with the authorities constitutes such a measure, since such legislation is liable to hinder trade between Member States.

5. It is only when Community directives, in pursuance of Article 100 of the Treaty, make provision for the full harmonization of all the measures needed to ensure the protection of human and animal life and institute Community procedures to monitor compliance therewith that recourse to Article 36 ceases to be justified.

6. In so far as uncertainties persist in the present state of scientific research, it is for the Member States, in the absence of harmonization, to decide what degree of protection of the health and life of humans they intend to assure, having regard however to the requirements of the free movement of goods within the Community.

   In that connection it is for the national authorities to demonstrate in each case that their rules are necessary to give effective protection to the interests referred to in Article 36 of the Treaty and, in particular, to show that the marketing of the product in question creates a serious risk to public health.

7. Where certain vitamin or multivitamin preparations imported from another Member State may be regarded as medicinal products within the meaning of Directive 65/65 on proprietary medicinal products, but are not covered by the legislation on medicinal products of one or more Member States, or are not covered by the Community definition of a medicinal product contained in that directive, the law of a Member State may prohibit the sale or holding in stock thereof for the purpose of supply, in particular when such preparations are presented in a pharmaceutical form or when they are highly concentrated. However, such rules are justified only if authorizations for marketing are granted when they are compatible with the requirements of health protection.

In Case 227/82

REFERENCE to the Court under Article 177 of the EEC Treaty by the Arrondissementsrechtbank [District Court], Amsterdam, for a preliminary ruling in the criminal proceedings pending before that court against

LEENDERT VAN BENNEKOM, resident at Fijnaart en Heijningen, accused, represented by H. A. Bouman of the Amsterdam Bar and C. T. Barbas of the Amsterdam Bar,

on the interpretation, on the one hand, of the term "medicinal product" in 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 (Official Journal, English Special Edition, 1965-66, p. 20) and, on the other hand, of Articles 30 to 36 of the EEC Treaty in connection with the Netherlands national legislation on medicinal products,

THE COURT (Fifth Chamber)

composed of: Y. Galmot, President of Chamber, Lord Mackenzie Stuart, O. Due, U. Everling, and C. Kakouris, Judges,

Advocate General: S. Rozès
Registrar: P. Heim

gives the following

## JUDGMENT

## Facts and Issues

### I — Facts and written procedure

Mr van Bennekom, who is a wholesale dealer in health foods, vitamins and mineral products, is charged, *inter alia*, with possession for the purpose of supply, on 22 June 1981 in Amsterdam, of a large quantity of packed and unregistered proprietary medicinal products or medicinal preparations contrary to Article 3 (5) (b) of the Wet of de Geneesmiddelenvoorziening [Law on the Supply of Medicinal Products]. On that ground a large quantity of vitamin and multi-vitamin preparations which were in pharmaceutical form (tablets, pills and capsules) but were unaccompanied by any indication or recommendation within the meaning of Article 1 of the Wet op de Geneesmiddelenvoorziening were confiscated. The accused admits possession of the goods in question for the purpose of supply, but he denies that they are medicinal products.

Under Netherlands law, any medicinal product in a pharmaceutical form must be registered by the public authorities before it may be marketed. Registration is designed to ensure that the medicinal product is subject to sufficient analysis before being put on the market in order, so far as possible, to exclude ineffective or harmful medicinal products.

The Wet op de Geneesmiddelenvoorziening assigns the following meaning to "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. healing, treating or preventing any infection, disease, symptom, pain, wound or illness in human beings;

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

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

Council Directive 65/65 assigns the following meaning to medicinal product:

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

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."

It should be noted, however, that the directive is applicable only to "proprietary medicinal products", that is to say ready-prepared medicinal products placed on the market under a special name and in a special pack. According to Article 3 of the directive, 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.

On the other hand, Article 19 of the Besluit Registratie Geneesmiddelen [Decree on the Registration of Medicinal Products] provides for the issue of an authorization to deal in pharmaceutical products throughout the territory of the EEC (in accordance with the provisions of the Second Council Directive, 75/319/EEC, published in Official Journal L 147 of 9 June 1975, p. 13, as amended on 2 May 1978 by Directive 78/420/EEC, published in Official Journal L 123 of 11 May 1978, p. 26). Manufacturers, importers and wholesalers of medicinal products must therefore hold manufacturing, importing and wholesale licences respectively. Van Bennekom did not hold such licences.

The Kantonrechter [Cantonal Court], Amsterdam, decided that highly concentrated vitamin preparations, such as those which had been seized in the present case, were medicinal products within the meaning of the Wet op Geneesmiddelen voorziening because, by reason of their composition (highly concentrated), they were intended to be used for healing, treating or preventing any infection, disease or illness in human beings, in particular an existing or potential deficiency of vitamins in the body.

