European Court of Justice, 21 March 1991, Delattre

PHARMACEUTICAL LAW

Medical product

- **A product presented as being intended to facilitate certain functions such as digestion or the hepato-biliary functions may come within the definition given in the second subparagraph of Article 1(2) of Directive 65/65 since it is capable of being administered with a view to restoring, correcting or modifying physiological functions**

The questions referred to the Court seek essentially to determine whether products displaying certain characteristics described by the national court can or must be classified as medicinal products. The first point raised is whether a product which is described in advertisements as being designed to activate natural physiological functions such as digestion or the elimination of bile may be classified in one Member State as a medicinal product although it is classified as a foodstuff in another Member State and Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters (Official Journal 1980 L 229, p. 1), which prohibits all indications "attributing to natural mineral water properties relating to the prevention or treatment or care of a human illness" (Article 9(2)(a)), allows it to be stated that such water may facilitate certain functions such as the hepato-biliary functions.

A product presented as being intended to facilitate certain functions such as digestion or the hepato-biliary functions may come within the definition given in the second subparagraph of Article 1(2) of Directive 65/65 since it is capable of being administered with a view to restoring, correcting or modifying physiological functions.

In order to decide whether a product of that kind must ultimately be classified as a foodstuff or as a medicinal product it is necessary, according to the judgment in Van Bennekom, supra, to consider each case individually having regard to the pharmacological properties of the product concerned, to such extent as they may have been established in the present state of scientific knowledge.

- **In any event, the fact that a product is classified as a foodstuff in another Member State cannot prevent its being classified as a medicinal product in the Member State concerned when it displays the characteristics of such a product.**

Although the essential purpose of Directive 65/65 may, as is indicated in the fourth recital in its preamble, be to remove obstacles to trade in proprietary medicinal products within the Community and although for that purpose Article 1 gives a definition of proprietary medicinal products and of medicinal products, it nevertheless constitutes, as is pointed out in the judgment in Van Bennekom, supra, merely a first stage in the approximation of national legislation on the production and distribution of pharmaceutical products. At the present stage of development of Community law, it is difficult to avoid the continued existence, for the time being and, doubtless, so long as harmonization of the measures necessary to ensure the protection of health is not more complete, of differences in the classification of products as between Member States.

- **no legislation requires Member States to consult such Community committees before taking a decision concerning a particular product**

The second point raised is whether a product classified as a foodstuff in one Member State may nevertheless be classified as a medicinal product in another Member State without prior consultation of the various committees which advise the Commission on such matters. In applying the definition of medicinal product given in Article 1(2) of Directive 65/65, the Member States must take account, as is the general rule in such matters, of the results of international scientific research and, in particular, the work of specialized Community committees (judgment in Case 247/84 Motte [1985] ECR 3887). However, no legislation requires them to consult such committees before taking a decision concerning a particular product.

- **hunger, heaviness in the legs, tiredness or itching is are ambiguous symptoms and a reference to such states or sensations in the presentation of a product is therefore not decisive**.

Such states or sensations are in themselves ambiguous. They may be the symptoms of a disease or illness and, combined with other clinical signs, may reveal a pathological condition. Alternatively, as in the case of short-lived tiredness or a need for nourishment, they may have no pathological significance. A reference to such states or sensations in the presentation of a product is therefore not decisive.

- **external form given to a product cannot 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.**

As has already been pointed out by the Court in its judgment in Van Bennekom, supra, to which, moreover, the national court refers, although the external form given to a product may serve as strong evidence of the seller' s or manufacturer' s intention to market the product as a medicinal product, it cannot 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. It must, however, be observed that, according to the same judgment, the first definition of medicinal products given by Directive 65/65, which relates to the presentation of the product at issue, must be construed fairly broadly by reason of its very purpose, which is to protect consumers against the marketing of products which do not have therapeutic properties or do not have the properties attributed to them. In the first place, form must be taken to mean not only the form of the product itself (tablets, pills or capsules) but also that of the packaging of the product, which may, for reasons of marketing policy, tend to make it resemble a medicinal product. In the second place, account must be taken of the attitude of an averagely well-informed consumer, in whom the form given to a product may inspire particular confidence similar to that normally inspired in him by a proprietary medicinal product, having regard to the safeguards normally associated with the manufacture and marketing of the latter type of product.
Whilst it is true that Council Directive 77/436/EEC of 15 July 1977 on the approximation of the laws of the Member States relating to coffee extracts and chicory extracts (Official Journal 1977 L 172, p. 20), referred to by the national court, speaks of products ordinarily presented "in powder, granular, flake, cube or other solid form", that fact cannot frustrate the application of the criteria relating to medicinal products laid down in Directive 65/65. Moreover, it must be observed that, as has already been pointed out, the form of the product itself is only one of the elements of its presentation to be taken into account in determining whether or not it should be classified as a medicinal product.

Source: **Eur-Lex**

European Court of Justice, 21 March 1991
(Moitinho de Almeida, Rodriguez Iglesias, Slynn, Grévisse, Zuleeg, Tessauro)
In Case C-369/88,
(…)
1 By order of 12 December 1988, which was received at the Court Registry on 19 December 1988, the Juge d' Instruction at the Tribunal de Grande Instance, Nice, referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty several questions on the concepts of illness or disease and medicinal products and their definition in Community law, on the compatibility with Community law of the monopoly granted to pharmacists for the distribution of medicinal products and on the interpretation of Council Directive 74/329/EEC on the approximation of laws of the Member States on emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (Official Journal 1974 L 189, p. 1).
2 The questions were raised in criminal proceedings brought against Jean-Marie Delattre, director of the company Svensson Tour Pol ("Svensson"), for marketing various products in France in breach of Articles L.512, L.596 and L.601 of the French Code de la Santé Publique (Public Health Code).
3 The first of those three articles reserves to pharmacists the right to sell, inter alia, medicinal products; the second provides that any establishment engaged in the preparation, wholesale sale or wholesale distribution of medicinal products and other products of which the sale is reserved to pharmacists must be owned by a pharmacist or by a company in whose management or overall administration a pharmacist is involved; and the third provides that before any proprietary medicinal product is marketed an authorization for that purpose must have been issued by the Minister for Social Affairs.
4 Svensson imports and sells by mail order in France various products manufactured in Belgium, where, it says, they are freely marketed either as foodstuffs or as cosmetic products.
5 Criminal proceedings were instituted against its director, Mr Delattre, following a complaint from the Conseil National de l' Ordre des Pharmaciens, on the ground that certain of the products marketed by his company were medicinal products, so that a special marketing authorization should have been obtained for them and they could be lawfully sold to the public only through pharmacies.
6 The complaint from the Conseil National de l' Ordre des Pharmaciens relates to 11 products, namely four slimming products, "SLIM 4", "Zero 3", "Kilomin" and "Chlorella", a product intended to facilitate digestion, "garlic oil extract", two products intended to improve circulation of the blood, "herbal treatment for legs" and "gel for the relief of tiredness in the legs", one intended to counteract itching, "M27", one to counteract tiredness, "wheatgerm oil + vitamin E", one for the joints, "Mineral 23", and one anti-smoking product, "Turn off", comprising an adjustable cigarette holder and herbal tablets.
7 The various products are presented in the form of tablets, creams or gels and all, except the last mentioned, carry a statement to the effect that they are not medicinal products.
8 Mr Delattre contended, before the national court, that the products in question could not be regarded as medicinal products under Community law but should be classified as foodstuffs, food supplements or cosmetic products, as the case might be, and therefore the Juge d' Instruction at the Tribunal de Grande Instance, Nice, referred the following questions to the Court for a preliminary ruling:
(I) Should the terms "disease" and "illness" as used in the abovementioned directives be interpreted uniformly in accordance with a Community definition, or is each Member State at liberty to implement the abovementioned directives by giving its own definition of them?
(II) If the terms "disease" and "illness" have a Community meaning, can product "A", which is designated as a food product in one Member State and whose advertisements refer to natural physiological functions (digestion, elimination of bile), be designated as a medicinal product in another Member State although a

