questions.

II — Observations submitted pursuant to Article 20 of the Protocol on the Statute of the Court of Justice of the EEC

The *observations of the Officier van Justitie for the District of Rotterdam* refers mainly to the charges set out above. Mr De Peijper's argument that the BFP does not come within the exceptions provided by Article 36 of the Treaty, because the health of the general public can be guaranteed in a less restrictive way, is irrelevant. In fact the alternative solution proposed by Mr De Peijper would be too complicated and would take too long to be able to guarantee effective supervision.

Mr De Peijper submits in particular the following observations:

Centrafarm's operations and its positions on the Netherlands market

Centrafarm carries on business as a manufacturer and wholesaler of pharmaceutical products. As a manufacturer its main operations are the processing of imported basic materials into tablets, capsules etc; the products arising out of such processing are sold in the Netherlands under their generic name. It also imports, in the manufacturer's package, 'proprietary medicinal products', that is to say, pharmaceutical preparations sold under a trade-mark including 'valium' manufactured by Hoffmann-La Roche. Centrafarm then carries out the packaging of these proprietary products, by affixing to each individual package a label bearing the trade-mark Centrafarm placed next to the original mark of the manufacturer. In addition these packages contain a leaflet in which Centrafarm guarantees the quality of the products.

Centrafarm only imports proprietary products in respect of which it has satisfied itself:

- that notice of the authorization to place them on the market has been published in the exporting State; such notice is provided for in all the Member States where the company buys proprietary medicinal products;
- that the vendor has obtained them from the manufacturer or importer duly approved by the latter.

An analysis of every proprietary medicine purchased in this way covering the identity, purity and the amount of active ingredients is carried out in the company's laboratories under the supervision of its pharmacists.

Since the judgments of the Court in Cases 15/74 and 16/74 the industry and the wholesalers' organizations have brought pressure to bear on the Netherlands authorities to apply Netherlands law with a view to prevent parallel imports. Hoffman-La Roche, in particular, whose trading policy is moreover being investigated by the Commission, is seeking to retain territorial frontiers within the Community.

The relevant Netherlands law

Pursuant to the 'Wet op de Geneesmiddelenvoorziening' (the Law relating to the supply of medicinal preparations, Staatsblad 1958, p. 408) and its implementing provisions, the manufacture of and trade in pharmaceutical products is subject to authorization being granted by the public authorities. This law distinguishes between a manufacturer's and a distributor's licence, the granting of the first implying the grant of the second. Centrafarm has a mnaufacturer's licence.

Mr De Peijper then submits the following observations on the provisions of the BFP set out or referred to above and on the way in which they are applied in practice:

— Articles 4 to 7 set out the conditions with which the manufacturer or importer must comply if he wishes to obtain the consent provided for in Article 3 (1) and the 'certification', provided for by Article 7, of the file referred to in Articles 5 and 6.
In fact the party concerned immediately produces the file to the Chief Inspector for the purpose of its certification; this is by implication equivalent to consent within the meaning of Article 3 (1).

— Articles 5 and 6 provide that the manufacturer or importer must keep a file for — in short — every pharmaceutical preparation which he wishes to market in the Netherlands.
— The provisions of Article 7 provide that the Chief Inspector shall keep one copy of the file; he is therefore at all times able to take note of the particulars relating to the proprietary medicinal products in respect of which he has granted his consent.
— The questions referred do not strictly speaking relate to Article 14 (1) of infringing of which Mr De Peijper is also accused. The obligation in question in this case arises out of the duty to compile a file (Article 5). The national court obviously took the view that, if this latter obligation is inconsistent with Community law, it follows that the obligation provided for by Article 14 is as well.

The practices adopted by manufacturers of proprietary medicinal products

It is in the interest of the manufacturer of such a proprietary product that it is manufactured as much as possible in accordance with a single formula and made up in one qualitative and quantitative composition only in whatever country it will be marketed. Any other practice would entail manufacturing complications and therefore cause disadvantages from the economic point of view.

The manufacturer who wishes to market a new medicinal preparation normally opens a master manufacturing file in which he puts all the data covered by Article 5 (2) of the BFP. By doing so he takes account of the conditions laid down by the national laws of countries into which he plans to export his product. A file kept in this way is a source of information on the notification procedures carried out by the manufacturer or his approved importers in the countries into which the product is imported.

The Hoffmann-La Roche company kept such a master file for valium. If the quantitative and qualitative composition of valium recorded in this file is compared with the data for valium sold on the Netherlands market which are found in the particulars supplied by Hoffmann-La Roche to the Chief Inspector it is evident that the two products are absolutely identical.

According to the particulars supplied by Hoffmann-La Roche, the quantitative data for valium sold in the United Kingdom differ nevertheless, to a certain extent, from the data for 'Netherlands' valium but only in so far as the non-active substances of the product (lactose and maize starch) are concerned.

However an analysis carried out at the request of Centrafarm by a Netherlands institute raises the presumption that there are no differences between 'English' and 'Netherlands' valium. On the other hand if these differences have to be acknowledged, they are in any event unimportant, since they do not relate to constituents which are therapeutically active.

The events leading up to the main action

Mr De Peijper refers to correspondence between Centrafarm and the Chief Inspector during the years 1972 to 1973 which establishes that there was a dispute concerning the question whether — as Centrafarm considered was the case having regard to the provisions of the BFP which were in force at that time — a parallel importer of a medicinal preparation already on sale in the Netherlands did not have to produce his own file for this medicinal preparation. The Chief Inspector's submission in support of the oppsosite view was essentially that it was not sufficient to argue that the public authorities already have a file for the medicinal preparation imported by the parallel importer; in fact the possibility cannot be rules out that a manufacturer of pharmaceutical products may market a specific medicinal preparation of his own manufacture and even under the same designation in every case, the qualitative and quantitative composition of which varies, however, according to the country where it is marketed.