The Arrondissementsrechtbank [District Court] Amsterdam, dealing with the case on appeal, decided that a ruling by the Court of Justice on the interpretation of the Community provisions was necessary and, staying the proceedings, asked the Court to answer the following questions:

1. Is it 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"?

2. Is it possible for a substance or combination of substances, such as a vitamin or multi-vitamin preparation similar to those 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 in animals, to be a "medicinal product" within the meaning of the directive?

3. (a) On the assumption that vitamins in certain low concentrations are intended for use in foodstuffs and not as medicinal products, even though they are marketed in the form of tablets, pills or capsules, can a high(er) concentration of those vitamins, whether or not they are in that form, be sufficient for the substance to be classified as a medicinal product within the meaning of the directive?

(b) If so, on the basis of what critera may that be established?

4. Is it permissible for Netherlands law to prohibit, or to be applied in the form of a criminal penalty to, the sale or holding in stock for the purpose of supply of vitamins and vitamin preparations by the use of a definition of medicinal product which, like that contained in the Wet op de Geneesmiddelenvoorziening, is so wide as to include such preparations if they are not, either alone or in combination, medicinal products within the meaning of the directive?

5. If vitamins or multi-vitamin preparations may be regarded as medicinal products within the meaning of the directive but the latter or the national legislation based thereon is drafted, interpreted or applied in one or more of the Member States in such a way that those preparations do not fall within the legislation governing medicinal products which is in force there, may Netherlands law prevent the sale or the holding in stock for the purpose of supply of such preparations imported from one of those Member States in reliance on the Wet op de Geneesmiddelenvoorziening or its implementing decrees, or would that be in conflict with the Treaty, in particular with Article 30 thereof, and with the prohibition of restrictions on trade between the Member States?

6. If the answer to the preceding questions leads to the conclusion that the definition of medicinal products 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 as indicated above in the same way as proprietary medicinal products and medicinal preparations, 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?

The judgment containing the reference was lodged at the Court Registry on 1 September 1982.

Pursuant to Article 20 of the Protocol on the Statute of the Court of Justice of the EEC written observations were submitted on 4 December 1982 by the accused in the main case, Leendert van Bennekom, represented by H. A. Bouman of the Amsterdam Bar and by C. T. Barbas of the Brussels Bar, on 15 November 1982 by the Commission of the European Communities, represented by its Agent, Auke Haagsma, a member of the Commission's Legal Department, on 3 December 1982 by the Government of the Netherlands, represented by the Secretary General for Foreign Affairs, F. Italianer, and the Government of the Federal Republic of Germany, represented by its Agents, Martin Seidel and Ernst Röder, and on 10 December 1982 by the Danish Government, represented by L. Mikaelsen, Legal Adviser on Foreign Affairs, and by the Italian Government, represented by I. M. Braguglia, Avvocato dello Stato.

Upon 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. However, it invited the parties to submit their observations on three specific questions in writing within four weeks and the parties did so within the period specified.

By order or 23 February 1983 the Court decided to assign the case to the Fifth Chamber.

## II — Written observations submitted to the Court

1. The *accused*, Mr van Bennekom, remarks that in Germany, the United Kingdom and in Belgium the great majority of vitamins are regarded as foodstuffs. According to him only Vitamins A and D are capable of having any toxic effect and then only if they are consumed in excessive quantities. The toxic effect is, however, no greater than that of many foodstuffs if they are consumed in excessive quantities.

Vitamins are organic compounds which are necessary for the normal functioning of the human body in its entirety and not for that of each individual bodily organ.

Scientific research has hitherto been unable to establish whether there is an optimum or maximum quantity which corresponds to the needs of the body; it has however been established that water-soluble vitamins (Vitamin C among others) are eliminated by the kidneys to the extent to which the body does not need them; lipo-soluble vitamins (A and D) are accumulated in the body and, when absorbed in large quantities, they may have a certain toxic effect which is, however, no greater than that of many foodstuffs absorbed in large quantities.

Owing to the composition of the vitamin preparations and in particular the high concentration in relation to the normal daily needs of the body, it is impossible to accept the view of the Netherlands Government that they are "medicinal products" within the meaning of the Law even though they carry neither "indications" nor "recommendations". The Netherlands Government concludes that these preparations are "intended" to be used for the purposes defined in the Netherlands Law; however, Directive 65/65, in defining medicinal products, does not mention their "intended use". According to the directive, the medicinal product need only be "presented for treating or preventing disease in human beings or animals".

The accused maintains that since the preparations include neither indications nor recommendations they are not "presented" within the meaning of the directive and that the directive does not admit of an interpretation according to which a substance becomes a "medicinal product" by reason either of its presentation (as a pill, for example), or of its degree of concentration.

Furthermore, a national rule which is not consistent with the directive, may not be used against him. Since the directive only deals with medicinal products which are proprietary medicinal products (by reason of their special packaging and their individual names), while the Wet op de Geneesmiddelenvoorziening is applicable to all medicinal products, the Netherlands definition cannot, in any case, be wider than that of the directive as far as medicinal products which are proprietary medicinal products within the meaning of the directive are concerned.

