JUDGMENT OF THE COURT (Fifth Chamber)

28 October 1992 *

In Case C-219/91,

REFERENCE to the Court under Article 177 of the EEC Treaty by the Arrondissementsrechtbank (District Court), Leeuwarden (Netherlands), for a preliminary ruling in the criminal proceedings before that court against

Johannes Stephanus Wilhelmus Ter Voort

on the interpretation of the first subparagraph of 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),

THE COURT (Fifth Chamber),

composed of: G. C. Rodríguez Iglesias, President of the Chamber, M. Zuleeg, R. Joliet, J. C. Moitinho de Almeida and F. Grévisse, Judges,

Advocate General: G. Tesauro,
Registrar: L. Hewlett, Administrator,

* Language of the case: Dutch.

after considering the written observations submitted on behalf of:

— Mr Ter Voort, the appellant in the main proceedings, by G. van de Wal, Advocate with the right of audience at the Hoge Raad der Nederlanden (Supreme Court of the Netherlands),

— the Netherlands Government, by B. R. Bot, Secretary-General of the Ministry for Foreign Affairs, acting as Agent,

— the Belgian Government, by R. Van Hellemont, Head of the Directorate for Administration of European Affairs in the Ministry for Foreign Affairs, acting as Agent,

— 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,

— the Commission of the European Communities, by Berend Jan Drijber, of its Legal Service, acting as Agent,

having regard to the Report for the Hearing,

after hearing the oral observations of Mr Ter Voort and the Commission of the European Communities at the hearing on 9 July 1992,

after hearing the Opinion of the Advocate General at the sitting on 22 September 1992,

gives the following

Judgment

1 By order of 15 August 1991, which was received at the Court on 26 August 1991, the Arrondissementsrechtbank, Leeuwarden (Netherlands), referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty four questions on the interpretation of the term 'medicinal product' within the meaning of the first subparagraph of 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, hereinafter referred to as 'Directive 65/65').

2 The questions arose in criminal proceedings brought against Mr Ter Voort, who was prosecuted for having, from the end of 1987 until 29 November 1988, or at least on that date, imported, held, prepared, sold or held in stock at Leeuwarden or, at least, in the Netherlands, proprietary medicinal products contrary to the provisions of Article 3(5) of the Netherlands Law on the Supply of Medicinal Products (Wet op de Geneesmiddelenvoorziening).

3 It appears from the case-file that Mr Ter Voort, trading as 'Fitness Foundations Nederland', markets in Leeuwarden herbal teas imported from South America. The herbal teas are sold without any indication of any therapeutic properties. However, a foundation, 'Stichting Nieuwe Horizon', which is based at Harlingen (Netherlands), sends consumers on request brochures describing the therapeutic or prophylactic properties of the herbal teas.

4 According to Article 3(5) of the Netherlands Law on the Supply of Medicinal Products, proprietary pharmaceutical products and preparations may not be prepared, sold, imported or held in stock until they have been registered by the public authorities.

5 Article 1(1) of that law 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 ...'.

6 In the Dutch courts, Mr Ter Voort argued in his defence that the herbal teas in question could not be described as medicinal products within the meaning of the Netherlands legislation without disregarding the provisions of Article 1(2) of Directive 65/65, cited above.

7 Since the Arrondissementsrechtbank, Leeuwarden, considered that an interpretation of the Community provisions was necessary, it stayed the proceedings and referred the following questions to the Court for a preliminary ruling:

'(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?'

8 Reference is made to the Report for the Hearing for a fuller account of the facts of the main proceedings, the applicable Community legislation, the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

9 It should be pointed out *in limine* that Article 1(1) of Directive 65/65, as amended on several occasions, defines 'proprietary medicinal product' as 'any ready-prepared medicinal product placed on the market under a special name and in a special pack'.

