OPINION OF ADVOCATE GENERAL TESAURO

delivered on 22 September 1992 *

Mr President,
Members of the Court,

1. The questions referred to the Court for a preliminary ruling by the Arrondissementsrechtbank (District Court), Leeuwarden (Netherlands), relate to the interpretation of the concept of medicinal products 'by virtue of their presentation' contained in 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. [1]

The questions were raised in criminal proceedings against Mr Ter Voort, who is charged with having prepared, imported, held, sold and/or marketed unregistered medicinal products — more specifically, herbal teas imported from South America and sold by Mr Ter Voort, trading as 'Fitness Foundation Nederland', at his place of residence — contrary to Article 3(5) of the Wet op de Geneesmiddelenvoorziening (Law on the Supply of Medicinal Products). Those teas, which are not recommended or described as medicinal products on the packaging, on the label or in the directions for use, are, however, presented as having therapeutic properties by the foundation 'Stichting Nieuwe Horizon' in an explanatory brochure sent to anyone on request.

After being found guilty on that charge by the Kantongerecht (Cantonal Court), Leeuwarden, Mr Ter Voort brought an appeal in the Arrondissementsrechtbank (District Court) in which he argued that the teas in question could not be regarded as medicinal products with the meaning of Directive 65/65. In order to establish whether the products in question fall within the Community definition of medicinal products, the national court has therefore submitted four questions to this court for a preliminary ruling.

2. Before considering the individual questions, it is appropriate to recall that Directive 65/65, whose aim is to eliminate hindrances to the free movement of medicinal products and, at the same time, to safeguard public health, requires Member States to subject to prior authorization the placing of proprietary medicinal products on the market (Article 3). [2] 'Proprietary medicinal product' is defined as 'any ready-prepared medicinal product placed on the market under a special name and in a special pack'.

For the purposes of the directive, a medicinal product is 'any substance or combination of substances presented for treating or preventing disease in human beings or animals' (first subparagraph of Article 1(2) — 'medicinal product by virtue of its presentation') or 'any substance or combination of substances

* Original language: Italian.

1 — OJ, English Special Edition 1965-66, p. 20.

2 — As from 1 January 1992, that obligation was extended to medicinal products which are not 'proprietary medicinal products' (see Council Directive 89/341/EEC of 3 May 1989, OJ 1989 L 142, p. 11).

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' (second subparagraph of Article 1(2) — 'medicinal product by virtue of its function').

The two definitions of 'medicinal product', as elucidated by the Court, [3] are not rigorously separate; in the case at issue, however, the national court's questions relate solely to the concept of 'medicinal product by virtue of its presentation': the national court considers it unquestionable that the herbal teas at issue have no therapeutic or prophylactic effects, at least in the present state of scientific knowledge.

3. The national court's first question seeks to establish whether a product presented as having curative or preventive properties falls within the definition in the first subparagraph of Article 1(2) of Directive 65/65 even where, as in this case, the product in general is regarded as a foodstuff and in accordance with current scientific knowledge does not possess any pharmacological properties.

In that connection, I would observe in the first place that, as from the judgment in *Van Bennekom*, the Court has held that 'the concept of the "presentation" of a product must be broadly construed'. [4] Through the criterion of presentation, Directive 65/65 is designed, as the Court explained in that judgment, to cover not only medicinal products having a genuine therapeutic or medical effect (which therefore are also caught by the definition of 'medicinal products by virtue of their function') 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 represented as proper remedies — regardless of the fact that they are completely harmless. In sum, it seeks to safeguard against quackery.

It follows that products presented as having therapeutic or prophylactic effects, albeit — according to the present state of scientific knowledge — completely lacking the properties attributed to them, are medicinal products within the meaning of Directive 65/65 and should therefore be subjected to the system of prior authorization, precisely to prevent their being placed on the market as 'medicinal products'. The fact that the product at issue in this case is generally regarded as a foodstuff does not detract from that conclusion in so far as it is in any event described or recommended as having therapeutic or prophylactic effects. Consequently, the first question should be answered in the affirmative.