Article 20 et seq. of the Treaty

National measures which discriminate between imported and home-produced products as well as measures impeding imports are measures having an effect equivalent to quantitative restrictions within the meaning of Article 30. This view is based on the objective of Article 30, on an analysis of Articles 36 and 37 in conjunction with Article 30, on a comparison with provisions of the Treaty similar to the provisions of this Article (Articles 48, 52, 59, 60, 68) and on Article 3 of Commission Directive No 70/50/EEC. However this directive does not contain an exhaustive enumeration of measures having equivalent effect; this emerges from its thirteenth recital and the words 'entre autres' ('must be taken to include') and 'notamment' ('in particular') appearing respectively at the beginning of Article 2 (3) and in the second sentence of Article 3.

The view defended in this case has also been accepted by the Court, in particular by its judgment of 11 February 1974 (*Dassonville,* Case 8/74, [1974] ECR 837). This judgment moreover allows the conclusion to be drawn that Article 30 also applies to a national measure which results in certain importers, in particular those who undertake parallel imports, having to fulfil requirements which they cannot satisfy or which they can satisfy less easily than other importers.

The case-law of the Court also shows that the exceptions specified by Article 36 must not be given a wide interpretation. This means that national measures, introduced for the purpose of protecting one of the interests referred to by this

article, are only admissible to the extent to which their restrictive effects are in proportion to the results sought and cannot be replaced by another regulation which, even though it is equally effective, would be less of a hindrance to intra-Community trade.

When the Community has adopted a directive for the harmonization or national laws in one of the fields referred to in Article 36, the Member States are entitled to supplement the Community provisions but not to take stricter measures which are not justified by the directive and which constitute arbitrary discrimination within the meaning of Article 36 (cf. Judgment of 8 July 1975, *Rewe,* Case 4/75 [1975] ECR 843). Moreover directives for the approximation of laws can only cover national measures which are compatible with Community law.

The particulars which have to be supplied to enable the Netherlands authorities to check a file and in the end to grant their authorization under Article 3 of the BFP can only be given either by the manufacturer or the importer duly appointed by him or by third parties with the cooperation of the manufacturer or the importer he has duly appointed.

The manner in which the Netherlands authorities apply the provisions in force amounts to a measure having equivalent effect within the meaning of Article 30. As the statement made above on the practices adopted by manufacturers of proprietary medicinal products makes clear, it is unrealistic to raise, as the Netherlands authorities, unlike those of the other Member States, do, a presumption that the product sold in the manufacturer's country is not the same as the product with the same name sold in the country into which it is imported. When during the main proceedings Mr De Peijper's counsel invited the Chief Public Health Inspector, whom the Kantongerecht heard as an expert witness, to give specific examples supporting the view of the Netherlands authorities, he was unable to do so. Further these authorities do not give anyone other than the duly appointed importer the opportunity of rebutting the said presumption that the products are dissimilar, although such a rebuttal could very well be proved, if necessary, by analyses made by these other persons or by an independant institution without in any way adversely affecting the interests of public health.

The disputed rules are not justified by reasons relating to the protection of health. They go further than is necessary, not only because the said presumption that the products are dissimilar is purely theoretical but also because, in order to check whether a proprietary product which has been marketed complies with the data in the manufacturer's file, all that is required is that the authorities in fact have these data in their possession. If these data have been supplied by the manufacturer or the duly appointed importer it is unecessary to ask other importers for this information as well.

In any case it is quite impossible to accept the view that the burden of proof lies on the parallel importer. The opposite view is the correct one namely that, since it is in the interest of the manufacturer to protect the identity of the medicinal preparations which he markets in different Member States, the authorities can require him or his duly appointed importer to produce a declaration certifying this identity or, failing that, to give partiulars of the differences. These persons are better placed to make such a declaration; moreover the manufacturer is always responsible for the products he manufactures. However effectively a manufacturer were to market a product in different forms — apart from the case where he does so in order to comply with the different requirements of the national laws concerned — he would probably do so for reasons which have nothing to do with the therapeutical efficacy of the product.

Even if the authorities are presumed to be entitled to place the burden of proof on the parallel importer, there are ways of discharging this burden which do not make the importer dependant on the cooperation of the manufacturer or his duly appointed importer. Belgian law for example has recourse to such means.

The rules prescribed by Netherlands law other than those at issue in this dispute provide the authorities with an effective way of protecting public health. For example these authorities are entitled to make the granting of a distribution licence subject to conditions and to withdraw it if it is in the interest of public health to do so.

Finally in the light of the Dassonville judgment there is no doubt whatever that placing obstacles in the way of parallel imports by insisting on formalities which the parallel importer either cannot or can only fulfil with greater difficulty amounts to arbitrary discrimination or a disguised restriction on trade between Member States.

The *British Government* makes the following observations:

On the first question

It is clear from the wording of this question that it envisages the case where the marketing of the product in question has already been authorized both in the Member State from which the product has been imported and in that in which it is to be marketed.

The applicability of Article 30 of the Treaty

The disputed measures are not measures having an effect equivalent to a quantitative restriction, because they are applied without any distinction to domestic and imported products and do not in fact make the sale of the latter more difficult than that of the former. Unlike the situation underlying the Dassonville judgment there is no reason in this case to think that the requirements of the national law are substantially more difficult to fulfil by importers of the product than by any other person wishing to sell the product on the market of a Member State. Moreover, having regard to the nature of the product in question, the requirements relating to its authenticity are entirely different from those which were appropriate for the products in the Dassonville case.