10 According to the first subparagraph of Article 1(2) of Directive 65/65, a 'medicinal product' is 'any substance or combination of substances presented for treating or preventing disease in human beings or animals'; according to the second subparagraph of Article 1(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 animals' is likewise to be considered a medicinal product.

11 Consequently, as the Court has consistently held (see, *inter alia*, the judgment in Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547, paragraph 11), the directive thus gives two definitions of medicinal products: a definition 'by virtue of their presentation' and a definition 'by virtue of their functions'. A product is a medicinal product if it falls within either of those definitions.

12 In this case, it appears from the wording of the order for reference that the national court's questions relate not to whether the products in question are medicinal products 'by virtue of their function', but only to whether they must be regarded as such 'by virtue of their presentation'. In their observations to the Court, Mr Ter Voort, the Belgian, Italian and Netherlands Governments and the Commission also agree that the questions relate solely to the interpretation of the provisions of the first subparagraph of Article 1(2) of Directive 65/65.

The first question

13 By its first question, the national court seeks to establish whether a product which in general is regarded as a foodstuff and does not possess any known pharmacological property must be regarded as a medicinal product 'by virtue of its presentation' within the meaning of Directive 65/65 if it is presented as having therapeutic or prophylactic properties.

14 Mr Ter Voort argues that a product which in general is regarded as a foodstuff and as not having any therapeutic effect cannot be categorized as a 'medicinal product' within the meaning of the directive unless its inherent characteristics are such as to cause it to be regarded as having therapeutic or prophylactic properties by an averagely well-informed consumer.

15 According to the Commission and the Belgian, Italian and Netherlands Governments, a product presented as having therapeutic or prophylactic properties is a medicinal product 'by virtue of its presentation' even if in general it is regarded as a foodstuff and even if it has no known therapeutic property.

16 As the Court has consistently held (see, most recently, the judgment in Case C-112/89 *Upjohn* [1991] ECR I-1703, paragraph 16), the 'presentation' criterion used in the first subparagraph of Article 1(2) of Directive 65/65 is designed to catch not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or do not have the effect which their presentation might lead to expect, in order 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.

17 As the Court has also consistently held (see, *inter alia*, the judgment in *Monteil and Samanni*, cited above, paragraph 23), a product is 'presented for treating or preventing disease' within the meaning of Directive 65/65 in particular when it is

expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation.

18 Consequently, a product expressly indicated or recommended as having therapeutic or prophylactic properties has to be regarded as a medicinal product 'by virtue of its presentation' even if it has no known therapeutic effect.

19 The Court has also held, in the judgments in Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 22, and in *Monteil and Samanni*, cited above, paragraph 17, that, even if it comes within the scope of other, less stringent Community rules, such as the rules on cosmetic products, a product must be held to be a medicinal product and be made subject to the corresponding rules if it is presented as possessing therapeutic or prophylactic properties or if it is intended to be administered with a view to restoring, correcting or modifying physiological functions.

20 No more can the fact that a product is in the nature of a foodstuff prevent it from being categorized as a 'medicinal product' within the meaning of the provisions of the first subparagraph of Article 1(2) of Directive 65/65 in so far as the indication or recommendation of its therapeutic or prophylactic properties is in itself of such a kind as to cause it to be regarded as a product presenting the characteristic properties of a therapeutic substance, that is to say, a medicinal product.

21 Accordingly the reply to be given to the national court's first question should be that a product recommended or indicated as having prophylactic or therapeutic properties is a medicinal product within the meaning of the provisions of the first subparagraph of Article 1(2) of Directive 65/65, even if it is generally regarded as a foodstuff and even if in the current state of scientific knowledge it has no known therapeutic effect.

The second and third questions

22 By its second and third questions, which are closely connected and should therefore be considered together, the national court essentially asks whether a product may be categorized as a medicinal product 'by virtue of its presentation' within the meaning of the first subparagraph of Article 1(2) of Directive 65/65 where its therapeutic properties are indicated solely in a publication, such as a brochure, which is sent to the purchaser at his request after the product has been sold or is distributed by a third party independently of the sale of the product, having regard, in the latter case, to the provisions of Article 10 of the European Convention on Human Rights concerning freedom of expression.

