OPINION OF MRS ADVOCATE GENERAL ROZÈS DELIVERED ON 5 OCTOBER 1983 [1]

Mr President,
Members of the Court,

Pursuant to the first and second paragraphs of Article 177 of the EEC Treaty, the Arrondissementsrechtbank [District Court] Amsterdam has referred to this Court for a preliminary ruling various questions concerning, on the one hand, the interpretation of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and, on the other hand, Articles 30 and 36 of the Treaty.

The questions were raised by the District Court in the context of criminal proceedings brought against a judgment given by the Kantonrechter [Cantonal Court] Amsterdam against Leendert van Bennekom, in his capacity as owner of a wholesale business dealing in vitamins and in dietary and mineral products.

I — The facts of the case are as follows:

Leendert van Bennekom is being prosecuted for stocking a number of products for the purpose of supply, including a large quantity of vitamin and multi-vitamin preparations put up in pharmaceutical form, which are the sole subject of these proceedings for a preliminary ruling. None of the products in question carried a notice or recommendation describing them as "medicinal products", nor had they undergone the registration required of all pharmaceutical products prior to marketing. Registration is designed to ensure that a proper preliminary analysis is carried out in order, in particular, to eliminate as far as possible any ineffective or harmful medicines. They thereby failed to comply with the requirements of the Netherlands Wet op de Geneesmiddelenvoorziening [Law on the Supply of Medicinal Products].

1. At first instance, Leendert van Bennekom admitted to having held the vitamin preparations at issue with a view to selling them, but he criticized their being described as medicinal products. He therefore took the view that he was not required to comply with the obligations which he was accused of having disregarded.

In his submissions the Public Prosecutor's representative, basing himself on expert opinions, claimed that the products in question were, on the contrary, medicinal products by reason of their composition, their degree of concentration and the instructions appearing on the packaging. A further aspect of those submissions deserves to be noted. It relates to the background of the case. It would seem that the substances seized from Leendert van Bennekom's business premises are prescribed by advocates of empirical medicine (homeopathy, plant medicine, and so on), so called so as to distinguish it from conventional medicine. It is beyond dispute that a great many of those substances come from the United States of America, where such medicine has met with some success. In the Netherlands, too, there is said to be a growing demand for that type of remedy.

1 — Translated from the French.

The Cantonal Court held in its judgment of 21 September 1981 that the vitamin preparations constituted medicinal products within the meaning of the Law on the Supply of Medicinal Products. It found that, since vitamins were necessary only in small quantities for the preservation of sound health, the high-dose vitamin preparations were intended to combat or forestall a vitamin deficiency in the user. It further found that they were used in the treatment of various diseases, including cancer, under the name of "dietary therapy". Moreover, it held that the pharmaceutical nature of their use implied that their purpose was to cure or forestall a deficiency, which was caused or might be caused by a shortage of vitamins, in human beings. Accordingly, it ordered Leendert van Bennekom to pay a fine of HFL 750 and to withdraw the disputed products from sale; these had, in any case, already been seized by the police.

2. In proceedings before the District Court exercising its appellate jurisdiction, Leendert van Bennekom supplemented his main defence by arguing that, should the vitamin preparations be held to be medicinal products within the meaning of the Netherlands Law, the latter was in conflict with the definition of the term "medicinal product" given by Directive 65/65/EEC. On account of the primacy of Community law, the Netherlands Law was overridden by the directive in the event of inconsistency. Leendert van Bennekom claims that the preparations at issue are not medicinal products within the meaning of either the first or the second of the two definitions in the directive. He also concludes from a comparison of the Community and national texts that the Netherlands Law differs fundamentally from the directive.

The District Court likewise takes the view that there are considerable differences, as regards the wording of the definitions in question, between Directive 65/65/EEC and the Law on the Supply of Medicinal Products, and hence that there is a possibility that the directive was incorrectly transported by the Netherlands Law. In its opinion, however, the answer depends on the interpretation given to the definition of the term "medicinal product" in the Community directive. Moreover, it raises the question whether the Netherlands legislation on vitamins is compatible with Article 30 *et seq.* of the Treaty, inasmuch as the legislation is more restrictive than that of other Member States. It was in order to obtain clarification of those points that, by an interlocutory order of 12 May 1982, it referred five question to this Court for a preliminary ruling, the first three of which relate to the interpretation of the directive and the other two to that of Article 30 *et seq.* of the Treaty.