Community directive harmonizing the rules applicable to product "B" (natural mineral waters, Directive 80/777/EEC) states expressly that those natural physiological functions must not be regarded as illnesses?
(III) If the word "disease" and "illness" have a Community definition, can references to sensations or states such as hunger, heaviness in the legs, tiredness and/or itching ("a sensation felt on the skin giving rise to an urge to scratch") be regarded as references to diseases or illnesses.
(IV) If, however, each Member State is at liberty to determine its own definition of illness, may a Member State freely block the sale of a food product which is lawfully controlled and freely sold in another Member State on the ground that the said product is for a "human illness or disease" (according to the meaning given to that concept by the Member State) without first having requested the opinion of the committees set up to ensure that national provisions do not conflict among themselves or with Community law, in particular the opinion of the Committee for Proprietary Medicinal Products (established by Directive 75/319/EEC), the Standing Committee for Foodstuffs (Decision 69/414/EEC), the Committee for Cosmetic Products (Directive 76/768/EEC) and/or the Standing Committee on Technical Standards and Regulations (Directives 83/189/EEC and 88/182/EEC)?
2(I) Having regard to the judgment in **Case 227/82 Van Bennekom [1983] ECR** 3883, in particular paragraph 19, may a Member State restrict the free importation and marketing of a food product extracted from a plant in common consumption (garlic), lawfully manufactured, controlled and sold in another Member State, on the ground that the external form of the product (pill, capsule, tablet) is medicinal although that same external form is permitted by Community Law (Directive 85/573/EEC) for another product which is also extracted from a plant in common consumption (chicory)?
(II) If the answer to the above question is in the affirmative, can a national provision of that type be justified with regard to Community law (in particular Article 36) and the case-law of the Court of Justice if those plants are presented in the form of a pill, capsule or tablet solely for reasons of hygiene and preservation and the product concerned (a) has no, and is not presented as having, curative or preventive properties with regard to human illness and is even packed in a container on which it is expressly stated that "this is not a medicinal product", (b) contains no constituent in such a high concentration that it constitutes a medicinal product and (c) does not constitute a serious (scientifically determinable) public health hazard?
3(I) Does the pharmacists' legal monopoly of the right to sell certain products to the public fall under the "commercial rules of the Member States"?
(II) If the reply to question 3(I) is in the affirmative, does the statement contained in Directive 85/342 concerning "the monopoly of the supply of medicinal products" refer to a medicinal product as defined by Directive 65/65/EEC or to medicinal products as defined by each Member State?
(III) If the Community definition of medicinal product applies in Question 3(II), can a "monopoly of the supply of medicinal products" be regarded as a measure having an effect equivalent to a quantitative restriction on the importation of a product if the result of that monopoly is to prevent the free marketing of that product even though it is (a) classified as a food product in the Member State in which it is manufactured, (b) subject to control by the competent authority (the Belgian Ministry of Health) of that same Member State, which certifies it as harmless to human health, and (c) sold freely to the public (that is to say, without a doctor' s prescription) solely by pharmacists in pharmacies in the importing State?
(IV) If the reply to Question 3(III) is in the affirmative, does such a legal monopoly of the free supply (that is to say, without a doctor' s prescription) of certain products to individuals need to be justified under Article 36 of the EEC Treaty, and in particular must it be justified as a protection against "a real threat to human health" (Case 216/84 Commission v French Republic (milk substitutes) [1988] ECR 793). Conversely, should the preamble and the text of the abovementioned Directive 85/432 be interpreted as meaning that a Member State may lawfully designate any product as a medicinal product and adopt any measures restrictive of competition in respect of that product, including granting to pharmacists in pharmacies the exclusive right of free sale (that is to say, without a doctor' s prescription) of that product to the public?
4(I) Should the provisions of Council Directive 74/329/EEC on the approximation of laws of the Member States on emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs, in particular the provisions in its preamble on the free circulation of foodstuffs and the provisions of Article 2, be interpreted as prohibiting a Member State from imposing restrictions (for example, a requirement that "administrative authorization for placing it on the market" be obtained) on the free marketing (and free movement) of the products (such as guar gum in particular) specifically referred to in Annex I to that directive?
(II) If the answer to Question 4(I) is in the negative, should not Community law be interpreted as requiring that at all events a decision by the authorities of a Member State imposing restrictions (for example, a requirement that "administrative authorization for placing it on the market" be obtained) on the free marketing (and free movement) of the products specifically referred to in Annex I to that directive should be accompanied by a general statement of reasons or be justified under Article 36 of the Treaty of Rome and that it should not constitute an arbitrary or disguised means of infringing Community law?"
9 Reference is made to the Report for the Hearing for a fuller account of the facts of the case, the course of 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.

10 It is necessary first to consider, together, the first three questions submitted by the national court and then, separately, the fourth question.

The first three questions

11 These questions relate to the concept of illness or disease as a Community concept, the classification of certain products in relation to the concept of medicinal product, and the pharmacists' monopoly.

Illness or disease as a Community concept

12 Council Directive 65/65 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (Official Journal, English Special Edition 1965-1966, p. 20), which has been amended several times, gives no definition of illness or disease. The only possible definitions for those terms are those most commonly accepted on the basis of scientific knowledge.