4. The second and third questions are concerned with the type of connection which has exist between the product and its presentation in order for it to be caught by the definition of 'medicinal product by virtue of its presentation' within the meaning of Direc-

3 — See, most recently, the judgment in Case C-112/89 *Upjohn* [1991] ECR I-1703, paragraph 18.

4 — Judgment in Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraph 17; similarly, see, most recently, the judgment in Case C-112/89 *Upjohn*, cited above, paragraph 16.

tive 65/65. In particular, the national court asks whether it is relevant that the therapeutic properties of the product emerge solely from a publication sent on request by the supplier or a third party after the product has been purchased. It also asks whether it is pertinent that the publication in question is made independently of the sale of the product and/or by a third party who is not the supplier or the seller, regard also being had to Article 10 of the European Convention on Human Rights.

I would observe in the first place that the fact that a product is not indicated or recommended as a medicinal product in the instructions, on the label or on the pack is as such not conclusive for the purposes of categorizing the product. In that connection, it is sufficient to recall that, as the Court has held, the definition of a medicinal product 'by virtue of presentation' also covers products indicated or recommended as having therapeutic or prophylactic properties by oral representation [5] and, more generally, all products which appear to the averagely well-informed consumer in the light of their presentation to be medicinal products. [6]

Neither does it appear to me to be of particular relevance that the information about the therapeutic properties of the teas at issue is set out in a publication sent on the purchaser's request after he has bought the product: manifestly such information may come to the notice of potential consumers and thus influence the sale of the product on account of the therapeutic properties attributed to it in the publication in question.

Indeed, since the concept of the 'presentation' of a product must be interpreted broadly so as to cover all products presented as medicinal products — even if merely for commercial purposes —, it is conclusive that the product in question is 'presented' in such a way as to disclose the producer's or the supplier's intention to market it as a medicinal product, thereby misleading consumers about its real properties.

It follows that a product presented as a medicinal product by means of a publication sent — albeit at the request of the consumer himself — by the producer or supplier of the product in question or even by a third party acting on their behalf falls within the Community definition of a medicinal product by virtue of its presentation within the meaning of the first subparagraph of Article 1(2) of Directive 65/65.

5. As for the possibility that the information about the therapeutic or prophylactic properties of a particular product was disclosed by a third party other than the seller or the supplier, I would say forthwith that that circumstance is *not in itself* conclusive for the purposes of the categorization of the product

5 — See the judgment in *Van Bennekom*, cited above, paragraph 18.

6 — See, to that effect, the judgment cited in the preceding footnote, the judgment in Case C-369/88 *Delattre* [1991] ECR I-1487, paragraphs 40 and 41, and the judgment in Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547, paragraph 23.

in question. What is conclusive, however, is whether or not the disclosure of such information was linked, even indirectly, with the producer or supplier of the product in question. The possible existence of any link whatsoever between the author of the publication and/or the person responsible for its distribution and the producer or supplier of the product in question will in fact constitute evidence of an intention to market it (or, rather, to make it appear) as a medicinal product, with the result that the product itself will have to be classed as a medicinal product by virtue of its presentation within the meaning of the first subparagraph of Article 1(2) of Directive 65/65.

In the final analysis, whilst it is true that a connection between the product and its presentation is essential in order for it to be classed as a medicinal product, it is also true that such a link may also be merely indirect. Consequently, if the 'presentation' of the therapeutic or prophylactic properties of the product is 'arranged' — on the assumption put forward by the national court — by means of a publication sent by a third party, it will be necessary to ascertain whether the third party is linked in some way with the producer or supplier of the product in question. For that purpose, it is sufficient, for example, that purchasers of the product should have come to know of the existence of the publication through the seller, whereas it is certainly not conclusive that the foundation which sent the publication is legally separate from the producer or the supplier of the product in question. In each case, it is for the national court, which alone has direct knowledge of the facts of the case, to establish whether any link exists between the third party in question and the producer or the supplier of the relevant product.

6. The national court also refers to Article 10 of the European Convention on Human Rights and asks essentially whether the prohibition on publishing information such as that at issue involves a violation of freedom of expression as enshrined in that article of the Convention.