In the absence of a complete harmonization of the national rules on the distribution and marketing of medical products the aims pursued by national laws in this field cannot in fact be attained at the present time by a method which exempts the importer from producing to the authorities documents relating to the method of preparing and to the composition of the product. In fact the protection which the law extends to medical products should not only cover their preparation and composition but also a number of other points (the origin of the constituents, the synthetic processes adopted, packaging, designation, directions for use, dosage, the period of presumed stability, contra-indications, etc.). In so far as two variants of a pharmaceutical product differ on one of these points there would then be two different products entailing different problems of safety, efficacy and quality which have to be examined. Further, a product may in time deteriorate or undergo a change in its composition with the result that its effects may alter. From another point of view, for reasons which the British Government states in detail, the safety, efficacy and quality of the presentation of most medical products cannot in practice be established by any method of analysis in a laboratory. The only possible way of checking these products is, on the one hand, to know the manufacturing process used for the packaging of the medicinal preparation and to be convinced that it is satisfactory and, on the other hand, to check whether the product intended for

the market has in fact been manufactured in accordance with the specification of the constituents and also with the known and approved processes of manufacture. The authorities should be able to carry out checks at all stages of production, distribution and marketing of the products.

These developments are confirmed by the two directives of the Council concerning the approximation of national provisions relating to proprietary medicinal products (No 65/65/EEC, OJ of 9. 2. 1965, p. 369; No 75/319/EEC, L 147 of 9. 6. 1975, p. 13) which the British Government analyses in detail; it makes the following observations:

- Under Article 3 of the first directive 'No proprietary medicinal product may be marketed in a Member State without an authorization issued by the competent authority of such Member State'.
- Article 4 of this directive provides that for the purpose of granting this authorization 'the person responsible for marketing shall make application to the competent authority of the Member States' giving the 'qualitative and quantitative composition of all constituents of the proprietary product' and 'a brief description of the method of preparation'.
- Under Article 5 of this directive the beforementioned authorization shall be refused if the required particulars are not produced or if 'the qualitative and quantitative composition of the proprietary medicinal product is not as declared'. In the latter case or, if the particulars supplied are incorrect, Article 11 provides that the authorization shall either be suspended or revoked.
- No provision of the said directives entitles a Member State to derogate from the obligations laid down by Directive No 65/65/EEC on the ground that it has already granted an authorization to another person for a specific product or that it already has the documents which have to be produced by the applicant or again on the ground that another Member State has granted such authorization and that it has in its possession the documents in question. Further the said directive does not distinguish in any way between home-produced proprietary medicinal products and imported proprietary products.
- The directives do not define the expression 'the person responsible for marketing'. For the purpose of interpreting this expression reference must be made to the first recital of Directive No 65/65/EEC which reads 'the essential purpose of any rules concerning production and distribution of proprietary medicinal products must be to protect public health'. Consequently in the case of an imported product the importer or the person who has arranged for it to be imported should be regarded as 'the responsible person'. If several operators import and distribute a product independently of each other each of these importers is 'the person responsible'. This is the only interpretation which allows the checks provided for by the directive to be carried out effectively.
- The national authorities would be unable to perform, wherever it was necessary, the obligations referred to above which are in Articles 5 and 11 of Directive No 65/65/EEC, if it had to consider whether an importer in the circumstances envisaged in the first question referred by the national court may market a product without having an authorization from the public authority and without having produced to them the necessary documents. In such a case, in the absence of an authorization, the importer would moreoever avoid the sanctions provided for in Article 11 of the directive.
  There is no evidence that the documents already produced by such a person are also valid for the product imported later by that other person.

It is to be expected that the view defended by the British Government could mean that a trader would be unable to import a product into his own state and market it there. But if this siutation arises the appropriate remedy is to be found in Articles 85 and 86 of the Treaty.

The applicability of Article 36 of the Treaty

If the Court does not share the British Government's view that the disputed measures do not have an effect equivalent to a quantitative restriction there would in any case be grounds for accepting the view that they fall within the exception provided for by Article 36.

'Supervision of the marketing and distribution of medical products must be regarded as the most important of all these exceptions'. Having said this the considerations set out above warrant the conclusion that the disputed rules are justified on the ground of the protection of health and life of humans without constituting a means of arbitrary discrimination or a disguised restriction on trade between Member States. It is fitting to add that all the Member States have adopted or are in the process of adopting similar rules pursuant to the beforementioned directives of the Council. Even if there was a single Community system for authorizing medical products those persons wishing to sell a pharmaceutical product on the market could be required to produce to the comptetent authorities particulars which they can only obtain with the manufacturer's cooperation.

The second question

Even apparently trivial differences in the method of preparing the product or in its quantitative or qualitative composition can have an effect on its therapeutic properties or entail unacceptable side effects. The possibility that such differences were introduced intentionally by the manufacturer either with a view to preventing parallel imports or for the purpose of complying with the requirements of different national laws is not a decisive factor under Article 36 but, to put it at its highest, could be of considerable relevance as regards other provisions of the Treaty, for example Article 86.

Therefore if the Court was to answer the first question in the negative the reasons put forward by the British Government in connexion with that question would lead to the Court answering the second question in the affirmative.

Although the *Danish Government* does not expressly deny that national measures such as those which are at issue have an effect equivalent to a quantitative restriction, it nevertheless takes the view that they are justified under Article 36 and comply with Directives Nos 65/65/EEC and 75/319/EEC of the Council which were also quoted by the British Government. The Danish Government invokes also Directive No 75/318/EEC of the Council relating to the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (OJ L 147 of 9. 6. 1975, p. 1). It also calls special attention to Articles 3 and 4 of Directive No 65/65.

