state of scientific knowledge it has no known therapeutic effect.

A product whose therapeutic properties are indicated solely in a publication, such as a brochure, which is sent, at his request, to the purchaser after sale by the manufacturer or the seller of the product or by a third party — where the third party does not act completely independently of the manufacturer or the seller — may be categorized as a medicinal product within the meaning of the aforementioned provisions.

2. Freedom of expression, enshrined in Article 10 of the European Convention on Human Rights, which is among the general principles of law the observance of which is ensured by the Court, is not affected by the fact that the publication by a third party, with regard to products which the manufacturer or the seller does not market as medicinal products, of information ascribing to them therapeutic or prophylactic effects may have the effect of bringing those products within the category of medicinal products, as laid down by the definitions set out in Article 1 of Directive 65/65, with all the consequences relating thereto.

3. A product which is not a medicinal product within the meaning of the provisions of Article 1(2) of Directive 65/65 on proprietary medicinal products may, subject to Article 30 et seq. of the Treaty concerning products imported from other Member States, be subject in the domestic law of a Member State to the rules governing medicinal products.

REPORT FOR THE HEARING
In Case C-219/91 *

I — Legal background and course of the proceedings

A — *Legal background*

(1) Applicable Community legislation

According to Article 1(2) 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 (OJ, English Special Edition 1965-66, p. 20), 'medicinal product' means

'(1) any substance or combination of substances presented for treating or pre-

* Language of the case: Dutch.

venting disease in human beings or animals;

(2) 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 ...'.

Under Article 3 of the directive, no proprietary medicinal product, that is to say, under Article 1(1) of the directive, 'any ready-prepared medicinal product placed on the market under a special name and in a special pack', and, as of 1 January 1992, no 'medicinal products' (Council Directive 89/341/EEC of 3 May 1989 amending Directive 65/65, as amended, OJ 1989 L 142, p. 11) may be placed on the market in a Member State unless an authorization, for which the directive, as severally amended in these respects, lays down the rules for its issue and withdrawal, has been given.

(2) National legislation

Article 1(1) of the Wet op de Geneesmiddelenvoorziening (Law of 28 July 1958 on the Supply of Medicinal Products, as amended, Staatsblad 408) contains the following definition:

'(e) 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 deficiency 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;

...

(h) proprietary medicinal product: a medicinal product in the form of a pharmaceutical product placed on the market under a special name and in a special pack;

(i) medicinal preparation: a medicinal product in the form of a pharmaceutical product placed on the market otherwise than under a special name or in a special pack ...'

Under Article 3(5) of that law, it is prohibited:

'(a) to prepare, sell, deliver, import or market ... unregistered proprietary medicinal products and unregistered medicinal preparations;

(b) to hold stocks of unregistered proprietary medicinal products and unregistered medicinal preparations for supply.'

B — *Facts and main proceedings*

Johannes Stephanus Wilhelmus Ter Voort carries on, at his place of residence, Leeuwarden (Netherlands), the business of the sale of herbal teas trading under the name 'Fitness Foundations Nederland'.

Those teas, which are imported from South America, are sold by Mr Ter Voort with any indication of their therapeutic or prophylactic properties. However, a foundation, 'Stichting Nieuwe Horizon', based at Harlingen (Netherlands), sends to persons at their request brochures setting out the therapeutic properties of the products sold and stating that the teas are regarded as complementing any medicines being taken.

Following the seizure of products at his place of residence on 29 November 1988, Mr Ter Voort was charged with having, according to the order for reference,

'in or around the period from the end of 1987 to 29 November 1988, or in any event on the latter date, prepared and/or sold, and/or supplied, and/or imported, and/or dealt in, and/or held in stock for supply in Leeuwarden, or in any event in the Netherlands, unregistered proprietary medicinal products referred to in Article 1(1)(h) and (i) of the Wet op de Geneesmiddelenvoorziening, namely Guarana (Em Po), and/or one or more unregistered pharmaceutical preparations, namely Taheebo and/or Stevia and/or Jatoba and/or Jurubeba and/or Maracuja and/or Marapuama and/or Pedra Huma Caa and/or Pata de Vaca (respectively) ... (Article 3(5) of the Wet op de Geneesmiddelenvoorziening)'.