The words "presented for" which appear in the directive are much more limited than the expression "intended to be used for" which appears in the Netherlands Law.

Barriers to trade within the Community are eliminated by rules made at Community level. Such rules restrict the free discretion of Member States to take measures within the limits set by the general provisions of Article 36 of the EEC Treaty. The Netherlands authorities demonstrate that the requirements of public health which are protected by the Netherlands authorities have not been taken into account in rules made at Community level.

The Netherlands authorities cannot take measures restricting trade between Member States and justify them on the grounds set out in Article 36 of the EEC Treaty when rules for the protection of public health have already been made at Community level.

2. The *Commission* of the European Communities states first that the term "presented" which appears in the Community definition does not refer solely to an instruction on the label of the product concerned. A product is also "presented" within the terms of that definition when curative or preventive properties are attributed to it by other means, such as publicity, the press, prospectuses, brochures and so forth, or even by verbal recommendation of the seller. The form of the products in question, namely that of tablets, pills or capsules, without being conclusive none the less raises a presumption that it was intended to present them as substances possessing the properties set out in the Community definition.

Other (material) circumstances may also suggest that they are presented in that way; that is true, for example, of products containing leatrile which, according to Dr Hannema who was quoted in the judgment of the trial judge, are "recommended for treating or healing cancer or cancerous symptoms".

In the opinion of the Commission the concentration of certain vitamins in particular products should also lead them to be regarded as medicinal products within the meaning of the directive.

According to the Commission, it is only if the first part of the Community definition is not satisfied that it is necessary to examine whether a product should none the less be considered a medicinal product under the second part of that definition. If a substance possesses properties "for treating or preventing disease in human beings or animals, but ... is not presented as such", then, according to the Commission, it falls into the second part of the definition *precisely* because it possesses those properties and is therefore to be regarded as a medicinal product. However, a product or substance which falls neither within the first nor within the second part of the Community definition cannot be regarded as a medicinal product within the meaning of the directive.

The Commission is of the opinion that generally vitamins in low concentrations constitute an essential element of daily nutrition and cannot be considered medicinal products. On the other hand, in high or very high concentrations vitamins should be considered medicinal products. Thus, for example, the Larousse de la Médecine states that vitamins may be used "generally in very high doses as therapeutic agents against various diseases in which the deficiency of vitamins is not the morbid cause, the vitamin thus being used as a true medicament".

The only criterion which may be applied in this respect is that in the case of a (very) low concentration a foodstuff is concerned and in the case of a (very) high concentration a medicinal product is concerned. In the light of present knowledge, however, no precise indication may be given of where the border lies.

The answer may therefore only be given case by case and will usually have to be provided by experts.

The Commission then points out that the directive does not seek complete uniformity with the legislation of the Member States and does not therefore prevent the national definition of a medicinal product from being much wider than the Community definition. Clearly, in such cases it is necessary to observe the other provisions of Community law and, in particular, Articles 30 to 36 of the EEC Treaty.

In so far as it is able to form an opinion from the documents on the file, the Commission believes that the measures taken in this case may be justified on the grounds of the protection of health under Article 36 of the Treaty.

Finally, the system of the directive may in fact lead to a situation in which a product is not regarded as a medicinal product within the meaning of the directive in one Member State whilst it is so regarded in another. However, where a product is not regarded as a medicinal product in one Member State, the competent authority of another Member State may arrive at a different conclusion (namely that the substance does constitute a medicinal product) unless it has good reasons for doing so and, generally, submit the question to the Committee for Proprietary Medical Products established by Article 8 of Directive 75/319/EEC.

In conclusion, the Commission does not exclude the possibility that some of the products in issue might not fall within the Community definition. However, on the basis of the facts as shown in the file, it believes that the application of the rules laid down in the Community directives to the products referred to it by the national court which do not fall within the definition of the directive are justified on the ground of the protection of health under Article 36 of the Treaty.

3. The *Government of the Netherlands* states that the terms used in the Netherlands definition ("intended", "indicated" and "recommended") in substance coincide with the definition used in the directive. A number of criteria which are equally relevant, such as publicity details, the form and the quantity or concentration, may be used to complement the three legal concepts mentioned above ("intended", "indicated" and "recommended"). For that reason substances which are not indicated or recommended as being suitable for healing may perfectly well be substances or combinations of substances presented for treating or preventing disease in human beings or animals.

On the other hand, products which do not fall within one of the two elements of the definition of the expression "medicinal product" in the directive cannot be "medicinal products" within the meaning of the directive.