It is essential that both the producer and the authorities responsible for public health are able to check a medicinal preparation at all stages of production and distribution to the point of sale to the consumer. These authorities should have the power to decide how these checks shall be carried out. In support of this, the Danish Government refers again to the obligations to carry out checks imposed upon Member States by the three abovementioned directives and in particular by Article 4 of Directive No 65/65 and Articles 5 of Directive No 75/319.

It is not sufficient that the authorities have in their possession corresponding data relating to the 'same' preparation which has already been lawfully placed on the market. If they were confined to these data, they could only embark upon random sampling checks or upon similar checks to make sure that the preparation which has to be examined corresponds to the composition specified, but would find it impossible to check whether it was in fact manufactured by the producer who was named and whether it was manufactured, despatched and kept in satisfactory conditions. If an application for authorization to place proprietary medicinal products on the market is made, the authorities must know to whom they have to apply in order to obtain the requisite data for the purpose of this verification and to be in a position to withdraw specific batches, because they have been found to produce serious side effects or because there has been some mistake in their production. In order to ensure that the identity of the product can be checked at any time the person wishin to place proprietary products on the market must be able to produce, in the case of each separate batch of the products, data relating to the manufacture of that batch of the products (time, conditions, producer, shelf life etc.). These objectives are also the main purpose of the provisions of Chapter IV of Directive No 75/319 and in particular of Article 17 (a) and the first paragraph of Article 22 thereof.

The Court has already held (in the judgments which have already been quoted in Cases 15/74 and 16/74) that the protection of the public against risks arising from defective pharmaceutical products is a matter of legitimate concern and is the main purpose of the exceptions specified in Article 36. Although in these judgments the Court has defined the limits of these exceptions, there are grounds for the view that, on the one hand, the subject-matter of the said cases was entirely different from that of the present dispute and, on the other hand, that the relevant subject-matter in this case has been covered by the provisions of the Council's directives.

Foolproof supervision is all the more necessary where the methods of manufacturing and making up a proprietary medicinal product are different from those used for a similar preparation which has already been marketed. If rules like the ones at issue are used by certain firms to prevent parallel imports the question has to be asked whether the application of the rules on competition laid down by the Treaty is not an adequate method of fighting such practices; on the other hand the latter do not have any influence on the application of Article 36.

The *Netherlands Government,* too, does not deny that the measures in question have an effect equivalent to a quantitative restriction but takes the view that they are covered by the exceptions specified in Article 36. It defines the scope of the disputed provisions in the sense that they prohibit the marketing of a proprietary medicinal product if, *inter alia:*

- its qualitative and quantitative composition does not correspond to that of the product for which authorization to place it on the market was granted;
- the product has not been prepared in accordance with the method of preparation which was approved when the authorization was granted;
- when the product was checked the methods used for analysing and checking it were not those agreed when the authorization was granted.

Even an apparently trivial change in the method of preparation or in the composition of the product may either have an unfavourable influence on its therapeutic efficacy or have unacceptable harmful side effects. If it were not for the disputed legislation the authorities would not have any guarantee concerning the composition of the imported product,

especially where products are involved which were not bought by the importer in question direct from the manufacturer. In fact, if there was no requirement that every importer responsible for placing a proprietary medicinal product on the market must have in his possession the same data as those produced and approved when an application for an earlier authorization was received for the same proprietary medicinal product, such importer would be unable to check whether the product which he imports is the same as the proprietary medicinal product for which the earlier authorization was granted.

There is neither discrimination nor a disguises restriction on trade between Member States. On the one hand the disputed rules do not distinguish between national and foreign products. On the other hand they do not have any restrictive effect on imports; the most that can be claimed is that, were it not for these rules, the pattern of trade might perhaps be different; but the rules do not restrict the total amount of imports.

The Netherlands Government invokes, in support of the same views as the British and Danish Governments, Directives No 65/65/EEC and No 75/319/EEC of the Council. It states that none of the provisions of these directives contain an exception to the requirement of an authorization when more than one person are responsible for putting the same product on the market. This is bound to be the position having regard to the obligations imposed upon such persons and upon the competent authorities under these directives (cf. for example Articles 8, 11 and 20 of Directive No 65/65; Articles 27 and 36 of Directive No 75/319). If Mr De Peijper's argument was accepted, the said authorities would find that it was impossible to fulfil the obligations to carry out checks imposed upon them by these provisions.

These considerations also make it possible for the second question referred by the national court to be answered. Under the provisions of the Council directives which have been quoted, when a proprietary medicinal product is marketed in a Member State it should correspond in every way to the product for which an authorization was granted in this State. In other words if a product which has been prepared or made up in a different way is released for sale in an importing country and this different method of preparing or making it up has not been approved in the importing country, such a product will not be able to be marketed in the importing country. It is for the national authorities of the importing country to ascertain whether a proprietary medicinal product may be authorized in that country if it has been modified in the way indicated above. Further, it follows from Article 11 of Directive No 65/65 — which provides that an authorization to market a proprietary medicinal product shall be suspended or revoked if its qualitative or quantitative composition does not correspond to that for which the authorization was granted — that any modification, however trivial, is prohibited in so far as it has not been accepted by the national authorities.

The *Commission* makes the following observations:

The Netherlands legislation

In accordance with a generally accepted practice 'pharmaceutical preparations' must be understood to mean medicinal preparations sold under a name derived from the substance used ('onder hun stofnaam'). 'Pharmaceutical preparations' are capable of being distinguished from 'medicinal preparations in packages' ('verpakte geneesmiddelen'), since this expression refers to medicinal preparations sold under a trade-mark.