II — Since the questions raised by the District Court on the directive were formulated on the assumption that the Netherlands Law might possibly be incompatible with the Community text, it will clearly be helpful, for the purposes of verifying whether that assumption is well-founded, to consider in turn the precise meaning of the Community and the Netherlands definitions of the term "medicinal product".

A — 1. Since the Community definition is contained in a directive, I shall begin by setting it out briefly.

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products aims to

eliminate some of the hindrances to intra-Community trade in pharmaceutical products which arise from disparities between national rules, whilst respecting the requirements of public health. The directive serves only as a first stage towards harmonizing national legislation because the field covering problems of health is a complex and sensitive one. In the first place, the directive does not cover all medicinal products but only proprietary ones, that is to say, ready-prepared medicinal products placed on the market under a special name and in a special pack. [1] In the second place, it leaves Member States with some latitude, owing to the general character of most of its provisions. [2] It is provided in particular that "No proprietary medicinal product may be placed on the market in a Member State unless an authorization has been issued by the competent authority of that Member State", [3] and that such authorization may be granted only on application. That application must be accompanied by numerous particulars and documents, amongst which mention may be made of therapeutic indications, contra-indications and side-effects, and the results of various kinds of test (physico-chemical, biological or microbiological, pharmacological, toxicological and clinical). [4]

The concern to safeguard public health is also present in the definition of "medicinal product" given by Article 1, Point 2, of the directive. As I remarked earlier, that definition is in fact twofold.

2. The first paragraph thereof defines a medicinal product as:

"Any substance or combination of substances presented for treating or preventing disease in human beings or animals."

The key expression in the above text, the meaning of which is the main issue in this case, is "presented for". In order to interpret it, it seems to me that a sensible approach is to refer to the purpose of the definition, the *ratio legis.*

As the Commission and the German Government have explained, the definition is intended to prevent the marketing, under the title of medicinal product, of products to which their manufacturer or seller attributes or purports to attribute properties for treating or preventing disease when they are devoid of such properties. It therefore aims to combat quackery.

A product which does actually match that desription is regarded as a medicinal product and consequently may not be marketed except with prior authorization. Such authorization is refused whenever investigation descloses that "its therapeutic efficacy is lacking". [5]

The conclusion may be drawn that the words "presented for" refer, not to the form of the product, but rather to the intention of the person marketing it. Where there is a manifest intent to market the product by attributing to it properties for treating or preventing disease, the medicinal product in

1 — Article 1, Point 1, and Article 2.

2 — It was, moreover, supplemented by a second Council directive bearing the same title (75/319/EEC of 20 May 1975), and by a directive on the approximation of the laws of Member States in respect of the testing of proprietary medicinal products (75/318/EEC, also of 20 May 1975).

3 — Article 3.

4 — Article 4, Points 5 and 8.

5 — First paragraph of Article 5.

question is one which falls within the first paragraph of the definition. That holds good even if the product does not in fact possess the properties ascribed to it. It follows that the intention of the manufacturer or seller serves as the criterion for classifying a product as a medicinal product within the meaning of the first definition in the directive.

It is more difficult to resolve the problem of proving the existence of such an intention. It is sufficient, in my view that such an intention should be expressed in an unequivocal manner. In practice, it may be so expressed by instructions on the product itself or on the attached leaflet, or again it may emerge from the advertising conducted for the product or even from the oral explanations of the seller.

The form in which the product is presented (for example, tablets, pills or capsules) serves only as a presumption, suggesting that its seller attributes to it properties for treating or preventing disease. However, the form in itself is insufficient to support that conclusion. Otherwise, as both Leendert van Bennekom and the Netherlands Government have observed, even mint pastilles put up in tablet form, for example, could be regarded as medicinal products.

3. The definition of "medicinal product" in the second paragraph serves a different purpose. It is formulated as follows: "Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product".

The above definition was inserted into the directive to take account of the fact that active medicines are generally toxic as well. As the Commission has convincingly explained, if the seller of a product presents it as a medicinal product — which is most often the case — it is the first paragraph of the definition which applies, with the result that most dangerous products are covered under that head. However, it may happen that a product which is a potential threat to health is not presented as a medicine; in such cases it needs to be brought within the ambit of the directive in order to be subjected to the system which the latter sets up. The product will then fall under the second paragraph of the definition.