If the product is *recommended* as a medicinal product, it is clear that the producer himself considers it to be a medicinal product, except in the case of deliberately deceitful publicity. The *form* in which the medicinal product is marketed may also provide an indication, in particular when the product under examination is presented in the form of tablets, powders, capsules or pills. The *quantity* or the *concentration* of the product must also be taken into account. An important role may also be played by the recommended daily dose of the substance (that is to say the quantity corresponding to the daily needs of a normal person) as scientifically established and recorded in agreements or in resolutions of international organizations such as the World Health Organization or foreign institutions such as the National Academy of Science — National Research Council (United States of America). Beyond that daily dose, the product becomes dangerous for public health or at least is no longer a normal foodstuff.

The Government of the Netherlands states that even though the definition of "medicinal product" in the Netherlands Law is no wider than that which appears in the directive, there is in fact nothing to prevent it from being so. The fact that the legislation on the subject does not necessarily correspond to that of other Member States does not mean that it is contrary to Community law. In the present case, if the products in question do not fall within the definition of the expression "medicinal product" in the directive, the Netherlands rules are justified by Article 36 of the Treaty.

Finally, the Netherlands Government points out that the present case concerns not *proprietary medicinal products* but medicinal *preparations* within the meaning of the Wet op de Geneesmiddelenvoorziening to which Directive 65/65 is not applicable.

4. On the first question the *Government of the Federal Republic of Germany* maintains (as appears from a document submitted by the German Government in response to questions put by the Court) that a product may be "presented" as a medicinal product within the meaning of the first branch of the Community definition even if it is not expressly so described, but for example — according to the circumstances of each individual case — if it is put on sale in the form of a medicinal product or according to information published on the packaging. The fact that a product is in the form of a capsule or tablet cannot however be considered conclusive in all cases.

On the other hand, even if the substances or combinations of substances are not presented as medicinal products and, in addition, it is not the intention of the person selling them that they should be administered as medicinal products, the substances or combinations of substances may nevertheless be medicinal products by virtue of the second subparagraph of Article 1 (2) of Directive 65/65/EEC. The question does not depend on the intention of the person selling the substances or combinations of substances, but on general opinion, that is to say on the opinion of a majority of consumers.

The Federal Government believes that, according to the use to which they are put, vitamin preparations may amount either to foodstuffs or to medicinal products within the meaning of Directive 65/65/EEC. The second branch of the Community definition does not make the task any simpler because its terms may equally be applied to foodstuffs, which are likewise given in order to "modify physiological functions in human beings".

According to the German Government, vitamins doubtless serve nutritional purposes to a large extent. Even to the extent to which vitamins contained in vitamin preparations are administered to compensate for seasonal fluctuations in the natural vitamin content of foodstuffs, such preparations constitute a dietary additive. The same applies when vitamin preparations are consumed because a need has arisen which cannot be satisfied by the natural vitamin content of foodstuffs, as is the case for example following a particular physical effort required of a sportsman, of a pregnant woman or of a growing child. On the other hand the vitamin preparations are medicinal products if they are used for the treatment or the direct prevention of diseases due to vitamin deficiency. In such cases, it is often necessary to administer large doses which are greatly in excess of normal vitamin requirements. Even when the vitamin is intended to cure a disease which is not due to a vitamin deficiency (such as an infectious disease), it is a medicinal product if the vitamin content is deliberately intended to cure, treat or prevent certain diseases. The latter condition is essential because otherwise all foodstuffs containing vitamins would be medicinal products to the extent to which, without them, diseases might arise. Moreover, the German Law on medicinal products (Arzneimittelgesetz) explicitly excludes foodstuffs from the definition of medicinal products.

In the opinion of the Federal Government Directive 65/65/EEC covers certain vitamins and vitamin preparations. It follows that such preparations are medicinal products in all Member States, so that they are

governed by harmonized rules, which makes it unnecessary to answer the last three questions put by the national court.

5. The *Danish Government* wishes simply to present a few observations on the vitamin preparations under examination in the present case. According to it, in the absence of more precise information on the level of concentration and doses in this particular case, it is possible only to indicate in a very general way that it is correct to regard vitamin preparations of normal levels of concentration, assessed for instance in relation to the normal daily intake of a human being, as foodstuffs and not therefore as "medicinal products", even if in certain circumstances it *might be* appropriate to classify more highly-concentrated vitamin preparations among medicinal products.

However precisely it is sought to formulate the definition of medicinal products, problems will arise as soon as is necessary to establish a precise borderline between medicinal products and, for example, food products and cosmetics. Sometimes information provided by the manufacturer on the purpose of the products or on their possible uses will determine the rules applicable to them. That is not always acceptable. For that reason it is necessary to take a decision on each product on the basis of an objective and scientific appraisal and within the limits drawn by the definition.

Under Article 177 of the Treaty of Rome, the only ruling which the Court of Justice may give in reply to the questions put to it is that, in the light of the Community law applicable to the matter, it is for the authorities of the Member States to apply the law on objective grounds. The Court may, however, indicate certain general limits on interpretation which are of use to the national authorities in relation to the establishment of the dividing line between medicinal products and foodstuffs.

Finally, if the vitamin preparations concerned in the present case are not medicinal products within the meaning of Directive 65/65/EEC, it is necessary to assess the national law in the light of Articles 30 and 36 of the EEC Treaty.