The present proceedings relate to pharmaceutical preparations in spite of the fact that the national court 'suddenly introduced into its questions the

expression "proprietary medicinal product" '.

In the Netherlands the supervision of the sale of medicinal preparations takes place in two stages, the first being the authorization to market the medicinal preparations on the Netherlands market (cf. Article 3 of the BFP) and the second the manufacture of and trade in the authorized medicinal preparations.

It appears from Articles 3 to 7 inclusive of the BFP that the authorization covers not only a specific substance having specific characteristics but also the method of preparation and the system of checks used during the preparation. 'In other words an authorized medicinal preparation is a product which has been manufactured in accordance with a method described with a high degree of accuracy and has undergone specific checks'.

Even if a medicinal preparation has been authorized the authorites are concerned to ensure that it is manufactured in a way which corresponds completely to the data produced for its authorization. The medicinal preparation which is placed on the market must therefore correspond in every way to the product which was authorized. As far as imported products are concerned the Netherlands legislature endeavours to obtain this guarantee by adopting two different methods: on the one hand it makes the manufacturer responsible for ensuring the above-mentioned conformity (Article 12 of the BFP); on the other hand the importer must himself be able to prove this conformity (cf. Article 14).

It can be assumed that the importer need only have in his possession copies, or a summary of the conclusions, of the records referred to in Article 11 of the BFP; which have to be drawn up by the manufacturer and from which it must follow that the provisions of Article 5 (1) (b) and (c) were complied with at the time of manufacture in order to fulfil the requirements of Article 14 (1) (a).

Read together these provisions have two objectives:

- they require that the records relating to the medicinal preparation which has in fact been imported (cf. Articles 14, 11) conform with the data on the file relating to the authorized medicinal preparation (cf. Articles 5, 6);
- in the case of imports they designate the person whose duty it is to prove this conformity.

In this way the Netherlands authorities are absolutely sure that there is conformity which makes it easier to carry out the later checks.

It appears from certain statements of the Netherlands Government that in its view the difficulties arising out of the laws and practices of the Netherlands in the case of parallel imports must be accepted not only for the purpose of protecting public health but also having regard to the technical aspects of the supervision which has to be undertaken.

The first question

This question assumes that there is a parallel import of a medicinal preparation which has been authorized in the importing as well as the exporting country on the basis in both cases of an identical method of preparation and qualitative and quantitative composition. In other words this question deals with the case where the medicinal preparations manufactured in the exporting country are in all respects the same whether they are intended for the domestic market or for export.

The court making the reference does not deny that the data which the Netherlands authorities endeavour to collect in respect of each batch of medicinal preparations supplied are important for public health. It simply wishes to know whether, for the purpose of establishing these facts, these authorities can proceed in the way they did. The question raised refers 'a little too

narrowly' to the obligation to provide a file imposed upon the importer by Article 6 of the BFP. It is true that the performance of this obligation does not provide the authorities with any additional information. However the aim of the legislature is not to provide the authorities with supplementary data but to ensure that the parallel importer is himself also able to prove, with the cooperation of the expert in his employment, the requisite conformity between the file and the records, that is to say, between the medicinal preparation which was authorized and the one which was in fact imported. In order to be able to comply with this condition the parallel importer must obviously have in his possession both the file and the records. Therefore the Netherlands legislature makes the parallel import dependent upon the cooperation of the manufacturer, which means that in practice such an import cannot be effected, as the manufacturer is under no legal obligation to cooperate in this way and it is very much in his interest not to do so.

Moreover the Netherlands authorities do not appear to adopt any other way of establishing this conformity. The fact that parallel imports of medicinal preparations are impossible is due to a combination of legal provisions and an administrative practice.

The Council directives referred to by the British, Danish and Netherlands Governments are in no way connected with the questions referred. On the one hand they only apply to medicinal preparations in packages ('proprietary medicinal products' according to the wording of the directives) whereas the questions refer to pharmaceutical preparations. On the other hand they aim at the harmonization of laws and can only therefore cover national provisions which are compatible with Community law.

An effective limitation on the number of importers is a measure having equivalent effect within the meaning of Article 30. The restriction in question in this case has an adverse quantitative effect on the supply of imported products. Further, it prevents offers being made at lower prices and this precludes the normal expansion of trade channels. The only question therefore is whether the restrictions in question come within the exceptions specified in Article 36.

There is no doubt that Member States are entitled to make the sale of medicinal preparations subject to regular checks. The only question is how this power may be used. Only those restrictions which are absolutely necessary for the protection of health and life of humans are admissible under the Treaty. This conclusion follows from the wording of Article 36 and from the fact that it constitutes an exception.

It is clear from the case-law of the Court that formalities with which only direct importers are in fact able to comply may constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States, but different treatment of imported and national products does not necessarily amount to such discrimination, since in each specific case account must be taken of the actual circumstances surrounding these two categories of products. All these considerations also apply to the different ways of treating imports by authorized importers and parallel imports. In this connexion it is appropriate to recall the judgment of the Court of 30 April 1974 (*Sacchi,* Case 155/73, [1974] ECR 409) which held that it is incompatible with Article 30 to favour particular trade channels in relation to others.

The restriction in question is not justified by concern for the protection of public health. In fact, as the Commission explains in detail, this objective can be attained by less restrictive methods.

Further, the method chosen by the Netherlands authorities involves arbitrary

discrimination, since it means that two different situations are dealt with in the same way. The parallel importer finds that in fact the same obligations are imposed upon him as upon a duly appointed importer in spite of the fact that he himself is unable to perform — that is to say through the expert in his employment — these obligations but is dependent upon the cooperation of a third party in whose interest it is to refuse such cooperation.

Finally Netherlands regulations imply some disguised restriction on trade since without any justification they prevent the development of potential trade channels.