The classification of certain products as medicinal products

13 The same directive defines proprietary medicinal products as "any ready-prepared medicinal product placed on the market under a special name and in a special pack".

14 Pursuant 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", and according to the second subparagraph "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 regarded as a medicinal product.

15 That directive thus gives two definitions of medicinal products: a definition of medicinal products "by virtue of their presentation" and a definition of medicinal products "by virtue of their function". A product is a medicinal product if it falls within either of those definitions.

16 It should be added that those two definitions cannot be regarded as strictly distinct from each other. As is stated in paragraph 22 of the judgment in **Case 227/82 Van Bennekom [1983] ECR** 3883, a substance which is endowed with "properties for treating or preventing disease in human beings or animals" within the meaning of the first Community definition but is not "presented" as such falls within the scope of the second Community definition of a medicinal product.

17 Before the questions raised by the national court are considered, it is appropriate to dispel such doubts as may exist as to the possibility of classifying one and the same product both as a medicinal product and as a cosmetic product within the meaning of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (Official Journal 1976 L 262, p. 169).

18 Article 1(1) of that directive defines a cosmetic product as "any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours".

19 As is stated in the fifth recital in the preamble to Directive 76/768, which indicates that that directive relates only to cosmetic products and not to pharmaceutical specialities and medicinal products, the rules which it contains relate only to cosmetic products and not to medicinal products.

20 Thus, whilst it is not impossible that, in dubious cases, the definition of a cosmetic product might be considered in conjunction with that of a medicinal product before a product is classified as a medicinal product by virtue of its function, the fact remains that a product which displays the character of a medicinal product or a proprietary medicinal product does not come within the scope of Directive 76/768 and is subject only to Directive 65/65 and the provisions amending it.

21 That conclusion is, moreover, the only one that fulfils the aim of protecting public health pursued by both directives, since the legal rules applicable to proprietary medicinal products are more rigorous than those applicable to cosmetic products, in view of the particular dangers which the former may present to public health and cosmetic products generally do not.

22 In those circumstances, even if it comes within the definition contained in Article 1(1) of Directive 76/768, a product must nevertheless be treated as a "medicinal product" and be made subject to the corresponding rules if it is presented as possessing properties for the treatment or prevention of illness or disease or if it is intended to be administered with a view to restoring, correcting or modifying physiological functions.

23 The questions referred to the Court seek essentially to determine whether products displaying certain characteristics described by the national court can or must be classified as medicinal products.

24 The first point raised is whether a product which is described in advertisements as being designed to activate natural physiological functions such as digestion or the elimination of bile may be classified in one Member State as a medicinal product although it is classified as a foodstuff in another Member State and Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters (Official Journal 1980 L 229, p. 1), which prohibits all indications "attributing to natural mineral water properties relating to the prevention or treatment or care of a human illness" (Article 9(2)(a)), allows it to be stated that such water may facilitate certain functions such as the hepato-biliary functions.

25 A product presented as being intended to facilitate certain functions such as digestion or the hepato-biliary functions may come within the definition given in the second subparagraph of Article 1(2) of Directive 65/65

since it is capable of being administered with a view to restoring, correcting or modifying physiological functions.

26 In order to decide whether a product of that kind must ultimately be classified as a foodstuff or as a medicinal product it is necessary, according to **the judgment in Van Bennekom,** supra, to consider each case individually having regard to the pharmacological properties of the product concerned, to such extent as they may have been established in the present state of scientific knowledge.

27 In any event, the fact that a product is classified as a foodstuff in another Member State cannot prevent its being classified as a medicinal product in the Member State concerned when it displays the characteristics of such a product.

28 Although the essential purpose of Directive 65/65 may, as is indicated in the fourth recital in its preamble, be to remove obstacles to trade in proprietary medicinal products within the Community and although for that purpose Article 1 gives a definition of proprietary medicinal products and of medicinal products, it nevertheless constitutes, as is pointed out in **the judgment in Van Bennekom**, supra, merely a first stage in the approximation of national legislation on the production and distribution of pharmaceutical products.

29 At the present stage of development of Community law, it is difficult to avoid the continued existence, for the time being and, doubtless, so long as harmonization of the measures necessary to ensure the protection of health is not more complete, of differences in the classification of products as between Member States.

30 Finally, the particular features of the legislation specific to natural mineral waters which enable all relevant information to be given to the consumer as to the properties of such waters, without any risk of their being confused with medicinal products, do not affect the definition of medicinal products contained in Directive 65/65.

31 The second point raised is whether a product classified as a foodstuff in one Member State may nevertheless be classified as a medicinal product in another Member State without prior consultation of the various committees which advise the Commission on such matters.

32 In applying the definition of medicinal product given in Article 1(2) of Directive 65/65, the Member States must take account, as is the general rule in such matters, of the results of international scientific research and, in particular, the work of specialized Community committees (judgment in Case 247/84 Motte [1985] ECR 3887). However, no legislation requires them to consult such committees before taking a decision concerning a particular product.

33 The third point raised is whether a product presented as being intended to counteract certain sensations or states such as hunger, heaviness in the legs, tiredness or itching is a medicinal product within the meaning of Directive 65/65.

34 Such states or sensations are in themselves ambiguous. They may be the symptoms of a disease or illness and, combined with other clinical signs, may reveal a pathological condition. Alternatively, as in the case of short-lived tiredness or a need for nourishment, they may have no pathological significance. A reference to such states or sensations in the presentation of a product is therefore not decisive.

35 Consequently, it is for the national authorities to determine, subject to review by the courts, whether or not, having regard to its composition, the risks which might be associated with prolonged consumption of it and its characteristics in general, a product presented in the manner just described constitutes a medicinal product.

36 The final point raised is the extent to which the external form of a product, such as a pill, capsule or tablet, may lead to its being regarded as a medicinal product, even if it is presented as not being a medicinal product and is not presented as possessing - and does not in fact possess - therapeutic or preventive properties.

37 This question must be construed as relating to the definition of a medicinal product given in the first subparagraph of Article 1(2) of Directive 65/65, namely that of a medicinal product by virtue of its presentation.

38 As has already been pointed out by the Court in its **judgment in Van Bennekom**, supra, to which, moreover, the national court refers, although the external form given to a product may serve as strong evidence of the seller' s or manufacturer' s intention to market the product as a medicinal product, it cannot 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.

39 It must, however, be observed that, according to the same judgment, the first definition of medicinal products given by Directive 65/65, which relates to the presentation of the product at issue, must be construed fairly broadly by reason of its very purpose, which is to protect consumers against the marketing of products which do not have therapeutic properties or do not have the properties attributed to them.