6. According to the *Italian Government*, vitamin preparations (whether they be of high or of low concentration) fall within the definition of "medicinal product" laid down by Directive 65/65/EEC. The Italian Government believes that the first branch of the Community definition covers not only substances or combinations of substances whose labels state explicitly that they possess curative or preventive properties, but also cases where the method of presentation, objectively considered, inevitably leads to the belief that those substances have curative or preventive properties. Thus, if a substance is presented in the form of a bottle containing an injection, a suppository, a capsule or other form, that form of presentation, objectively considered, in conjunction with information relating to the composition and dose, would necessarily lead to the belief that that substance has therapeutic properties. In the eyes of the consumer, it is immaterial whether a curative or preventive property is expressly indicated or stated or whether it appears objectively from the method of presentation and, consequently, from the manner in which the substance is administered.

In the interpretation of the second branch of the Community definition, contrary to the view which the accused and the national court appear to take, importance may not be attached to the *purely subjective* purpose (for example purely dietary) which the manufacturer or the consumer of the vitamin preparations may set out to achieve. The purpose of that second branch should, on the contrary, be considered *in an objective manner,* namely as a result which may be achieved by means of the administration of those substances. For that reason, and because of their indisputable therapeutic effect, vitamin preparations are also included in the definition of "medicinal product" which appears in the second branch of the Community definition.

In any case, even if vitamin preparations are not proprietary medicinal products within the meaning of the directive, their free circulation may encounter legitimate barriers (such as controls, permits, registration and others) for obvious reasons relating to the protection of public health within the meaning of Article 36 of the EEC Treaty (judgment of the Court of 20 May 1976 in Case 104/75 *de Peijper* [1976] ECR 613; judgment of 5 February 1981 in Case 53/80 *Officier van Justitie* v *Koninklijk Kaasfabriek Eyssen BV* [1981] ECR 409 and judgment of 17 December 1981 in Case 272/80 *Frans-Nederlandse Maatschappij voor Biologische Producten BV* [1981] ECR 3277).

## III — Replies to the questions put by the Court

In reply to the questions put by the Court, the Commission of the European Communities, the Danish Government, the Italian Government and the Government of the Federal Republic of Germany stated, in essence, that the purpose of the first part of the Community definition was to protect the consumer, *inter alia,* against products which had no therapeutic effect, but which were offered to the consumer as such. A patient's health may be affected by ineffectual medicinal products. For that reason, they say, it is possible that a product without therapeutic effect which is put on sale in a pharmaceutical form should be considered a medicinal product under the first part of the Community definition. The Netherlands Government specifies that the main question is whether the product is "presented" as having certain properties. The question whether a product has a curative or preventive effect only arises upon a request for a licence and during the procedure for granting it.

In reply to the question whether *all* vitamins above a certain level of concentration have a therapeutic effect as described in the second part of the Community definition, the same parties indicate only that there is a strong likelihood that highly concentrated vitamins fall within that second part, but that, in any event, the dispute relates to the first part of the definition. Similary, most vitamins in high concentrations are capable of having a toxic effect.

According to Mr van Bennekom, the first part of the definition should be strictly construed. It is true that a product may fall within the first part of the definition if it is presented as a medicinal product, whether expressly or by implication, whether orally or in writing. However, in that respect, neither the form, nor the concentration nor the dose can play any part, in connection

either with the first or with the second part of the definition. It can only be assumed that, beyond a certain degree of concentration, vitamin preparations become medicinal products. Finally, certain vitamins (but not vitamins B and C) have a toxic effect in high concentrations, but that is also true of many foodstuffs.

IV — Oral procedure

At the sitting on 18 May 1983, the accused in the main proceedings, represented by H. A. Bouman of the Amsterdam Bar, the Netherlands Government, represented by its Agent, A. Bos, the Italian Government, represented by I. M. Braguglia, Avvocato dello Stato, and the Commission of the European Communities, represented by its Agent, A. Haagsma, a member of its Legal Department, presented oral argument and replied to the questions put to them by the Court.

The Advocate General delivered her opinion at the sitting on 5 October 1983.

## Decision

1 By judgment of 12 May 1982, received by the Court on 1 September 1982, the Arrondissementsrechtbank [District Court] Amsterdam referred for a preliminary ruling under Article 177 of the EEC Treaty a number of questions concerning 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 (Official Journal, English Special Edition 1965-66, p. 20) and also of Articles 30 to 36 of the EEC Treaty, with a view to appraising the compatibility with Community law of the Netherlands Law on the Supply of Medicinal Products (Wet op de Geneesmiddelenvoorziening).

2 The questions were raised in the context of criminal proceedings brought against Mr van Bennekom, who is being prosecuted in the Netherlands for possessing, for the purpose of resale, a large quantity of vitamin and multivitamin preparations contrary to the aforesaid Netherlands Law.