23 Mr Ter Voort considers that a product is presented as a medicinal product within the meaning of Directive 65/65 where the presentation is made by the seller, the manufacturer or a third party acting on their behalf if it discloses an intention to market the product as a medicinal product and if it gives the averagely well-informed consumer the impression that a therapeutic substance is involved. He argues that, whereas the dispatch, at the purchaser's request, of information concerning the therapeutic properties of the product may be evidence — moreover not conclusive evidence — of the seller's or the manufacturer's intention to market that product as a medicinal product, that is not the case where the information is disseminated by a third party independently of the seller or the manufacturer.

24 According to the Commission and the Belgian, Italian and Netherlands Governments, a product is presented as a medicinal product within the meaning of Directive 65/65 where there is a direct or indirect link between the presentation and the product. In particular, a publication, sent to the purchaser at his request and setting out the therapeutic properties of the product, constitutes a presentation of the product within the meaning of the directive where it emanates from the supplier or the seller of the product or from a third party acting on behalf of or in connection with the supplier or the seller. The Netherlands Government submits that that may be the case, *inter alia*, where the seller or the supplier does not expressly disassociate himself from a publication made by a third party of which he has had notice.

25 It follows from paragraph 16 above that the provisions of Directive 65/65 are designed among other things to avoid products being placed on the market which do not have therapeutic effects but, for a commercial purpose, are presented as medicinal products by the manufacturer or the seller.

26 The conduct, action and approaches of the manufacturer or the seller which disclose his intention to make the product he markets appear to be a medicinal product in the eyes of an averagely well-informed consumer may therefore be conclusive for the purposes of deciding whether a product should be regarded as a medicinal product by virtue of its presentation.

27 In particular, the fact that the manufacturer or the seller sends the purchaser of the product a publication describing or recommending it as having therapeutic effects constitutes conclusive evidence of the manufacturer's or the seller's intention to market it as a medicinal product.

28 The mere fact that the publication is sent to the purchaser only at his request is not capable of rebutting such an intention on the part of the manufacturer or the seller. The information contained in a publication of the type referred to in the national court's order is of such a kind as to cause the product to appear to be a medicinal product in the eyes of an averagely well-informed consumer who asked to receive the publication and, moreover, in the eyes of any consumers who might learn of the existence of the publication.

29 Likewise, the fact that the publication is sent, not by the manufacturer or the seller, but by a third party acting on their behalf or in connection with them cannot rule out any intention on the part of the seller or the manufacturer to market the product as a medicinal product.

30 In particular, the product may appear to be a medicinal product in the eyes of an averagely well-informed consumer where he is encouraged by the manufacturer or the seller, in particular by indications on the product, to obtain information about its properties from the third party.

31 In contrast, the dissemination of information about the product, in particular about its therapeutic or prophylactic properties, by a third party acting on his own initiative and completely independently, *de jure* and *de facto*, of the manufacturer or the seller does not constitute by itself a 'presentation' within the meaning of the directive, since it does not disclose an intention on the part of the manufacturer or the seller to market the product as a medicinal product.

32 It is for the national court to assess, having regard to the circumstances in question, whether a publication such as a brochure containing indications regarding the therapeutic and prophylactic properties of a product is made completely independently of the manufacturer or the seller of the product and, if it is not so made, whether when the publication is sent to the purchaser of the product at his request it discloses an intention on the part of the manufacturer or the seller to make the product appear to be a medicinal product in the eyes of an averagely well-informed consumer.

33 However, in the event that the publication is disseminated by a third partly independently of the sale of the product, the national court's questions refer to Article 10 of the European Convention on Human Rights concerning freedom of expression.