40 In the first place, form must be taken to mean not only the form of the product itself (tablets, pills or capsules) but also that of the packaging of the product, which may, for reasons of marketing policy, tend to make it resemble a medicinal product. In the second place, account must be taken of the attitude of an averagely well-informed consumer, in whom the form given to a product may inspire particular confidence similar to that normally inspired in him by a proprietary medicinal product, having regard to the safeguards normally associated with the manufacture and marketing of the latter type of product.

41 In those circumstances, a product may be regarded as a medicinal product by virtue of its presentation if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product and, in particular, if on its packing and the information provided with it reference is made to research by pharmaceutical laboratories or to methods or substances developed by medical practitioners or even to testimonials from

medical practitioners commending the qualities of the product in question. A statement that a product is not a medicinal product is persuasive evidence which the national court may take into consideration, but it is not in itself conclusive.

42 Whilst it is true that Council Directive 77/436/EEC of 15 July 1977 on the approximation of the laws of the Member States relating to coffee extracts and chicory extracts (Official Journal 1977 L 172, p. 20), referred to by the national court, speaks of products ordinarily presented "in powder, granular, flake, cube or other solid form", that fact cannot frustrate the application of the criteria relating to medicinal products laid down in Directive 65/65. Moreover, it must be observed that, as has already been pointed out, the form of the product itself is only one of the elements of its presentation to be taken into account in determining whether or not it should be classified as a medicinal product.

43 It must therefore be stated in reply to the questions relating to the definition of medicinal product in Community law that:

(a) a product presented as being intended to facilitate certain physiological functions falls within the scope of the Community definition of medicinal product in the second subparagraph of Article 1(2) of Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. In order to decide whether that product is to be categorized as a medicinal product or as a foodstuff, it is necessary to have regard to its pharmacological properties. The fact that such a product is classified as a foodstuff in one Member State does not preclude its being treated as a medicinal product in the State concerned if it possesses the relevant characteristics. The specific features of the legislation concerning natural mineral waters have no relevance to the definition of medicinal product within the meaning of Directive 65/65/EEC;

(b) there is no provision obliging Member States to consult the consultative committees specialized in medicinal products attached to the Community institutions before taking the steps dictated in internal law by the definitions of medicinal product given in Directive 65/65/EEC;

(c) it is for the national authorities to determine, subject to judicial review, whether or not, having regard to its composition, the risks which its prolonged consumption may entail or its side-effects and, more generally, all of its characteristics, a product presented as counteracting certain conditions or sensations, such as hunger, heaviness in the legs, tiredness or itching constitutes a medicinal product;

(d) a product may be regarded as being presented as a medicinal product if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product and, in particular, if on its packing and in the information provided with it reference is made to research by pharmaceutical laboratories, to methods or substances developed by medical practitioners or even to testimonials from medical practitioners commending the qualities of the product. A statement that the product is not medicinal is persuasive evidence which the national court may take into consideration but is not in itself conclusive.

The pharmacists' monopoly

44 The national court wishes to know, essentially, whether the pharmacists' monopoly is a Community concept; whether, in defining the limits of that monopoly, a medicinal product must be defined according to the Community meaning or the national meaning of the term; whether that monopoly constitutes a measure having en effect equivalent to a quantitative restriction and, if so, under what conditions that measure might be considered compatible with Community law.

45 It is necessary first to recall the aim pursued by the Community rules on medicinal products.

46 The sole purpose of Directive 65/65 and the various directives amending it is to give a Community definition of medicinal products and proprietary medicinal products, with the exception of the proprietary medicinal products mentioned in Article 34 of the second Council directive, Directive 75/319/EEC of 20 May 1975 (Official Journal 1975 L 147, p. 13), in order to determine the scope of the harmonized procedure for marketing authorizations introduced by it with a view to facilitating the free movement of such products.

47 That finding is supported by the preamble to Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy (Official Journal 1985 L 253, p. 34). It states that "the geographical distribution of pharmacies and the monopoly of the supply of medicinal products continue to be matters for the Member States".

48 It follows that as Community law stands at present, no harmonization of the rules on the marketing of medicinal products in each Member State having been carried out (judgment in Joined Cases 87/85 and 88/85 Legia v Minister for Health [1986] ECR 1707), the Member States continue to be empowered to lay down rules on the distribution, in the strict sense of the term, of pharmaceutical products, subject to compliance with the Treaty, in particular the provisions on the free movement of goods.

49 Similarly, the Member States may, subject to the same reservation, impose restrictions on the sale or marketing of products not covered by Directive 65/65, whether they be other medicinal products or substances, pharmaceutical compositions or other products similar to them (**judgments in Van Bennekom**, supra, and in Case 35/85 Tissier [1986] ECR 1207).

50 As the Court has already held, legislation which restricts or prohibits certain forms of advertising and certain means of sales promotion may, although it does not directly affect imports, be such as to restrict their volume because it affects marketing opportunities for the imported products. The possibility cannot be ruled out that to compel a producer either to adopt advertising or sales promotion schemes which differ from one Member State to another or to discontinue a scheme which he considers to be particularly effective may

constitute an obstacle to imports even if the legislation in question applies to domestic products and imported products without distinction. That finding applies a fortiori when the rules in question deprive the trader concerned of the possibility of using not a means of advertising but a method of marketing whereby he realizes almost all his sales, for example mail order (judgments in Case 286/81 Oosthoek' s Uitgeversmaatschappij [1982] ECR 4575 and Case 382/87 Buet v Ministère Publique [1989] ECR 1235). 51 It follows that a monopoly granted to dispensing pharmacists in respect of the marketing of medicinal or other products is capable, in so far as it restricts sales to certain channels, of affecting the possibilities of marketing imported products and may accordingly constitute a measure having an effect equivalent to a quantitative restriction on imports within the meaning of Article 30 of the Treaty.

52 However, a monopoly for pharmacists may be justified by one of the general interests mentioned in Article 36 of the Treaty, which include the protection of health and life of humans. Moreover, since in principle it applies without distinction to domestic and imported products, that monopoly may also be justified on grounds of consumer protection, which, as the Court has held, is one of the imperative requirements which may justify a measure liable to hinder intra-Community trade (judgment in Case 25/88 Wurmser [1989] ECR 1105, paragraph 10).

53 In the absence of harmonization of the rules on the distribution both of medicinal products and of "para-pharmaceutical" products, it is for the Member States to choose the level to which they wish to ensure the protection of public health.

54 In the case of medicinal products within the meaning of Directive 65/65, account must be taken of the very particular nature of the product and the market involved, which explains the fact that in all the Member States there are, albeit with differences of detail, rules restricting their marketing and, in particular, some form of monopoly on the retail sale of such products is granted to pharmacists by reason of the safeguards which pharmacists must provide and the information which they must be in a position to furnish to the consumer.