3 It is common ground that the preparations in question were put up in pharmaceutical form (tablets, pills and capsules) and were highly concentrated.

4 Under Article 3 (5) (b) of the Netherlands Law on the Supply of Medicinal Products, such products may not be marketed until they have been registered by the public authorities. Manufacturers, importers or wholesalers must, moreover, hold manufacturing, import or wholesale authorizations.

5 Those registration and authorization requirements are also laid down by Community provisions on the approximation of legislative provisions relating to proprietary medicinal products.

6 Mr van Bennekom, who is being prosecuted for failure to comply with either of those two requirements, contended in his defence before the Netherlands courts that the preparations in question were not medicinal products but foodstuffs for the purposes of both the Netherlands Law and the aforesaid Directive 65/65.

7 The Netherlands Law on the Supply of Medicinal Products defines "medicinal product" as:

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

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

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

8 Council Directive 65/65 defines "medicinal product" in the first place as "Any substance or combination of substances presented for treating or preventing disease in human beings or animals", and, in the second place, as "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."

9 In the appeal proceedings before it, the Arrondissementsrechtbank Amsterdam, concluding that it needed an interpretation of the Community provisions, stayed the proceedings and referred the following questions to the Court of Justice:

"1. Is it possible for substances or combinations of substances, such as vitamin preparations in certain concentrations and doses and in the form (tables, 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'?

2. Is it possible for a substance or combination of substances, such as a vitamin or multi-vitamin preparation similar to those 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 in animals, to be a 'medicinal product' within the meaning of the directive?

3. (a) On the assumption that vitamins in certain low concentrations are intended for use in foodstuffs and not as medicinal products, even though they are marketed in the form of tablets, pills or capsules, can a high(er) concentration of those vitamins, whether or not they are in that form, be sufficient for the substance to be classified as a medicinal product within the meaning of the directive?

(b) If so, on the basis of what criteria may that be established?

4. Is it permissible for Netherlands law to prohibit, or to be applied in the form of a criminal penalty to, the sale or holding in stock for the purpose of supply of vitamins and vitamin preparations by the use of a definition of medicinal product which, like that contained in the Wet op de Geneesmiddelenvoorziening, is so wide as to include such preparations if they are not, either alone or in combination, medicinal products within the meaning of the directive?

5. If vitamins or multi-vitamin preparations may be regarded as medicinal products within the meaning of the directive but the latter or the national legislation based thereon is drafted, interpreted or applied in one or more of the Member States in such a way that those preparations do not fall within the legislation governing medicinal products which is in force there, may Netherlands law prevent the sale or the holding in stock for the purpose of supply of such preparations imported from one of those Member States in reliance on the Wet op de Geneesmiddelenvoorziening or its implementing decrees, or would that be in conflict with the Treaty, in particular with Article 30 thereof, and with the prohibition of restrictions on trade between the Member States?

6. If the answer to the preceding questions leads to the conclusion that the definition of medicinal products in Netherland 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 as indicated above in the same way as proprietary medicinal products and medicinal preparations, 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?"

10 It should be observed at the outset that, whilst it is not for the Court, in the context of Article 177 of the EEC Treaty, to rule on the compatibility of national legislative provisions with the Treaty, it many none the less furnish the national court with all those criteria for the interpretation of Community law which may enable it to judge the issue of such compatibility.

11 As to the substantive issues, it should be stressed that Directive 65/65 constitutes only the first stage in the harmonization of national laws dealing with the production and distribution of pharmaceutical products.

12 The directive is limited in its scope to "proprietary medicinal products" which are defined as any ready-prepared medicinal products placed on the market under a special name and in a special pack. Furthermore, "medicinal products" are defined as "substances", which in turn are the subject of closer definition. Finally, Article 2 limits the scope of the directive to proprietary

medicinal products for human use intended to be placed on the market in Member States.

13 In view of the technicalities of the definition of medicinal products contained in Directve 65/65, the Court of Justice can do no more than provide a number of general guidelines enabling the dividing line to be drawn between medicinal products and foods.

14 Directive 65/65 is designed to eliminate — at least in part — obstacles to trade in proprietary medicinal products within the Community whilst at the same time attaining the essential objective of safeguarding public health. As a result of such harmonization recourse to Article 36 of the EEC Treaty must gradually become unnecessary.

15 It is in the light of those considerations that replies should first be given to the first three question of the Arrondissementsrechtbank Amsterdam, concerning the interpretation of the directive, and then, in the alternative, should the vitamin preparations at issue prove not to be covered by the directive, to the questions concerning Articles 30 *et seq.* of the Treaty.

## First question

16 In the first question the Court is asked, essentially, whether products such as the vitamin preparations at issue, which are not "indicated or recommended" expressly as being suitable for curing, treating or preventing an infection, may none the less be substances "presented for treating or preventing disease in human being or animals" within the meaning of the Community definition of "medicinal product" in Directive 65/65.