To sum up, the Commission submits that the first question should be answered as follows:

National rules relating to the sale of imported medicinal preparations which provide as a condition precedent to such sale that importers must have in their possession the manufacturer's data which establish the conformity of the imported with the authorized medicinal preparation only comes within the limits of Article 36 if the national authorities concerned also make use, where necessary, of other data enabling the requisite compatibility to be established or demand the necessary data directly from the manufacturer.

The second question

It is appropriate to call attention first of all to the fact that the difference in the composition etc. referred to in the question may in certain cases also be explained by the differences between the national laws relating to pharmaceutics. In so far as these differences have been brought about artifically by the manufacturer the problems which arise do not come within Article 36. In fact, this provision is concerned with the maintenance of national standards in the fields which it enumerates. However, on the assumption which has been made these standards are not at issue.

However a Member State which applies national restrictions, which are lawful in themselves, or authorizations in such a way that they raise obstacles over and above the minimal obstacles inherent in these rules endangers the attainment of the objectives of the Treaty and for this reason may infringe Article 5 of the Treaty.

Member States are under a general duty and consequently have the power to combat abuses such as the one envisaged by the national court. A Member State cannot therefore argue that its own laws do not expressly entitle it to proceed in this way.

It is clear from what has been said in connexion with the first question that the national authorities have the necessary means to decide whether the differences recorded between the two variants of the medicinal preparation in question may have a therapeutic effect. If they do not, there is no need to retain the obstacles to the sale of this product in the importing country. In the event of doubt or dispute, an independent expert can give his opinion on this question. If they do, the protection of public health is a valid ground for opposing the sale of these two variants on one and the same market.

To sum up the Commission submits that the second question should be answered as follows:

When the sale of the same medicinal preparation is authorized in more than one country and there are differences between various authorized forms, a ban on the import of another form of this product can be justified on the ground of protecting public health only if, by applying objective criteria, the differences in question are found to have a therapeutic effect.

During the oral proceedings on 18 February 1976 the Netherlands Government, the Officier van Justitie for the

District of Rotterdam represented by Mr H. R. G. Feber, Mr De Peijper, represented by Professor W. Van Gerven of the Brussels Bar and Mr A. F. De Savornin Lohman of the Rotterdam Bar, the British Government represented by Mr Robin Auld Q. C. of Gray's Inn and Mr Francis Jacobs of the Middle Temple and the Commission represented by its Legal Adviser, Mr B. Van der Esch, developed the arguments put forward in the written procedure.

The new matters raised on this occasion may be summarized as follows:

The Court invited the Netherlands Government to state whether the Netherlands authorities already had in their possession the file relating to the medicinal preparations in question, of failing to compile which Mr De Peijper has been accused and which the Netherlands representative of the Hoffmann-La Roche firm handed over to them.

The *Officier van Justitie for the District of Rotterdam* in his answer to this question in the name of the Netherlands Government states that the British manufacturer of the Hoffmann-La Roche group never placed the said file at the disposal of the Netherlands authorities. On the other hand the latter have the file relating to the products manufactured by Hoffmann-La Roche in Switzerland. These however are not the products at issue and it is in no way proved that, although the products of the two manufacturers bear the same name, their method of preparation and composition are in every respect identical.

The *Officier van Justitie and the Commission* also answered another question raised by the Court relating to the connexion between the Royal Netherlands decree of 10 September 1974 relating to packaged medicinal preparations and the Netherlands decree of 21 October mentioned in the order making the reference.

The Commission answered a third question put by the Court asking what explanation the Netherlands Government gave the Commission concerning the said decree and whether there was an exchange of views on this matter, whether the Commission has finished its examination of the decree and, if so, whether it has stated its views on the conformity of the decree with Community law.

Mr De Peijper, in answer to a question by the Court during the hearing asking what opportunities the manufacturer has of following what happens to each batch which he produces, although it has been packaged by the importer, produced to the Court by way of example a bottle originating from the manufacturer and containing tablets. The label on this bottle shows that the medicinal preparation was produced in the United Kingdom. The batch number ('batch-nummer') is on the right hand side of the label. After packaging Centrafarm puts on the left hand side of the label on its own bottle its own file number ('chargenummer'). The company adopts a daily system of accounting which enables it to determine in the case of each batch the relationship between the English and the Netherlands numbers.

The *British Government* calls attention to the fact that a large number of factors concerning the method of manufacture, even including the nature of the inactive ingredients, can have a therapeutic effect simply because they have for example an effect on the rate at which the human body can absorb a medicinal preparation.

The Advocate-General delivered his opinion at the hearing on 17 March 1976.

Law

1 By order of 29 September 1975, which reached the Court on 2 October 1975, the Kantonrechter of Rotterdam referred to the Court pursuant to Article 177 of the EEC Treaty two questions concerning the interpretation of Article 30 et seq., and in particular of Article 36, of the said Treaty.

2 These questions were raised during criminal proceedings instituted by the Officier van Justitie for the district of Rotterdam against a Netherlands trader whom he accuses of having infringed the Netherlands public health legislation, on the one hand by supplying pharmacies in that Member State with medicinal preparations which he had imported from the United Kingdom without the consent of the Netherlands authorities and, on the other hand, by failing to have in his possession certain documents connected with these medicinal preparations, namely the 'file' and the 'records' prescribed by the said legislation.

3 Under that legislation 'file' means a document which the importer must keep for 'every pharmaceutical packaging of a pharmaceutical preparation which he imports' and which must contain detailed particulars concerning the said packaging and especially of the quantitative and qualitative composition as well as the method of preparation; these particulars have to be signed and endorsed 'seen and approved' by 'the person who is responsible for the manufacture abroad'.