55 It must nevertheless be observed that, in the above-mentioned part of the preamble to Directive 85/432, the Council refers to and thus acknowledges the existence of a pharmacists' monopoly in the Member States, but does not, in view of the fact that it is not a Community concept, give any definition of it.

56 It follows that although in principle the Member States may reserve to pharmacists the right to make retail sales of products that fall within the Community definition of medicinal products and although, in those circumstances, their monopoly over those products may be presumed to constitute an appropriate way of protecting public health, evidence to the contrary may be produced with respect to certain products whose use would not involve any serious danger to public health and whose inclusion within the pharmacists' monopoly would seem manifestly disproportionate, that is to say contrary to the principles laid down by the Court for the interpretation of Articles 30 to 36 of the Treaty.

57 If pharmacists are granted a monopoly of other products, such as "para-pharmaceutical" products, which may be of widely varying kinds, the need for such a monopoly in order to protect public health or consumers must, regardless of how the products concerned are classified under national law, be established in each individual case, and those two aims must not be attainable by measures less restrictive of intra-Community trade.

58 With regard, in particular, to products of the type at issue in the main proceedings, which are presented inter alia as facilitating weight loss, promoting certain physiological functions, such as digestion, or counteracting certain sensations or states, such as tiredness, account must be taken, in cases where the products do not fall within the Community definition of medicinal products, of the real dangers which they may present to public health, in general or under certain conditions of use, and of the possible errors into which they might lead an averagely well-informed consumer.

59 It is for the national court to decide, having regard to those criteria, whether the action before it is well founded.

60 It must therefore be stated in reply to the questions concerning the pharmacists' monopoly that:

under Community law as it now stands, the determination of the rules governing the distribution of pharmaceutical products remains a matter for the Member States, provided that the provisions of the Treaty, and in particular those relating to the free movement of goods, are respected;

a monopoly of the right to distribute medicinal or other products, granted to dispensing pharmacists, may constitute a barrier to importation;

if a Member State chooses to restrict to pharmacists the right to distribute products of that kind, such a barrier is, in principle and in the absence of any evidence to the contrary, justified in so far as it concerns medicinal products within the meaning of Council Directive 65/65/EEC;

where other products are concerned, however they may be classified in national law, it is for the national court to determine whether a monopoly of the right to market such products granted to pharmacists is necessary for the protection of public health or of consumers and whether those two aims cannot be achieved by measures less restrictive of intra-Community trade.

The fourth question

61 The national court' s fourth question seeks to determine whether Directive 74/329 prevents a Member State from restricting trade in a product such as guar gum, referred to in Annex I to the directive, and if not, under what conditions such a restriction is justified under Community law.

62 Directive 74/329 is concerned solely with the approximation of the laws of the Member States on emulsifiers, stabilizers, thickeners and gelling agents for use as additives in the processing of foodstuffs. The

measures which may be taken by the Member States concerning the substances listed in Annex I to the directive where they are used for another purpose therefore fall outside its scope.
63 That is the case as regards guar gum, which is at issue in the main proceedings. According to the observations submitted to the Court by Mr Delattre, of the 11 products with which the proceedings against him are concerned only "Zero 3" is composed of guar gum, and that product "creates a feeling of satiety which makes it possible to eat less".
64 It follows that the compatibility with Community law of restrictions on trade in a product such as "Zero 3" must be assessed in relation to Articles 30 and 36 of the Treaty.
65 A measure whereby a Member State makes a substance such as guar gum, when employed as part of a method intended to facilitate weight loss, subject to marketing authorization and to the pharmacists' monopoly, however that product may be classified in any other sphere of national law, may constitute a restriction on imports.
66 Under Articles 30 and 36 of the Treaty, such a restriction is, however, permissible within the limits and on the grounds mentioned above with respect to the pharmacists' monopoly. In order to decide, in a case where a product made of guar gum is not a medicinal product within the meaning of Directive 65/65, whether that restriction is justified, it is necessary in particular to take account of the risk that may be associated with a considerable loss of weight without special supervision and of the risk of consumers being misled in so far as they might attribute special properties to the product by reason of its presentation or packaging.
67 It must therefore be stated in reply to the fourth question that Council Directive 74/329/EEC and Articles 30 and 36 of the EEC Treaty must be interpreted as meaning that a measure whereby a Member State makes a product such as guar gum subject to marketing authorization and to the sales monopoly of pharmacists when it is used as part of a method intended to facilitate weight loss, however that product may be classified in any other sphere of national law, does not fall within the scope of that directive, but may constitute a barrier to importation. When the product in issue is not a medicinal product within the meaning of Directive 65/65/EEC, such a measure is not permissible under Community law unless it is necessary in order to protect public health or consumers and is proportionate to those aims.

Decision on costs

Costs

68 The costs incurred by the French Government, the Italian Government and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, in so far as the parties to the main proceedings are concerned, in the nature of a step in the action pending before the national court, the decision on costs is a matter for that court.

Operative part

On those grounds,

THE COURT (Fifth Chamber),

in answer to the questions referred to it by the Juge d' Instruction at the Tribunal de Grande Instance, Nice, by order of 12 December 1988, hereby rules:

1. 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 gives no definition of disease.

2. (a) A product presented as being intended to facilitate certain physiological functions falls within the scope of the Community definition of medicinal product in the second subparagraph of Article 1(2) of Council Directive 65/65/EEC. In order to decide whether that product is to be categorized as a medicinal product or as a foodstuff, it is necessary to have regard to its pharmacological properties. The fact that such a product is classified as a foodstuff in one Member State does not preclude its being treated as a medicinal product in the State concerned if it possesses the relevant characteristics. The specific features of the legislation concerning natural mineral waters have no relevance to the definition of medicinal product within the meaning of Directive 65/65/EEC;

(b) There is no provision obliging Member States to consult the consultative committees specialized in medicinal products attached to the Community institutions before taking the steps dictated in internal law by the definitions of medicinal product given in Directive 65/65/EEC;

(c) It is for the national authorities to determine, subject to judicial review, whether or not, having regard to its composition, the risks which its prolonged consumption may entail or its side-effects and, more generally, all of its characteristics, a product presented as counteracting certain conditions or sensations, such as hunger, heaviness in the legs, tiredness or itching constitutes a medicinal product;

(d) A product may be regarded as being presented as a medicinal product if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product and, in particular, if on its packing and in the information provided with it reference is made to research by pharmaceutical laboratories, to methods or substances developed by medical practitioners or even to testimonials from medical practitioners commending the qualities of the product. A statement that the product is not medicinal is persuasive evidence which the national court may take into consideration but is not in itself conclusive.

