European Court of Justice, 20 May 1976, De Peijper

PHARMACEUTICAL LAW – FREE MOVEMENT OF GOODS

Measures having equivalent effect

- **Rules of practices which result in imports being channelled in such a way that only certain traders can effect these imports constitute a maesure having equivalent effect to a quantative restriction**

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. 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.

- **National rules or practices which make it possible for a manufacturer of a pharmaceutical product to enjoy a monopoly of the importing and marketing of the product simply by refusing to produce the documents relating to the medicinal preparation of the product, are unnecessarily restrictive and cannot therefore come within the exceptions specified in arti-cle 36 of the treaty**

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.

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.

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 admini-stration to rebut this presumption.

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.

- **Only differences with a therapeutic effect justify treating variants as different medicinal products**

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.

Source: **www.eur-lex.eu**

European Court of Justice, 20 May 1976

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,

Subject of the case

On the interpretation of article 36 of the EEC treaty,

Grounds

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 obtain 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.

Decision on costs

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.

Operative part

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.