For that purpose the wording chosen was very wide-ranging. If taken literally, it can apply as much to food as to medicines, since food may indeed be administered with a view to modifying physiological functions in human beings. However, the third recital in the preamble to the directive shows that foods and animal feedingstuffs are excluded from its scope. As with the first definition, therefore, the problem arises of distinguishing those products which must be regarded as medicinal products within the meaning of the second paragraph from the others.

The distinguishing criterion is no longer subjective here; it no longer resides in the intention of the seller or the manufacturer. The definition of a medicinal product in this paragraph has, on the contrary, an objective character, or at least one which is as objective as possible. As the Italian Government has noted, a substance is to be regarded as a

medicinal product under this paragraph if it has or may have the effects mentioned therein. However, for the purpose of determining whether the latter condition is fulfilled, or in other words whether the substance or composition may be administered with a view to restoring, correcting or modifying physiological functions,[1] no strict and absolute criterion is available, owing to the evolving state of scientific knowledge. That is why I said earlier that the definition in the second paragraph is as objective in character as possible.

It is my opinion that, to ascertain whether a substance is indeed liable to have the effects enumerated in the definition, the only point of reference, as the Government of the Federal Republic of Germany has suggested, is the view generally held by consumers.

4. The difficulty which I have just expounded should not be overestimated, however. To repeat: medicinal products are usually "presented for treating or preventing disease"; they therefore come within the scope of the first definition. The second definition is thus merely ancillary in character; to borrow the imagery used by the Commission, it is intended as it were to provide a kind of safety net (see its reply to the second question of the Court).

Nevertheless, that ancillary character does not mean that a product can only be classified under one of the definitions and not under both at the same time.

Indeed, as most medicinal products are presented as such and may also be administered with a view to restoring, correcting or modifying physiological functions, they satisfy simultaneously the conditions laid down by both definitions. However, substances presented as having properties for treating or preventing disease but which are in fact devoid of such properties are medicinal products only within the meaning of the first paragraph. Conversely, there are substances such as aspirin which is known to consumers as a medicinal product without there being any need to present it as such. Such a product, which is not presented as a medicinal product but has the effects mentioned in the second paragraph, is covered by the definition given in that paragraph.

B — I come now to the transposition of that definition into national law by the Netherlands legislature.

Since we are concerned here with a national law, I shall, in the context of these preliminary proceedings, take care not to place my own interpretation on it. I shall content myself with summarizing the grounds on which Leendert van Bennekom claims that the Netherlands definition deviates materially from that of the directive and with recalling the explanations of the Netherlands Government of the way in which it claims to have embodied the directive in the Law on the Supply of Medicinal Products.

The term "medicinal product" is defined in the law of the Netherlands by Article 1 (1) (e) of the Law on the Supply of Medicinal Products. The text reads as follows:

"Medicinal product: Any substance or combination of substances which is intended to be used or which is in any way indicated or recommended as being suitable for:

1 — The making of a medical diagnosis may be ignored in the context of a case dealing with vitamins, which clearly cannot be administered for that purpose.

1. healing, treating or preventing any infection, disease, symptom, pain, wound or illness in human beings;

2. restoring, correcting or modifying the functions of bodily organs in human beings;

3. making a medical diagnosis by its administration to or use upon human beings."

In Leendert van Bennekom's opinion, the above definition is incompatible with the Community definition because it encompasses in the term "medicinal product" substances which are not so described in the directive. The latter, he claims, requires not only that the substance should possess properties for treating or preventing disease but also that it should be presented as possessing them. The expression "presented for" constitutes an extra requirement in comparison with the expression "intended to be used" in the Netherlands Law.

That line of argument does not stand up to a straightforward reading of the texts. The first remark overlooks the second part of the Community definition, which, as seen above, does not require the substance to be "presented". The second observation ignores the point that an equivalent expression to "presented for", within the meaning which I have placed upon those words, is to be found in the Netherlands Law in the words "in any way indicated or recommended as being suitable for".

Indeed, as the Netherlands Government has explained, the Netherlands definition of the word "medicinal product" does not repeat *verbatim* the two components of the definition contained in the directive ("presented" and "which may be administered"), but it combines them and then divides them between the terms "intended to be used" and "indicated or recommended".