4 It is the practice for the importer to produce the 'file' to the competent authorities for 'certification' which at the same time authorizes him to market the packaging in the Netherlands so that only an importer who has the 'file' in his possession can obtain this authorization.

5 Under the Netherlands legislation 'records' mean documents which an importer must have in his possession when he supplies a pharmaceutical preparation which he has imported and which establish that the latter has in fact been manufactured and checked in accordance with the particulars on the above mentioned 'file' and relating to the manufacturing formula as well as the rules for checking the preparation and the substances of which this preparation is composed.

6 It appears that the 'file' relates to the product in general whereas the 'records' refer to each specific batch of the product which the importer wishes to place on the market.

7 The accused in the main proceedings does not deny the matters of which he is accused but argues that he could not comply with the rules in question because he was unable to obtain the documents which are at issue in those proceedings.

8 The explanation for this is that the medicinal preparations in question were manufactured by a British producer — belonging to a group whose operational centre is in Switzerland —, that the accused in the main proceedings purchased them from a wholesaler established in the United Kingdom and then imported them 'in parallel' into the Netherlands and finally that the said manufacturer or the representative of the group in the Netherlands refused to give the accused the help which was absolutely necessary if the latter was to obtain possession of the above-mentioned documents.

9 The main purpose of the questions referred by the national court is to find out whether rules and practice such as the ones in issue are contrary to Community law because they constitute a measure having an effect equivalent to a quantitative restriction which is prohibited by Article 30 of the Treaty and cannot fall within the exception specified in Article 36 of the Treaty in favour of restrictive measures justified on grounds of the protection of health and the life of humans.

The first question

10 The first question envisages a factual situation which the Kantonrechter describes as follows:

— a pharmaceutical product prepared in accordance with a uniform method of preparation and qualitative and quantitative composition is lawfully in circulation in several Member States, in the sense that, in pursuance of the national systems of legislation of these States, the requisite authorizations have been granted in relation to that product to the manufacturer 'or the person responsible for putting the product on the market' in the Member State in question;

— the fact that such authorizations have been granted in each of the Member States is made known by general notice given by official publication or in some other way; and

— this product is in every respect similar to a product in respect of which the public health authorities of the Member State into which the first product has been imported already possess the documents relating to the method of preparation and also to the quantitative and qualitative composition, since these documents were produced to them previously by the manufacturer or his duly appointed importer in support of an application for authorization to place them on the market.

11 The Court is asked to rule whether national authorities faced with such a situation adopt a measure equivalent to a quantitative restriction and prohibited by the Treaty when they make the authorization to place a product on the market, for which a parallel importer has applied, conditional upon the production of documents identical with those which the manufacturer or his duly appointed importer has already lodged with them.

12 1. National measures of the kind in question have an effect equivalent to a quantitative restriction and are prohibited under Article 30 of the Treaty if they are likely to constitute an obstacle, directly or indirectly, actually or potentially, to imports between Member States.

13 Rules of practices which result in imports being channelled in such a way that only certain traders can effect these imports, whereas others are prevented from doing so, constitute such an obstacle to imports.

14 2. A. — However, according to Article 36 'the provisions of Articles 30 to 34 shall not preclude prohibitions or restrictions on imports ... justified on grounds of ... the protection of health and the life of humans' which do not 'constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.

15 Health and the life of humans rank first among the property or interests protected by Article 36 and it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they intend to assure and in particular how strict the checks to be carried out are to be.

16 Nevertheless it emerges from Article 36 that national rules or practices which do 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.

17 National rules or practices do not fall within the exception specified in Article 36 if the health and life of humans can as effectively protected by measures which do not restrict intra-Community trade so much.

18 In particular Article 36 cannot be relied on to justify rules or practices which, even though they are beneficial, contain restrictions which are explained primarily by a concern to lighten the administration's burden or reduce public expenditure, unless, in the absence of the said rules or practices, this burden or expenditure clearly would exceed the limits of what can reasonably be required.

19 The situation described by the national court must be examined in the light of these considerations.

20 B. — For this purpose a distinction must be drawn between on the one hand the documents relating to a medicinal preparation in general, in this case the 'file' prescribed by the Netherlands legislation, and, on the other hand, those relating to a specific batch of this medicinal preparation imported by a particular trader, in this case the 'records' which have to be kept under the said legislation.

21 (a) With regard to the documents relating to the medicinal preparation in general, if the public health authorities of the importing Member State already have in their possession, as a result of importation on a previous occasion, all the pharmaceutical particulars relating to the medicinal preparation in question and considered to be absolutely necessary for the purpose of checking that the medicinal preparation is effective and not harmful, it is clearly unnecessary, in order to protect the health and life of humans, for the said authorities to require a second trader who has imported a medicinal preparation which is in every respect the same, to produce the above-mentioned particulars to them again.

22 Therefore national rules or practices which lay down such a requirement are not justified on grounds of the protection of health and life of humans within the meaning of Article 36 of the Treaty.

23 (b) With regard to the documents relating to a specific batch of a medicinal preparation imported at a time when the public health authorities of the Member State of importation already, have in their possession a file relating to this medicinal preparation, these authorities have a legitimate interest in being able at any time to carry out a thorough check to make certain that the said batch complies with the particulars on the file.

24 Nevertheless, having regard to the nature of the market for the pharmaceutical product in question, it is necessary to ask whether this objective cannot be equally well achieved if the national administrations, instead of waiting passively for the desired evidence to be produced to them — and in a form calculated to give the manufacturer of the product and his duly appointed representatives an advantage — were to admit, where appropriate, similar evidence and, in particular, to adopt a more active policy which could enable every trader to abtain the necessary evidence.