17 In order to answer this question, it should be observed that the directive, by basing itself, in the first Community definition of a medicinal product, on the criterion of the product's "presentation", is designed to cover not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or which do not have the effect which consumers would be entitled to expect in view of their presentation.

The directive thereby seeks to preserve consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies. For that reason, the concept of the "presentation" of a product must be broadly construed.

18 It is therefore necessary to take the view that a product is "presented for treating or preventing disease" within the meaning of Directive 65/65 not only when it is expressly "indicated" or "recommended" as such, possibly by means of labels, leaflets or oral representation, but also whenever any averagely will-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, regard being had to its presentation, have an effect such as is described by the first part of the Community definition.

19 In particular, the external form given to the product in question — such as that of a tablet, pill or capsule — may in this connection serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product. Such evidence cannot, however, be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to pharmaceutical products would also be covered.

20 The answer to the first question should therefore be that substances such as the vitamin preparations at issue, which are not "indicated or recommended" expressly as being suitable for curing, treating or preventing an infection, may none the less constitute substances "presented for treating or preventing disease in human beings or animals" within the meaning of the Community definition of "medicinal products" contained in Directive 65/65.

## Second question

21 The second question seeks to ascertain whether a substance which may have curative or preventive properties in relation to human or animal diseases, but which is not presented as such and cannot be administered to a human being or an animal with a view to making a medical diagnosis or to restoring,

correcting or modifying physiological functions in human beings or animals, nevertheless falls within the definition of a medicinal product for the purposes of Directive 65/65.

22 It is apparent in this connection that a substance which is endowed with properties "for treating or preventing disease in human beings or animals" within the meaning of the first part of the Community definition, but which is not "presented" as such, falls in principle within the scope of the second part of the Community definition of a medicinal product.

23 On the other hand, a product which is covered by neither the first nor the second part of the Community definition of a medicinal product may not be regarded as a medicinal product within the meaning of Directive 65/65.

## Third question

24 In its third question, the national court, proceeding on the assumption that vitamins in low concentrations may be regarded as foodstuffs, asks in substance whether a higher concentration should lead to their being regarded as medicinal products within the meaning of the directive, and, if so, on the basis of what criteria.

25 The answer to that question must be such as to enable the national court to assess the importance of the criterion of concentration for the purpose of establishing whether a vitamin falls within the second part of the Community definition of a medicinal product.

26 Inasmuch as vitamins are usually defined as substances which, in minute quantities, form an essential part of the daily diet and are indispensable for the proper functioning of the body, they may not, as a general rule, be regarded as medicinal products when they are consumed in small quantities.

27 Similarly, it is a fact that vitamin or multi-vitamin preparations are sometimes used, generally in large doses, for therapeutic purposes in combating certain diseases other than those of which the morbid cause is a vitamin deficiency. In such cases, it is beyond dispute that the vitamin preparations constitute medicinal products.

28 It is, however, apparent from the file and from the observations submitted to the Court, taken as a whole, that it is impossible in the present state of scientific knowledge to state whether the criterion of concentration alone is always sufficient in order to be able to determine whether a vitamin preparation constitutes a medicinal product; still less therefore is it possible to specify the level of concentration above which such a vitamin preparation would fall within the Community definition of a medicinal product.

29 The answer to be given to the national court should therefore be that the classification of a vitamin as a medicinal product within the meaning of the second part of the definition in Directive 65/65 must be carried out case by case, having regard to the pharmacological properties of each such vitamin to the extent to which they have been established in the present state of scientific knowledge.

## Fourth, fifth and sixth questions

30 The fourth, fifth and sixth questions ask, in substance, whether, where the certain vitamin or multi-vitamin preparations may

(a) be regarded as medicinal products within the meaning of Directive 65/65, but are not covered by the legislation on medicinal products of one or more Member States, or

(b) are not covered by the Community definition of medicinal product,

the law of one Member State may none the less prohibit the sale or the holding in stock for the purpose of supply of such preparations imported from another Member State.

31 In this connection it is apparent from the last recital in the preamble to Directive 65/65 that the directive aims to achieve only a progressive approximation of the relevant provisions laid down by law, regulation or administrative action. Therefore, whilst seeking to remove as far as possible obstacles to trade within the Community in respect of the products to which it relates, the directive does not preclude as such the possibility that products not covered by its provisions may be subjected by Member States to restrictions on their sale or marketing, provided always that the other provisions of Community law are complied with.

32 Under Article 30 of the Treaty quantitative restrictions on imports and all measures having equivalent effect are prohibited in trade between Member States. According to a consistent line of decisions of the Court, any commercial legislation by Member States which is liable to hinder trade within the Community, whether directly or indirectly, actually or potentially, is to be regarded as a measure having an effect equivalent to quantitative restrictions.

33 In that light it is clear that legislation which prohibits the marketing of vitamins and vitamin preparations without prior registration with the administrative authorities constitutes a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 30 of the EEC Treaty, since such a measure is liable to hinder trade between Member States.