The Court has consistently held [7] that fundamental rights form an integral part of the general principles of law, the observance of which it ensures. For that purpose the Court draws inspiration from the constitutional traditions common to the Member States and from international treaties on which the Member States have collaborated or of which they are signatories. In particular, the Court has held that Article 10 of the European Convention is a general principle the observance of which is ensured by the Court. [8]

Having said that, I completely rule out the possibility that the prohibition on disclosing information about the 'non-existent' (at least in the present state of scientific knowledge) therapeutic or prophylactic properties of a product may constitute a violation of Article 10 of the European Convention, especially since Article 10(2) provides for the possibil-

7 — See, most recently, the judgment in Case C-260/89 *Elliniki Radiophonia Tileorassi AE* [1991] ECR I-2925, paragraph 41.

8 — See the judgment in *Elliniki Radiophonia Tileorassi AE*, cited above, paragraph 44.

ity of restrictions on freedom of expression on grounds of the protection of public health.

What is more, the Community legislation on medicinal products, as is clear from the answer given to the second question, has no effect whatsoever on freedom of expression where information on a product is published by a third party who has no link — not even indirectly — with the supplier or the seller of the product in question. It is scarcely necessary to emphasize that in the event, however, that such a link were established — which would mean that the product in question would have to be subjected to the system of prior authorization — freedom of expression unquestionably could not serve to circumvent the rules on the marketing of medicinal products to the detriment of consumers.

7. In its fourth question, the national court asks whether it is compatible with the first subparagraph of Article 1(2) of Directive 65/65 that some Member States regard as medicinal products, not only products presented as such within the meaning of that provision, but also foodstuffs which, albeit not possessing any pharmacological properties, are presented by the seller or a third party as having prophylactic or therapeutic properties.

It has already been stated in answering the first three questions that even a product which is generally regarded as a foodstuff and, in the present state of scientific knowledge, has no pharmacological properties whatsoever, falls within the Community definition of a medicinal product by virtue of its presentation within the meaning of the first subparagraph of Article 1(2) of Directive 65/65 where it is presented by the seller or a third party linked to the seller as having therapeutic or prophylactic properties. It is therefore clear that, if those conditions are satisfied, the product in question must in any event be subjected to the system of prior authorization, which, moreover, is intended to ensure that a product which is solely in the nature of a foodstuff is not marketed as a medicinal product.

The question under consideration must therefore be interpreted as covering only such products as do not fall within the Community definition of medicinal products by virtue of their presentation and therefore in this case only such products as are presented as medicinal products by a third party who is completely independent, *de jure* and *de facto*, of the producer or the supplier.

In this connection, I would merely point out that, as the Court has already held, '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 such substances to controls or to require prior autho-

rization in accordance with their own national law on medicinal products'. [9]

In the final analysis, the Member States may legitimately subject to their own legislation on medicines products which do not fall within the Community definition of medicinal products by virtue of their presentation, provided that they can show — with respect to imported products — that the constraints on placing the products on the market, which are in principle incompatible with Article 30 of the Treaty, are necessary in order effectively to protect the interests mentioned in Article 36 of the Treaty.

8. In the light of the foregoing considerations, I therefore propose that the Court should answer as follows the questions referred by the Arrondissementsrechtbank, Leeuwarden:

(1) A product presented as having prophylactic or therapeutic properties is a medicinal product within the meaning of the first subparagraph of Article 1(2) of Directive 65/65/EEC even if it is generally regarded as a foodstuff and, in the present state of scientific knowledge, has no therapeutic effect.

(2) A product whose therapeutic properties are indicated solely in a publication which is sent to the purchaser after he has purchased the product and at his request should be classed as a medicinal product within the meaning of the first paragraph of Article 1(2) of Directive 65/65/EEC if the publication in question is sent by the producer or the supplier of the product in question or even by a third party who is linked to the producer or the supplier in some way. It is for the national court to establish whether there is a link between the third party in question and the producer or the supplier of the product in question.

(3) A product which does not fall within the Community definition of a medicinal product by virtue of its presentation may be subjected by the Member States — subject to Article 30 et seq. of the Treaty as regards imported products — to their own domestic legislation on medicinal products.

9 — Judgment in Case 35/85 *Procureur de la République* v *Tissier* [1986] ECR 1207, paragraph 22.