In the Kantongerecht (Cantonal Court), Leeuwarden, Mr Ter Voort did not deny having held and sold the products in question, but argued that the herbal teas could not be categorized as 'medicinal products' within the meaning of the Wet op de Geneesmiddelenvoorziening without disregarding the provisions of Article 1(2) of Directive 65/65, cited above.

By judgment of 22 March 1990, the Kantongerecht, Leeuwarden, dismissed that defence on the ground, *inter alia*, that the provisions of the Netherlands Law were not contrary to the Community directive.

Mr Ter Voort brought an appeal against that judgment in the Arrondissementsrechtbank (District Court), Leeuwarden, on the basis of the same argument.

In those circumstances, the Arrondissementsrechtbank, Leeuwarden, referred to the Court for a preliminary ruling the following questions by order of 15 August 1991:

'(1) Is a product such as a herbal tea which in general is regarded as a foodstuff and in accordance with current scientific knowledge does not possess any pharmacological properties but is presented as having therapeutic or prophylactic properties a medicinal product within the meaning of the first subparagraph of Article 1(2) of Directive 65/65/EEC?

(2) Does it make any difference to the answer to the first question:

(a) If the description or properties on the packaging, label or enclosed leaflets, but only in documentation (a brochure) which is sent upon request by the supplier of the product or by a third party (other than the supplier)?

(b) If the description or properties of the product are not mentioned on the packaging, label or enclosed leaflets, but are described in a publication (a brochure) whose distribution is unconnected with the sale of the product and/or is arranged by or on the direction of a third party who is not the seller or supplier of the product, regard being had also to Article 10 of the European Convention on Human Rights?

(3) Does the word "presented" in the first subparagraph of Article 1(2) of Directive 65/65/EEC mean that there must be a link between the product and the presentation?

(4) Is it compatible with the first subparagraph of Article 1(2) of Directive 65/65/EEC for the legislation of Member States to regard as medicinal products, in addition to products presented as medicinal products within the meaning of that provision, foodstuffs to which therapeutic or prophylactic properties are ascribed by the seller or third parties, although in the light of present-day scientific knowledge those products possess no pharmacological properties?'

C — *Procedure before the Court*

The national court's order was received at the Court Registry on 26 August 1991.

Pursuant to Article 20 of the Protocol on the Statute of the Court of Justice of the EEC, written observations were lodged by Mr Ter Voort, the appellant in the main proceedings, represented by G. van der Wal, Advocate with right of audience at the Hoge Raad der Nederlanden (Supreme Court of the Netherlands); by the Netherlands Government, the respondent in the main proceedings, represented by B. R. Bot, Secretary-General of the Ministry for Foreign Affairs; by the Belgian Government, represented by R. Van Hellemont, Head of the Directorate for Administration of European Affairs in the Ministry for Foreign Affairs, acting as Agent; by the Italian Government, represented by Luigi Ferrari Bravo, Head of the Department for Contentious Diplomatic Affairs of the Ministry for Foreign Affairs, acting as Agent, assisted by Oscar Fiumara, Avvocato dello Stato; and by the Commission of the European Communities, represented by Berend Jan Drijber, of its Legal Service, acting as Agent.

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.

By decision of 3 June 1992 under Article 95(1) and (2) of the Rules of Procedure, the Court decided to refer the case to the Fifth Chamber.

II — Written observations submitted by the parties

The parties agree that, according to the Court's case-law (the judgments in Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547 and in Case C-112/89 *Upjohn* [1991] ECR I-1703), Directive 65/65 gives two definitions of the expression 'medicinal products': a definition 'by virtue of their presentation' (first subparagraph of Article 1(2)) and a definition 'by virtue of their functions' (second subparagraph of Article 1(2)).

A product is a medicinal product if it falls within either of those definitions.