34 Under Article 36 of the Treaty, however, "The provisions of Articles 30 to 34 shall not preclude prohibitions or restrictions on imports ... justified on grounds of ... the protection of health and life of humans ...", unless they constitute "a means of arbitrary discrimination or a disguised restriction on trade between Member States."

35 It is only when Community directives, in pursuance of Article 100 of the Treaty, make provision for the full harmonization of all the measures needed to ensure the protection of human and animal life and institute Community procedures to monitor compliance therewith that recourse to Article 36 ceases to be justified. It is, however not in dispute that such is not the case with the directives dealing with pharmaceutical products. It is therefore necessary to consider whether measures which restrict the marketing of vitamins may be justified by Article 36 of the Treaty.

36 As the Court has had occasion to affirm in its judgment of 14 July 1983 (*Officier van Justitie* v *Sandoz*, Case 174/82, [1983] ECR 2445), the excessive consumption of vitamins over a prolonged period may have harmful effects, the extent of which varies according to the type of vitamin, there being generally a greater risk with vitamins soluble in fat than with those soluble in water. It is further apparent that it is principally in high concentrations that

vitamins constitute a serious risk to health. According to the observations submitted to the Court, however, scientific research does not appear to be sufficiently advanced to be able to determine with certainty the critical quantities and the precise effects.

37 In a consistent line of decision the Court has stated that, in so far as uncertainties persist in the present state of scientific research, it is for the Member States, in the absence of harmonization, to decide what degree of protection of health and life of humans they intend to ensure, having regard however to the requirements of the free movement of goods within the Community.

38 Those principles also apply to substances such as vitamins which are not as a general rule harmful in themselves but may have special harmful effects if taken to excess. In view of the uncertainties inherent in scientific assessment, national rules which subject vitamin or multi-vitamin preparations presented in pharmaceutical form or having a high degree of concentration to the procedures laid down by Directive 65/65 are therefore justified in principle within the meaning of Article 36 of the Treaty on grounds of the protection of public health, even if the various Member States have adopted different solutions in that regard.

39 Nevertheless, the principle of proportionality which underlies the last sentence of Article 36 of the Treaty requires that the power of the Member States to prohibit imports of the products in question from other Member States should be restricted to what is necessary to attain the legitimate aim of protecting health. Accordingly, national rules imposing such restrictions are justified only if authorizations for marketing are granted when they are compatible with the requirements of health protection.

40 In this connection it is for the national authorities to demonstrate in each case that their rules are necessary to give effective protection to the interests referred to in Article 36 of the Treaty and, in particular, to show that the marketing of the product in question creates a serious risk to public health.

41 The answer to be given to the national court should therefore be that where certain vitamin or multi-vitamin preparations may

(a) be regarded as medicinal products within the meaning of Directive 65/65, but are not covered by the legislation on medicinal products of one or more Member States, or

(b) are not covered by the Community definition of medicinal products,

the law of a Member State may prohibit the sale, or the holding in stock for the purpose of supply, of such preparations imported from another Member State, in particular when they are presented in a pharmaceutical form or when they are highly concentrated. However, such rules are justified only if authorizations for marketing are granted when they are compatible with the requirements of health protection.

## Costs

42 The costs incurred by the Governments of the Member States and by the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. 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 before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Fifth Chamber),

in answer to the questions submitted to it by the Arrondissementsrechtbank, Amsterdam by judgment of 12 May 1982, hereby rules:

1. **Substances, such as the vitamin preparations at issue, which are not "indicated or recommended" expressly as being suitable for curing, treating or preventing an infection, may none the less constitute sub-**

stances "presented for treating or preventing disease in human beings or animals" within the meaning of the Community definition of "medicinal product" contained in Directive 65/65.

2. A product which falls neither under the first nor the second part of the Community definition of "medicinal product" cannot be considered a medicinal product within the meaning of Directive 65/65.

3. The classification of a vitamin as a medicinal product within the meaning of the second part of the definition in Directive 65/65 must be carried out case by case, having regard to the pharmacological properties of each of them, to the extent to which they have been established in the present state of scientific knowledge.

4. Where certain vitamin or multi-vitamin preparations may

   (a) be regarded as medicinal products within the meaning of Directive 65/65, but are not covered by the legislation on medicinal products of one or more Member States, or

   (b) are not covered by the Community definition of medicinal products,

   the law of a Member State may prohibit the sale, or the holding in stock for the purpose of supply, of such preparations imported from another Member State, in particular when they are presented in pharmaceutical form or when they are highly concentrated. However, such rules are justified only if authorizations for marketing are granted when they are compatible with the requirements of health protection.

Galmot Mackenzie Stuart

Due Everling Kakouris

Delivered in open court in Luxembourg on 30 November 1983.

For the Registrar

H. A. Rühl

Principal Administrator

Y. Galmot

President of the Fifth Chamber