It therefore seems possible to conclude, without encroaching upon the jurisdiction of the national court, that the Netherlands definition is very close to the Community definition. It follows that the questions raised rest on a false premise, inasmuch as they are founded on the idea that there are considerable differences between those two definitions.

III — In those circumstances, I shall take the liberty of giving relatively brief answers to the first four questions of the Arrondissementsrechtbank Amsterdam, which concern the interpretation of Directive 65/65/EEC.

1. In its first question, it asks whether it is possible for substances or combinations of substances, such as vitamin preparations in certain concentrations and doses and in the form (tablets, pills and capsules) referred to in the present case, which are not indicated or recommended as being suitable for treating, relieving or preventing any infection, disease or symptom, pain, wound or infirmity in human beings, to constitute substances or combinations of substances "presented for treating or preventing disease in human beings or animals".

The Court will have noticed that the first part of the question adopts one of the definitions of a medicinal product in the Netherlands Law and that the second part repeats the wording of the corresponding definition in the directive.

The question is therefore ultimately an inquiry as to whether the directive (by virtue of the definition in question) has a wider meaning than the Netherlands Law (by virtue of its corresponding definition).

That would be the case if the words "presented for", contained in the directive, were wider in scope than the words "indicated or recommended as", employed by the Law. Were that so, the directive would in that respect be broader in scope than the Netherlands Law and hence, conversely, the Netherlands Law would have a narrower scope than the directive. As the Commission has appositely observed, it would follow that the Netherlands Law would not comply with the directive.

I find it difficult to reach that verdict. Even at a first reading, the terms of the Netherlands Law may be seen to coincide with those of the directive. Similarly, if the view is taken, on analysis, that the words "presented for" relate to the manufacturer's or the seller's expression of intent, such a conclusion is quite defensible because it is equally possible to interpret an indication or recommendation given by the manufacturer or seller as referring to an expression of his intent. It is therefore my opinion that the directive was not incorrectly implemented by the Netherlands authorities in that regard.

2. In its second question the Netherlands court inquires whether it is possible for a substance or combination of substances, such as the vitamin or multi-vitamin preparations referred to in the present case, which may be suitable for treating or preventing disease in human beings or animals but which is not presented as such and cannot be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals, to be a "medicinal product" within the meaning of the directive. As the Court will have noticed, in view of the wording used the question is tantamount to asking whether a substance which is not a medicinal product within the meaning either of the first or of the second definition thereof in the directive may none the less be a medicinal product for the purposes of the latter definition.

If taken literally, the question can obviously be answered only in the negative.

It seems to me, however, that if a helpful reply is to be given to the Netherlands court, it is necessary to go somewhat further in our explanations. I am indeed convinced, as is the Commission, that the situation alluded to cannot occur in reality. A substance which has properties for treating or preventing disease but which is not presented as such falls within the second Community definition.[1] Admittedly, the expression "for treating or preventing disease" does not have the same meaning as the words "which may be administered . . . with a view to . . . restoring, correcting or modifying physiological functions". There are indeed substances which may in particular *modify* physiological functions without having properties for treating or preventing disease. Leendert

1 — Second paragraph of Article 1, Point 2, of the directive.

van Bennekom appositely cited the contraceptive pill in this connection, which is a medicinal product within the meaning of the second definition and yet does not have properties for treating or preventing disease. But the converse, which is all that is contemplated by the question raised, does not hold good. Any substance which has properties for treating or preventing disease necessarily has the effect of restoring, correcting or modifying physiological functions.

3. The third question raised by the Netherlands court is inspired by the idea of concentration. The court proceeds on the assumption that vitamins in certain low concentrations are intended for use as foods and not as medicinal products even if they are marketed in a form which is characteristic of medicinal products. It raises the question whether a higher concentration of those same vitamins, whether or not they are in that form, may be sufficient to turn them into a medicinal product within the meaning of the directive. Should the reply be affirmative, it wishes to know the criteria on the basis of which such a finding may be made.

Since the question is scientific rather than legal in character, I shall reply to it with the requisite caution.

Moreover, in the context of proceedings for a preliminary ruling, I can do no more than suggest a reply in the abstract, leaving to the national court the task of applying it to the preparations at issue.