3. Under Community law as it now stands, the determination of the rules governing the distribution of pharmaceutical products remains a matter for the Member States, provided that the provisions of the Treaty, and in particular those relating to the free movement of goods, are respected;

A monopoly of the right to distribute medicinal or other products, granted to dispensing pharmacists, may constitute a barrier to importation;

If a Member State chooses to restrict to pharmacists the right to distribute products of that kind, such a barrier

is, in principle and in the absence of any evidence to the contrary, justified in so far as it concerns medicinal products within the meaning of Council Directive 65/65/EEC;
Where other products are concerned, however they may be classified in national law, it is for the national court to determine whether a monopoly of the right to market such products granted to pharmacists is necessary for the protection of public health or of consumers and whether those two aims cannot be achieved by measures less restrictive of intra-Community trade.
4. Council Directive 74/329/EEC and Articles 30 and 36 of the EEC Treaty must be interpreted as meaning that a measure whereby a Member State makes a product such as guar gum subject to marketing authorization and to the sales monopoly of pharmacists when it is used as part of a method intended to facilitate weight loss, however that product may be classified in any other sphere of national law, does not fall within the scope of that directive, but may constitute a barrier to importation. When the product in issue is not a medicinal product within the meaning of Directive 65/65/EEC, such a measure is not permissible under Community law unless it is necessary in order to protect public health or consumers and is proportionate to those aims.

Opinion of the Advocate-General
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Mr President,
Members of the Court,
1. The questions submitted to this Court for a preliminary ruling by the Tribunal de Grande Instance, Nice, relate to the interpretation of the Community legislation on medicinal products (1) and other Community provisions concerning products (in particular cosmetics and foodstuffs) which may have an impact on health, (2) and to Articles 30 and 36 of the Treaty.
I refer you to the Report for the Hearing for matters of detail but will summarize here the essential facts of the case.
2. Following the complaint by the Conseil National de l' Ordre des Pharmaciens, Mr Delattre, a director of the French company Svensson Tour Pol S.à r.l. ("Svensson"), was charged with unlawfully practising the profession of pharmacist on the ground that he had sold certain products which, under the applicable French legislation, are regarded as medicinal products; an authorization is required to place such products on the market and, in addition, they may be sold only through pharmacies. (3)
The products with which the criminal proceedings before the national court are concerned are 11 in number: four slimming products ("Slim 4", "Zero 3", "Kilomin" and "Chlorella"), a garlic-based product to assist digestion (Macérat huileux d' ail"), two products to improve the circulation of the blood (herbal treatment for the legs and a gel for tiredness in the legs), an anti-itching product ("M27"), a product for the relief of tiredness (wheatgerm oil with vitamin E), a product for the joints ("Mineral 23") and, finally, a product to help people stop smoking ("Turn-off"). (4)
Svensson, whose registered office is in Nice, imports and sells by mail order those products, which are manufactured in Belgium where they are classified not as medicinal products but (with the exception of "Turn-off") either as food supplements or as cosmetic products; the same products are also distributed, under the same classifications, in the Netherlands, Luxembourg, Germany, the United Kingdom and Spain.
Mr Delattre maintains that the products in question are not medicinal products, eight of them being classified in Belgium as foodstuffs and two ("M27" and gel for the legs) as cosmetic products. Consequently, the application to them in France of the provisions governing medicinal products, involving the prior issue of a marketing authorization, is, in Mr Delattre' s opinion, incompatible with Community law, in particular the provisions on the free movement of goods.
3. The Juge d' Instruction at the Tribunal de Grande Instance, Nice, therefore submitted four questions for a preliminary ruling, which I think it is reasonable to summarize as follows:
I. Is there a Community definition of the terms "disease" and "illness" (with regard to the treatment of which the term "medicinal product" is used) which prevents one and the same product from being classified as food in one Member State and as a medicine in another, and does such a definition extend to natural physiological states such as hunger, tiredness, heaviness in the legs and itching, account being taken of the fact that, for example, Directive 80/777/EEC on natural mineral waters does not treat as illnesses physiological conditions concerning digestion and the elimination of bile; if, on the other hand, each Member State were free to adopt its own definition of "maladie", with the result that it was able to prohibit on its own territory the sale of a product legally marketed as food in another Member State, on the ground that it was a medicinal product, would it be free to do so without even consulting the special committees set up under the applicable legislation?
II. Having regard **to the judgment in Van Bennekom**, is a Member State allowed to limit the import and marketing of a product extracted from a commonly consumed plant (garlic) simply because the external form of the product (thus, without any indication or recommendation showing it to be "medicinal") is typical of medicinal products, even though Directive 85/573 permits the use of such a presentation for extracts of chicory, without requiring the latter to be classified as medicinal product; and is the measure in question justified under Article 36 even though the product concerned bears a clear statement that it is not a medicinal product, it is not presented as having therapeutic properties, its ingredients are not of a high concentration and consumption of it involves no scientifically ascertained risk to health?
III. Does the creation of a monopoly for pharmacists fall within the powers of the Member States and does it extend only to medicinal products of the kind defined

in Directive 65/65 or also to those defined by each Member State; and does the prohibition of sale otherwise than through pharmacies of certain products classified differently in one or more Member States constitute a measure contrary to Articles 30 and 36, having regard in particular to the fact that in the State where the product is classified as a medicinal product it is none the less sold without a medical prescription?

IV. Finally, does Directive 89/463/EEC 74/329 prevent the Member States from imposing restrictions on the free movement of products (such as guar gum) referred to in Annex I to that directive; or must any such restrictions be explained and justified under Article 36?

A - GENERAL OBSERVATIONS

4. The preliminary questions, thus summarized, show clearly that the national court wishes to determine, on the basis of an interpretation by the Court of Justice, whether it is possible to trace a clear borderline between medicinal and other products (be they cosmetics or foodstuffs), a delimitation which, above all, would allow the products at issue to be classified according to Community criteria. Secondly, the national court asks whether, in the absence of a Community classification for the products in question, which would of course result in the reservation in Article 36 being inapplicable, the obligation to obtain prior authorization for the marketing of a product which is classified differently in one or more other Member States is compatible with Article 30 et seq. of the Treaty; and, finally, whether the different extent of the sales monopoly accorded to pharmacists, which is thus separate from the question whether all the Member States classify the same products as medicinal, is justified under Article 36.

These are not new problems, therefore, but they are not without considerable importance in so far as they reflect two fundamental values for the Community and the Member States: the free movement of goods and the protection of health.