The parties also agree that only the definition 'by virtue of presentation' is at issue in this case, and that that definition is intended to avoid products without therapeutic effects being used instead of the proper remedies (judgments in Case 227/82 *Van Bennekom* [1983] ECR 3883 and in *Monteil and Samanni* and *Upjohn*, cited above) in accordance with the directive's objective of safeguarding public health (judgment in *Van Bennekom*, cited above).

(1) The first question

(a) *Mr Ter Voort* submits that the first question should be answered in the negative.

He argues that the national court seeks to establish whether a foodstuff which, in the present state of scientific knowledge, is not regarded as having therapeutic or prophylactic properties, but is presented as having such properties, must invariably be categorized as a medicinal product within the meaning of the directive. In this case, it is a question as to whether it is necessary to categorize as a 'medicinal product' a product whose presentation does not create the impression in the mind of an averagely well-informed consumer that it is to be used instead of the proper remedy, but merely attributes to it a complementary effect to that of the remedy.

Mr Ter Voort considers that in order to give an affirmative answer to that question it would entail giving the wording of the directive a very broad meaning inconsistent with its objectives, since it aims to safeguard public health and not to protect consumers.

Mr Ter Voort submits that, whilst it was held in the judgment in *Van Bennekom*, cited above, on the basis of the material facts that vitamin preparations were capable of being regarded as medicinal products by virtue of their presentation and, in some circumstances, as medicinal products by virtue of their function, the Community definition of a medicinal product by virtue of its presentation could not cover products other than medicines which have a genuine therapeutic effect and are presented as such together with products which, in view of their manner of presentation (including their external appearance), the averagely well-informed consumer is bound to expect to have a particular effect where they are purported to have such effect.

In particular, that definition cannot be applied to products which have no pharmacological properties and are generally regarded as foodstuffs unless an averagely

well-informed consumer is induced to believe, on the basis of the products' inherent characteristics, that they have therapeutic or prophylactic properties.

(b) The *Commission* and the *Belgian, Italian and Netherlands Governments* submit, in contrast, that the national court's first question should be answered in the affirmative.

In the first place, the Commission and the Netherlands Government argue that, according to the Court's case-law (judgments in *Van Bennekom* and *Upjohn*, cited above), the concept of 'medicinal products by virtue of their presentation' has to be given a broad interpretation.

According to the Commission and the Belgian, Italian and Netherlands Governments, it is clear from the Court's case-law, in particular the judgment in *Upjohn*, cited above, that a product which is unambiguously presented as having therapeutic or prophylactic properties with regard to diseases of human beings, such as the product described by the national court, must be regarded as a 'medicinal product' within the meaning of the first subparagraph of Article 1(2) of the directive, even if it has no known pharmacological property.

The Netherlands Government points out that for such a product to be placed on the market it must be authorized; marketing without authorization may lead to criminal proceedings under the Netherlands legislation on medicinal products.

(2) The second question

(a) *Mr Ter Voort* divides the question into two parts.

In his view, the first part of the question has two aspects relating (a) to the time when the product's properties are communicated and (b) to the person who communicates those properties.

The first aspect raises the question whether the fact that the alleged properties are indicated at the purchaser's request after the product has been purchased has a bearing on how the product is to be categorized.

Mr Ter Voort considers that this question should be answered in the negative.

He argues in the first place that if the product is presented after it is purchased, that presentation has no effect on the product and is not directly connected with it.

In the second place, he argues that to date the Court's case-law has regarded as significant only factors connected with the time of purchase (judgments in *Van Bennekom*, cited above, paragraphs 18 and 19, in Case C-369/88 *Delattre* [1991] ECR I-1487, and in *Monteil and Samanni*, cited above, paragraph 23).

He adds that, by analogy with that which the Court held in the judgment in *Van Bennekom*, cited above, at paragraph 19, sending information on the product after sale may be

evidence of the seller's intention to market a medicinal product, but cannot constitute the sole or conclusive evidence.

The second aspect raises the question whether, for the purposes of the definition of a medicinal product by virtue of its presentation, a third party's conduct may have implications for the seller's or the supplier's intentions, which, according to the Court's case-law, are conclusive in order to assess whether a product is a medicinal product.