Broadly speaking, it appears justifiable, as the Commission and the Danish Government have observed, to regard vitamin preparations in low concentrations as foodstuffs and not as medicinal products. Conversely, it is possible to classify vitamin preparations in high or very high concentrations as medicinal products.

On the other hand, it seems impossible in the present state of scientific knowledge to indicate precisely the limit at which the designation changes. Certain parties suggested in their observations that the limit should be the recommended daily dose of the substance, that is to say the quantity equal to the daily needs of a normal man. However, I feel that it is better to answer the question solely with reference to each individual case, on the basis of expert reports.

4. Like its first question, the fourth question raised by the Netherlands court concerns the scope of the Netherlands Law and of the directive.

The Netherlands court wishes to know whether the Netherlands Law may forbid — or impose penalties on — the sale, or holding in stock for the purpose of supply, of vitamins and vitamin preparations by providing a definition of the term "medicinal product" which is sufficiently broad to bring such preparations within the ambit of the Law on the Supply of Medicinal Products, when they are not, *qua* substances or combinations thereof, medicinal products within the meaning of the directive.

The question therefore proceeds on the assumption that the definition of "medicinal" product is broader in the Law than in the directive.

In so far as that might be so, I agree with the Commission that the text, as the first stage towards the harmonization of legislation, does not prevent products other than medicinal products from being subjected to the procedure laid down for medicinal products, in particular the authorization requirement. Nevertheless, such an extension is unlawful under Community law unless it complies with Article 30 *et seq.* of the

Treaty and any relevant provisions of secondary legislation, such as the Council directive of 21 December 1976 relating to foodstuffs for particular nutritional uses. [1]

A further finding contained in the question strikes me as equally dubious. Whilst it seems possible that vitamin preparations may not be medicinal products within the meaning of the directive, it is none the less my opinion that in the great majority of cases they will have to be analysed as such, in particular because they are presented as having properties for treating or preventing disease. However, in the absence of proper presentation, it will usually transpire that they may be administered with a view to restoring, correcting or modifying physiological functions. The discrepancy described in the question between the Community and the Netherlands definitions therefore does not exist.

IV — I turn now to the questions on the interpretation of Article 30 *et seq.* of the Treaty.

1. The fifth question proceeds on the assumption that the vitamin or multi-vitamin preparations must be regarded as medicinal products by the directive but are not so regarded by the legislation of certain Member States adopted in pursuance of the directive. If that is so, the Amsterdam court asks whether the Netherlands Law may prohibit the sale of preparations imported from a more liberal Member State, or whether that is contrary to the prohibition of restrictions on trade between Member States.

A reading of the question raises, at the outset, the question how a preparation defined by the directive as a medicinal product could be defined otherwise in certain national legislation adopted for its implementation. But it must be borne in mind that the directive leaves the national authorities a margin of discretion. Hence it is possible for one and the same product not to be regarded as a medicinal product in one Member State but to be so regarded in another, without its being possible to consider either of the legislative texts in question to be *ipso facto* incompatible with the directive.

It is also because the directive does not constitute an exhaustive set of rules on medicinal products that the compatibility of the Netherlands legislation with Community law cannot be assessed solely by reference to the directive, but must be assessed with reference to Articles 30 and 36 of the Treaty as well. [2]

In my opinion it can hardly be disputed that the enforcement of the Netherlands legislation, which is more restrictive than that of other Member States, constitutes an obstacle to the importation of vitamin preparations which have been legally marketed in those Member States.

However, at the present stage of the harmonization of legislation, such obstacles seem to me justifiable on the ground of the protection of public health under Article 36 of the Treaty.

This case seems similar, in particular, to the case of *Officer van Justitie* v *Kaasfabriek Eyssen*, inasmuch as both show evidence of uncertainty as to the critical

1 — Directive 77/94/EEC.