That said, I would point out at the outset that the questions submitted, in particular the first two, have to a large extent been answered in the **judgment in Van Bennekom**, (5) but they also raise different issues, concerning in particular a systematic approach to Directive 65/65 in relation to other Community legislation which may be regarded as helping in some way to define the scope of that directive.

I think that it is therefore appropriate, before going on to examine the individual questions, to analyse briefly the extent to which national provisions on the manufacture and marketing of medicinal products have been harmonized and to consider possible links with the legislation concerning cosmetics and foodstuffs, and also the existing or potential problems concerning the free movement of medicinal products and of the products now described as "para-pharmaceutical" products.

5. Directive 65/65, the purpose of which is to remove obstacles to the free movement of medicinal products, is the basic instrument. It represents only the first stage in the harmonization of the national provisions which, although taken further by the second directive referred to earlier, Directive 75/319, is still only partial since, on the one hand, it does not apply to certain categories of medicinal products (for example vaccines, serums, homeopathic proprietary medicinal products and certain others - see Article 34 of the second directive); on the other, it has not yet introduced machinery for Community authorization or for reciprocal recognition of national authorizations.

Pursuant to Article 1 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" (first definition, medicinal product by virtue of presentation). The same article states that "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 also to be regarded as a medicinal product (second definition, medicinal product by virtue of function).

Any ready-prepared product placed on the market under a special name and in a special pack is defined as a proprietary medicinal product.

Article 3 of the same directive prohibits the marketing of proprietary medicinal products in a Member State "unless an authorization has been issued by a competent authority of the Member State concerned".

This gives rise, therefore, to a specific obligation for Member States to impose the requirement of a prior authorization only for the marketing of proprietary medicinal products. On the other hand, the Member States have no obligation but rather a mere power, to be exercised within the limits imposed by Articles 30 and 36 of the EEC Treaty with respect to imported products, to subject to the requirement of prior authorization the marketing of products (a) which conform to the Community definition of medicinal products but not to that of proprietary medicinal products or those which are expressly excluded from the scope of the directive, and (b) those which, although not falling within the Community definition of medicinal products, are classified as such by one or more Member States or are in any event liable to have an impact on health.

The Court itself has confirmed 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 such substances to controls or to require prior authorization in accordance with their own national laws on medicinal products". (6)

Indeed, notwithstanding the fact that the Court stated that the Community concept of medicinal product must be interpreted broadly, (7) it is quite possible for one or more Member States to adopt an even wider definition of medicinal products; in any event, other than in the case of the "proprietary medicinal products" referred to in Directive 65/65, it is necessary to ascertain, as regards imported products, whether the national restrictions on marketing are compatible with Articles 30 and 36.

6. As far as the present case is concerned, it is clear that the following alternative presents itself with respect to

the products referred to by the national court: they are either proprietary medicinal products within the meaning of Directive 65/65 and for that very reason their marketing must be subject to prior authorization in all the Member States; or else they do not fall within that concept and therefore, if they are imported, the question arises of the compatibility of prior authorization with Articles 30 and 36 of the Treaty, since the requirement of that authorization appear prima facie to be an obstacle to the free movement of goods.

Again in general terms, therefore, I would observe that in most cases a product covered by the term medicinal product has a special name and special packaging, so that it also comes within the definition of proprietary medicinal products. That means that a product which falls within one of the definitions of medicinal products contained in Directive 65/65 will also normally be a proprietary medicinal product, with the result that its marketing must be subject to prior authorization, unless it is one of the products expressly excluded (Article 34 of the second directive).

That having been said, it is necessary to determine the nature of the products in question to see whether they come within the Community definition of medicinal product. Such an examination is extremely complex precisely because, in view of the particular features of the sector in question, scientific rather than legal considerations are involved. In addition, the Community definitions mentioned earlier raise more than a few problems concerning not only those products which purport to treat an illness (first definition) but also, in particular, products which aim at "restoring, correcting or modifying physiological functions" (second definition), in view of the looser terms used in the second case.

7. In particular, with regard to the first definition, the difficulty lies precisely in the fact that medicinal products are - obviously - defined by reference to the illness concerned, but the latter term is not itself defined. And the second definition is formulated in such broad terms that, if read literally, it can apply both to medicinal products and to foodstuffs, and also to some cosmetics.

In practice, that lack of precision (which in some degree is inherent in the very nature of the products to be defined) makes it difficult to draw a precise dividing line between medicinal products and, for example, food and cosmetic products. It may therefore be useful, in order better to define the concept of medicinal product, to refer, as the national court appears inclined to do, to the Community legislation on cosmetics and food products.

8. With respect to cosmetics, it will be remembered that, pursuant to Article 1 of Directive 76/768, a cosmetic product means "any substance or preparation intended for placing in contact with the various external parts of the human body ... or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odours". As is apparent, that is a very precise and detailed definition which, in principle, enables the sector in question to be distinguished from that of medicinal products. None the less, problems may arise regarding products which come not only within that definition but also within that of medicinal products (a circumstance which is liable to arise above all in the case of cosmetics which serve a protective function); in such cases, a useful criterion may be derived from the predominant use and therefore, in some degree, from the view generally held by consumers.

For example, in the case of the Svensson products classified as cosmetics, namely "M27" (a basil-based anti-itching product) and the gel for relieving tiredness in the legs (a herbal product presented as being beneficial to the circulation), it having been established that both are intended to be applied externally, it is necessary to verify whether they are used for any of the purposes envisaged in the directive on cosmetic products. I think it is reasonable to conclude that those products should be classified as cosmetics in so far as their penetration into the tissue is entirely superficial and their impact on physiological functions is virtually nil, since, for instance, one has a merely refreshing effect (I leave it to the experts to say what properties basil has other than those relating to its normal use, for food purposes) and the other has a primarily preventive effect (in the same way as normal hand creams). On the other hand, if it should be found that those products have a significant impact on the physiological functions (if, for example, the leg gel acts on the tissue in such a way as to cure or prevent poor circulation) then this is clearly a case of a medicinal product.

It is for the national court, perhaps with the help of an expert, ultimately to decide how the products in question are to be classified on the basis of the criteria suggested here.

9. More complex is the relationship with the legislation on food products - which of course does not give a Community definition of such products.

It is important to remember that under Directive 79/112 (8) it is prohibited to "attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties". A partial exception to that prohibition of presenting food products as having therapeutic products is provided for in Article 9 of Directive 80/777 on natural mineral waters which allows statements such as "stimulates digestion" or "may facilitate the hepato-biliary functions", although that directive does not apply to waters used for curative purposes and it is also forbidden to refer to such properties. An exception of that kind may therefore reasonably be interpreted as meaning that products displaying the properties referred to (stimulation of the digestion and improvement of the hepato-biliary functions) do not thereby lose their status as foodstuffs, being consumed in any event for nutritional purposes; in other words, they are still used primarily for nutrition.