34 As the Court has consistently held (see, *inter alia*, the judgment in Case C-260/89 *Elliniki Radiophonia Tileorassi AE* [1991] ECR I-2925, paragraph 41), fundamental rights form an integral part of the general principles of law, the observance of which the Court observes. For that purpose the Court draws inspiration from the constitutional traditions common to the Member States and from the guidelines supplied by international treaties for the protection of human rights on which the Member States have collaborated or of which they are signatories. The

European Convention on Human Rights has special significance in that respect. It follows that the Community cannot accept measures which are incompatible with observance of human rights thus recognized and guaranteed.

35 Freedom of expression, as embodied in Article 10 of the European Convention on Human Rights, is among the general principles of law the observance of which is ensured by the Court (judgment in *Elliniki Radiophonia Tileorassi AE*, cited above, paragraph 44).

36 But the freedom of expression of a third party who, in accordance with that which has been stated in paragraph 31 above, acts completely independently of the manufacturer or the seller is not affected, directly or indirectly, by the application of Directive 65/65. The presentation made by such a third party of a product has no bearing on the definition of that product in accordance with the directive.

37 In general, the definition of 'medicinal product' set out in the directive neither aims at, or has the effect of, restricting the freedom of expression of a third party disseminating information about the product. The directive does not prevent or hamper the dissemination of such information. It merely lays down the consequences which the dissemination of that information may possibly have as regards the placing of the product on the market, which will then be subject to special rules.

38 Moreover, even assuming — a not altogether unsurprising assumption since the aim of the involvement of the third party is to bring out the nature of the product as a medicinal product — that the freedom of expression of a third party acting on behalf of the manufacturer or the seller or in connection with one of them can be regarded as limited, and hence as affected, by the risk of bringing the product within the definition of a medicinal product laid down in Directive 65/65, it should be borne in mind that the inherent requirements of the exercise of that freedom must be judged against the requirements of the objective of the protection of public health pursued by Directive 65/65. Moreover, Article 10(2) of the European Convention on Human Rights provides that the exercise of freedom of expression

may be 'subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society ... for the protection of health ...'.

39 Accordingly, the reply to be given to the national court's second and third questions should be that 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 — in the latter case, 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 provisions of the first subparagraph of Article 1(2) of Directive 65/65.

The fourth question

40 The fourth question is concerned with whether a product which is not a medicinal product within the meaning of the provisions of Article 1(2) of Directive 65/65 may nevertheless be subject in the domestic law of a Member State to the rules governing medicinal products.

41 In the judgment in Case 35/85 *Tissier* [1986] ECR 1207, paragraph 22, the Court held that, subject to Article 30 et seq. of the Treaty concerning products imported from other Member States, Community law does not affect the right of Member States to subject substances not meeting the Community definition of medicinal product to controls or to require prior authorization in accordance with their own national law on medicinal products.

42 Accordingly, the reply to be given to the fourth question should be that a product which is not a medicinal product within the meaning of the provisions of Article 1(2) of Directive 65/65 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.

Costs

43 The costs incurred by the Governments of the Kingdom of the Netherlands, the Kingdom of Belgium, the Italian Republic and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending 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 referred to it by the Arrondissementsrechtbank, Leeuwarden, by order of 15 August 1991, hereby rules:

1. **A product recommended or indicated as having prophylactic or therapeutic properties is a medicinal product within the meaning of the provisions of the first subparagraph of 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, even if it is generally regarded as a foodstuff and even if in the current state of scientific knowledge it has no known therapeutic effect;**

2. **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 — in the latter case, 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 provisions of the first subparagraph of Article 1(2) of Directive 65/65;**

3. A product which is not a medicinal product within the meaning of the provisions of Article 1(2) of Directive 65/65 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.

Rodríguez Iglesias Zuleeg

Joliet Moitinho de Almeida Grévisse

Delivered in open court in Luxembourg on 28 October 1992.

J.-G. Giraud G. C. Rodríguez Iglesias

Registrar President of the Fifth Chamber