2 — See my Opinion of 10 February 1983 in Case 172/82 (the so-called "waste oil" case), [1983] ECR 555, at p. 568.

threshold at which health is endangered by the consumption of the products in question. [1] That is why I propose that the Court should hold that legislation which makes vitamins subject to the supervisory measures introduced in respect of medicinal products "is included amongst the measures which Article 36 of the Treaty permits Member States to adopt on grounds of the protection of health of humans and for that reason ... escapes the prohibitions resulting from Articles 30 and 34 of the Treaty". [2]

None the less, the view that such legislation is lawful in principle must, in my opinion, be tempered by two considerations. The first is that Article 36 may not be pleaded with regard to vitamins preparations which are indisputably harmless to public health. The second is that, even if the more restrictive national legislation appears to be justified by the protection of public health, it is further required that it should not constitute "a means of arbitrary discrimination or a disguised restriction on trade between Member States". [3]

2. The last question of the Netherlands court is worded as follows:

"If the answer to the preceding questions leads to the conclusion that the definition of medicinal product in Netherlands law, in contrast to the definition contained in the EEC directive, includes the vitamin preparations referred to in this case, with the result that they must be registered ... in the same way as proprietary medicinal products ..., must the Netherlands statutory provisions be regarded as constituting to that extent a measure having an effect equivalent to a quantitative restriction on trade within the meaning of Article 30 *et seq.* of the EEC Treaty, in view of the fact that the EEC directive only contains rules concerning proprietary medicinal products?"

It seems to me that the above question, too, rests on a false premise. In the circumstances envisaged the question of the compatibility of the Netherlands legislation would no longer arise in relation to the directive, but in relation to the rules of the Treaty, because the substances at issue would be defined as medicinal products for the purposes of the Netherlands Law, but not for the purposes of the directive. [4]

Nevertheless, as may be inferred from the final observation contained in the question, the directive could still be disregarded on the ground that it does not concern all types of medicinal product but only proprietary medicinal products.

Usually, however, vitamin preparations are covered by the directive, *qua* proprietary medicinal products. They are very often regarded as medicinal products, but they are for the most part prepared in advance and put on the market under a special name and in a distinctive packaging. The national court alone is directly acquainted with the circumstances of the case; it is therefore a matter for that court to ascertain whether such is the case in this particular instance.

1 — The *Kaasfabriek* case was concerned with a food preservative called nisin.

2 — Judgment of 5 February 1981, *Kaasfabriek Eyssen*, Case 53/80, [1981] ECR 409, at p. 423 (paragraph 16).

3 — Second sentence of Article 36.

4 — Whilst I clearly cannot pass judgment on the vitamin preparations of L. van Bennekom, I have on the other hand been able to establish that, broadly speaking, preparations of that kind are medicinal products within the meaning of the directive.

However, in so far as vitamin or multivitamin preparations may be either medicinal products other than proprietary medicinal products or foods rather than medicinal products, it seems to me that the reply given to the previous question is applicable. The national authorities of Member States have the right, by virtue of Articles 30 and 36 of the Treaty, to subject them to inspection and registration, which is what the Netherlands Law provides in respect of medicinal products. Nevertheless, that right seems to me to be limited in the manner stated above.

Taking all those considerations together, I submit that this Court should answer the questions raised by the Netherlands court in the following manner:

1. Substances or combinations of substances which are not indicated or recommended as being suitable for curing, treating or preventing any infection, disease or symptom, pain, wound or infirmity in human beings cannot be considered to be presented for treating or preventing disease in human beings or animals, within the meaning of the first paragraph of Article 1, Point 2, of Council Directive 65/65/EEC of 26 January 1965.

2. A substance or combination of substances which has properties for treating or preventing disease in human beings or animals but which is not presented as such falls within the definition contained in the second paragraph of Article 1, Point 2, of the directive, because it may be administered with a view to restoring, correcting or modifying physiological functions in human beings or in animals.

3. If a vitamin preparation is not presented as having properties for treating or preventing disease, the fact that it contains a high concentration of vitamins may be sufficient to classify it as a medicinal product within the meaning of the definition in the second paragraph of Article 1, Point 2, of the directive. It must be determined on a case-by-case basis whether it may be administered with a view to restoring, correcting or modifying physiological functions.

4. The legislation of a Member State may make the sale, or the holding in stock for the purpose of supply, of vitamin preparations subject to certain restrictive measures, on condition that it does not infringe other provisions of Community law, in particular Article 30 *et seq.* of the EEC Treaty.

5. The application of a restrictive system to imports from other Member States where they are legally marketed constitutes a measure having an equivalent effect to quantitative restrictions on imports within the meaning of Article 30 of the Treaty. Such restrictions, however, may be justified on grounds of the protection of public health under Article 36 of the Treaty. None the less, that exception is inapplicable in the case of preparations known to be harmless to health. It is likewise inapplicable if the measures constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.