According to Mr Ter Voort, whilst information sent by the seller after the product has been sold may constitute evidence of his intentions, information sent by a third party cannot constitute such evidence unless the seller has expressly instructed the third party to disseminate the information.

Thus, in the view of the appellant in the main proceedings, the fact that, after the product has been sold, information about the product is sent by the supplier or a third party acting on his behalf constitutes one piece of evidence which the national court should take into account in order to determine the seller's intention but not conclusive evidence for the purposes of making that determination.

Mr Ter Voort adds that, accordingly, it should be considered that a product presented and purchased as a foodstuff will not be regarded as a medicinal product by an averagely well-informed consumer where he receives information about the product after he has purchased it and at his request.

According to Mr Ter Voort, the second part of the question relates to the situation of products whose therapeutic or prophylactic properties are mentioned in a publication distributed by and on behalf of a third party other than the seller or the supplier, independently of the purchase of the product.

Accordingly, the publication does not constitute evidence of the seller's or the supplier's intention or 'presentation' within the meaning of the first subparagraph of Article 1(2) of the directive.

Mr Ter Voort argues that, if a publication relating to the therapeutic properties of a product, in particular of a foodstuff, were to suffice to cause it to be regarded as a medicinal product, that might result in unjustified restrictions on freedom of expression, as guaranteed by Article 10 of the European Convention on Human Rights, in so far as the supplier might require such publications to be banned.

(b) The *Commission* observes in the first place that the second and third questions on the product's presentation are closely connected.

As far as the first part of the national court's second question is concerned, the Commission argues, by reference to the judgment in *Van Bennekom*, paragraph 18, that it is important above all to determine whether, regard being had to all the aspects connected with the product's presentation, it is perceived by the averagely well-informed consumer as having therapeutic benefits. In its view, sending a brochure setting out those properties of the product will, as a general rule, satisfy that condition.

As regards the second part of that question, the Commission considers that attention should be paid to the nature of the publication and to the manner in which the information is brought to consumers' notice. In its view, the role played by the third party making the presentation has to be assessed in the light of its links with the seller: if the seller acts in close relations with the third party, the product must be regarded as a medicinal product. In this case, the Commission does not rule out the possibility that the appellant created a separate legal structure with the sole aim of separating the functions of sale and presentation.

(c) The *Belgian Government* considers that the answer to be given to the second question should be that a product presented as having therapeutic or prophylactic properties is a medicinal product even if that presentation does not appear on the packaging but is the result of separately distributed brochures.

(d) The *Italian Government* considers the second and third questions together. It takes the view that the presentation may ensue from a separate publication, provided that the publication is carried out by the person responsible for placing the product on the market or with his consent.

It considers that this will also be the case where publication is effected by the seller of the product. However, only products sold by that seller will be able to be categorized as 'medicinal products'.

In contrast, where publication is effected by or on behalf of a third party who is independent of the seller or manufacturer, the product should not be regarded as a medicinal product in view of the fact that there is no connection between the 'presentation' and the 'product'.

(e) As regards the first part of the second question, the *Netherlands Government* argues that whilst, in principle, the time when the product is presented as having therapeutic or prophylactic properties has no bearing on whether it should be classed as a 'medicinal product', that time is conclusive for the purpose of identifying the person responsible for placing the product on the market.

In its view, where a product is presented as having therapeutic or prophylactic properties in a publication which is sent to the purchaser at his request, the product must be regarded as being a medicinal product 'by virtue of its presentation' if the supplier sends the publication. On the other hand, if publication is carried out by a third party acting independently of the seller or the supplier, the supplier cannot be held responsible for it and the product does not have to be regarded as a 'medicinal product'.

The Netherlands Government takes the view that it is for the national court to decide this issue in light of the facts of the case.

As for the second part of the second question, the Netherlands Government states that it is possible to hold that there is a connection between the supplier and publication where the publication relates to a very specific product and where the supplier is aware of the publication and does not expressly dissociate himself from it. The supplier may be deemed to have tacitly accepted the purpose attributed to the product by a third party. According to the Netherlands Government, the national court should determine whether this is so in the light of the relevant circumstances.