25 This question is all the more important because parallel importers are very often in a position to offer the goods at a price lower than the one applied by the duly appointed importer for the same product, a fact which, where medicinal preparations are concerned, should, where appropriate, encourage the public health authorities not to place parallel imports at a disadvantage, since the effective protection of health and like of humans also demands that medicinal preparations should be sold at reasonable prices.

26 National authorities possess legislative and administrative methods capable of compelling the manufacturer or his duly appointed representative to supply particulars making it possible to ascertain that the medicinal preparation which is in fact the subject of parallel importation is identical with the medicinal preparation in respekt of which they are already informed.

27 Moreover, simple co-operation between the authorities of the Member States would enable them to obtain on a reciprocal basis the documents necessary for checking certain largely standardized and widely distributed products.

28 Taking into account all these possible ways of obtaining information the national public health authorities must consider whether the effective protection of health and life of humans' justifies a presumption of the non-conformity of an imported batch with the description of the medicinal preparation, or wether on the contrary it would not be sufficient to lay down a presumption of conformity with the result that, in appropriate cases, it would be for the administration to rebut this presumption.

29 Finally, even if it were absolutely necessary to require the parallel importer to prove this conformity, there would in any case be no justification under Article 36 for compelling him to do so with the help of documents to which he does not have access, when the administration, or as the case may be, the court, finds that the evidence can be produced by other

30 The British, Danish and Netherlands Governments are of the opinion that measures such as those which are the subject-matter of the main proceedings are necessary in order to comply with the requirements of Council Directives Nos 65/65/EEC, 75/318/EEC and 75/319/EEC (OJ, English Special Edition 1965, p. 20; OJ L 147 of 9. 6. 1975, p. 1 and p. 13) concerning the approximation of national provisions relating to proprietary medicinal products.

31 However the sole aim of these directives is to harmonize national provisions in this field; they do not and cannot aim at extending the very considerable powers left to Member States in the field of public health by Article 36.

32 Given a factual situation such as that described in the first question the answer must therefore be that rules or practices which make it possible for a manufacturer and his duly appointed representatives simply by refusing to produce the 'file' or the 'records' to enjoy a monopoly of the importation and marketing of the product in question must be regarded as being unnecessarily restrictive and cannot therefore come within the exceptions specified in Article 36 of the Treaty, unless it is clearly proved that any other rules or practice would obviously be beyond the means which can reasonably be expected of an administration operating in a normal manner.

The second question

33 By the second question the Court is asked to say whether in principle the answer which must be given to the first question also applies to the case where (a) the process of manufacture and the qualitative and quantitative composition of the medicinal preparation imported by the parallel importer coming from another Member State are different from those of the medicinal preparation bearing the same name and in respect of which the authorities of the Member State into which it has been imported already have these data but (b) 'the differences between the one and the other product are of such minor importance that it is likely that the manufacturer is applying or introducing ... these differences with the conscious and exclusive intention of using these differences ... in order to prevent or impede the possibility of the parallel importation of the proprietary medicinal product'.

34 The answer must be in the affirmative.

35 The competent administration of the importing Member State is clearly entitled to require the manufacturer or his duly appointed importer, when the person concerned applies for an authorization to market the medicinal preparation and lodges the relevant documentation (a) to state whether the manufacturer or, as the case may be, the group of manufacturers to which he belongs, manufactures under the same name for different Member States several variants of the medicinal preparation and (b) if his answer is in the affirmative, to produce similar documentation for the other variants too, specifying what are differences between all these variants.

36 It is only if the documents produced in this way show that there are differences which have a therapeutic effect that there would be any justification for treating the variants as different medicinal preparations, for the purposes of authorizing them to be placed on the market and as regards producing the relevant documents, it being understood that the answer to the first question remains valid as regards each of the authorization procedures which have become necessary.

Costs

37 The costs incurred by the British, Danish and Netherlands Governments and the Commission of the European Communities, which have submitted their observations to the Court, are not recoverable.

38 As these proceedings are, in so far as the parties to the main proceedings are concerned, in the nature of a step in the proceedings pending before the Kantonrechter of Rotterdam, the decision as to costs is a matter for that court.

On those grounds,

THE COURT

in answer to the questions referred to it by the Kantongerecht of Rotterdam hereby rules:

1. **National rules or practices which result in imports being channelled in such a way that only certain traders can effect these imports, whereas others are prevented from doing so, constitute a measure having an effect equivalent to a quantitative restriction within the meaning of Article 30 of the Treaty.**

2. **Given a factual situation such as that described in the first question national rules or practices which make possible for a manufacturer of the pharmaceutical product in question and his duly appointed representatives, simply by refusing to produce the documents relating to the medicinal preparation in general or to a specific batch of that preparation, to enjoy a monopoly of the importing and marketing of the product, must be regarded as being unnecessarily restrictive and cannot therefore come within the exceptions specified in Article 36 of the Treaty, unless it is clearly proved that any other rules or practices would obviously be beyond the means which can reasonably be expected of an administration operating in a normal manner.**

3. **It is only if the information or documents to be produced by the manufacturer or his duly appointed importer show that there are several variants of the medicinal preparation and that the differences between these variants have a therapeutic effect that there would be any justification for treating the variants as different medicinal preparations, for the purpose of authorizing them to be placed on the market and as regards producing the relevant documents, it being understood that the answer to the first question remains valid as regards each of the authorization produres which have become necessary.**

Lecourt Kutscher O'Keeffe

Donner Mertens de Wilmars Sørensen Mackenzie Stuart

Delivered in open court in Luxembourg on 20 May 1976.

A. Van Houtte
Registrar

R. Lecourt
President