The Netherlands Government also argues that it is not contrary to freedom of expression to take account of a publication effected by a third party in order to determine whether a product is a medicinal product, and that Article 10 of the European Convention on Human Rights authorizes restrictions on that freedom in the interests of public health.

(3) The third question

(a) *Mr Ter Voort* maintains that that question summarizes the first two questions and asks the Court to set out the general criteria by means of which the national court can determine the legally material facts for the purposes of assessing the connection between the product and its presentation.

He considers that there is a 'presentation' within the meaning of the first paragraph of Article 1(2) of the directive where the presentation:

— is made by the seller, the manufacturer or a third party acting on the seller's or the manufacturer's behalf;

— discloses an intention on the part of the seller or the manufacturer to market the product as a medicinal product;

— and, regard being had to other evidence, gives the averagely well-formed consumer the impression that a medicinal product having the stated effect is involved.

He argues that a presentation made by third parties who do not satisfy the first condition does not disclose a sufficient connection with the product and cannot constitute evidence of the seller's or the manufacturer's intention.

(b) The *Commission* and the *Belgian and Netherlands Governments* consider that the question should be answered in the affirmative.

The Commission maintains that the matter falls to be decided in accordance with the circumstances of the case. For example, a product can be regarded as a medicinal product if the supplier ensures that all his customers receive a copy of a press article emphasizing in general the therapeutic or prophylactic properties of the product, as this will establish a link between the presentation and the product.

The Belgian Government likewise considers that a publication initially intended to be distributed independently of sale may constitute a presentation of the product if it is used to inform the purchaser about the properties of the product sold.

The Belgian and Netherlands Governments also argue that the relationship between the product and its presentation may be merely indirect. The Netherlands Government argues in particular that the supplier or the seller may attribute the quality of a medicinal product to a product after it has been sold.

(4) The fourth question

(a) *Mr Ter Voort* considers that the national court seeks to establish whether a product which is not a 'medicinal product' within the meaning of the directive may nevertheless be categorized as a 'medicinal product' under national legislation.

Mr Ter Voort considers that that question should be answered in the negative.

He argues that whilst, as the Court held in the judgments in *Van Bennekom*, cited above, paragraph 31, and in *Monteil and Samanni*, cited above, paragraphs 27 and 28, there has been only partial harmonization in the sector of pharmaceutical products and the Member States are therefore at liberty to adopt specific rules, provided that they are consistent with Community law, it should be considered that Directive 65/65 fully harmonized the concept of 'medicinal product', thereby precluding any competence on the part of the Member States in this area. It observes in particular that the Community concept of 'medicinal product' is used in related fields (in particular, in the Commission's proposal for a directive on the supervision of medical products).

(b) The *Commission* and the *Belgian, Italian and Netherlands Governments* suggest that the question should be answered in the affirmative.

According to the Commission, any product presented directly or indirectly by the seller or by the supplier as having therapeutic or prophylactic properties must be regarded as a medicinal product.

The Italian and Netherlands Governments state that that rule applies even where the product has no known pharmacological properties. According to the Netherlands Government, if the product has no pharmacological properties, it will not be given marketing authorization and will not be able to be marketed as a medicinal product, except in the specific case where the product is presented as a medicinal product by a third party.

The Italian Government considers that national legislation under which foodstuffs to which the seller or third parties connected with the seller in any way whatsoever attribute therapeutic or prophylactic properties are regarded as medicinal products although the foodstuffs in question do not have any pharmacological property, is consistent with the objectives of the directive, which aims, *inter alia*, at preventing consumers from utilizing the products instead of effective remedies.

For its part, the Belgian legislation argues that, by analogy with the judgment in *Upjohn*, cited above, any foodstuff falling within one of the definitions set out in Article 1(2) of Directive 65/65 must be regarded as a medicinal product and subject to the legal rules corresponding to the exclusion of the rules on foodstuffs.

F. Grévisse
Judge-Rapporteur