Further and even more significant confirmation of the view I have expressed is provided by Council Directive 89/398 of 3 May 1989 on the approximation of the laws

of the Member States relation to foodstuffs for particular nutritional uses. (9) That directive applies to those products which, although clearly different from everyday food products, have, in view of their particular composition or the particular way in which they are manufactured, a nutritional use designed to meet special requirements. In other words, they are food products intended for certain categories of people whose assimilative processes or metabolism are disturbed, or people who are able to obtain special benefit from the controlled consumption of certain substances in foodstuffs (Article 1(2)(b)).

It is important to emphasize at this point that such products, although having a specific beneficial effect on health, do not lose their status as food products. As a result, it is possible - although due caution must be exercised - to arrive at a more precise definition of medicinal products, having regard in particular to the second definition given in Directive 65/65. And it follows from the remarks which I have just made that, although it restores, corrects or modifies physiological functions, a product does not cease to be classified as a food product if its purpose continues to be essentially nutritional, even if it is used, albeit as a food product, either for its beneficial effect on a natural physiological condition (such as, for example, a few pounds excess weight) or as an effective adjunct to the treatment (using medicinal products) of an illness properly so called (such as diabetes). (10)

All the foregoing considerations prompt me to conclude that the second definition of medicinal products in Directive 65/65 must, when problems arise concerning the dividing line between food and medicinal products, be read in conjunction with the provisions concerning foodstuffs: essentially, therefore, a product will be a medicinal product where it is used exclusively or at least mainly to treat an illness or where it has a sufficiently far-reaching impact on the physiological functions to exceed the effects which food products have on such functions, whether they are everyday foods or are intended for special nutritional purposes.

I consider that such an interpretation is consonant with the aim pursued by that legislation. And whilst it is true that the second definition concerns those products which, regardless of presentation, are suitable for "restoring, correcting or modifying physiological functions", it is also true, on the one hand, that it is formulated in broad terms in order to embrace substances which may in particular modify physiological functions without having properties enabling them to treat or prevent an illness properly so called; on the other hand, it seems to me beyond doubt that such a formulation cannot be interpreted so as to extend to those products which, although without doubt inherently able to affect physiological functions, have an essentially nutritional purpose. Otherwise, salt, for example, which, in the absence of other products, is used by sportsmen to prevent or cure cramp, would have to be classified as a medicinal product.

Accordingly, I consider, for example, that a product such as Kilomin, a powder intended to be dissolved in water or milk to give a drink which, when taken before meals, reduces the appetite, whilst at the same time providing certain vitamins needed by the body, can be properly classified, subject to any contrary finding by the national court, as a dietetic food product, thus falling within the scope of Directive 89/398.

10. The same conclusion must be arrived at, in my opinion, in cases not of food products intended for a particular nutritional purpose but of substances normally contained in everyday food products which are intended for nutrition and are considered an essential part of the daily diet and are indispensable for the proper functioning of the body. It is clear that in such cases, as the Court itself stated **in Van Bennekom** with respect to vitamins, (11) the substances in question cannot be regarded as medicinal products when they are consumed in quantities corresponding to normal requirements and to make up for a deficiency thereof resulting from particular physiological conditions which are not attributable to a pathological abnormality.

Against the background of those general observations, we can now formulate a more specific answer to the individual questions submitted by the French court, where such answers do not follow directly from the foregoing considerations.

B - THE QUESTIONS

11. The first question raises in particular the problem of how to define the term disease or illness. I shall rule out the possibility that there might be a precise and exhaustive Community, and in more general terms a legal, concept of illness, it being a term which is used in numerous Community instruments and doubtless has a similar meaning in all the Member States. Essentially, I do not think we can go far beyond the common meaning of the term and consider pathological conditions of the human organism, which for that very reason require medical treatment and recourse to products which provide a specific remedy. On the other hand, particular physiological conditions, such as mere tiredness (resulting from physical or mental effort) or bad digestion (due to bad eating habits) cannot reasonably - and I refer here to common experience rather than common sense - be regarded intrinsically as illnesses. It seems to me that the question submitted by the national court on this point is almost rhetorical.

It is indeed true that tiredness or indigestion may also be a symptom or effect of a pathological condition; however, in such cases products made from natural substances, which merely amount to a food supplement designed to promote the proper functioning of the body, will certainly not provide an adequate remedy for the pathological condition in question: the primary need will be for products - medicinal products - which treat the illness itself and do not merely provide relief from the tiredness which it causes.

Thus, for example, a product to combat tiredness (made up of wheatgerm oil and vitamin E), such as that at issue in the main proceedings, cannot in my view reasonably be classified as a medicinal product since it is not intended, as such, to treat any pathological condi-

tion but merely has a beneficial effect and provides relief for a physiological condition the causes of which are natural and, I would add, entirely normal.
That having been said, I shall merely observe that the lack of a codified definition in Community legislation of the term illness, a term which relates to common experience and is a concept shared by the Member States, is not in itself such as to justify a different classification of the same product in different Member States. Furthermore, as was pointed out in my earlier observations, a systematic reading of the other instruments concerning food products and cosmetics makes it possible, in the present case, to arrive at a sufficiently clear dividing line between those products and the medicinal products defined by Directive 65/65.
It follows that differing classifications of one and the same product can legitimately exist not because the term illness is defined differently in the various Member States but rather because there are products which, although capable of being brought within the definition of medicinal products by virtue of their function within the meaning of the directive, are primarily intended for nutritional purposes. I refer in particular to those substances, essential for human nourishment, which are taken in order to remedy a deficiency of them resulting from what might be called temporary physiological conditions and therefore in amounts not exceeding a specified level.
In such cases of course it becomes difficult, above all in the absence of harmonization, to say to what extent such a substance is merely a food supplement (intended exclusively to add to daily nourishment) and when, on the other hand, because of its high concentration or a dosage which exceeds normal requirements, it becomes a medicinal product. As the Court itself stated **in Van Bennekom** with regard to vitamins, their classification as medicinal products "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". (12)
In view of the uncertainty and the development of scientific knowledge in many areas of pharmacology and, in particular, for the present purposes, regarding determination of the level of concentration at which the consumption of substances intended essentially for nutritional purposes may become harmful, it will be necessary to decide case by case how the products in question are to be classified. Therefore, it is entirely possible that a Member State might, on the basis of domestic legislation, regard such products as medicinal products, subject to the possibility of review by the courts to ensure compliance with Community law in other respects, in particular the question of compatibility with Article 30 et seq. of the EEC Treaty.
From that standpoint, consultation of the Committee for Proprietary Medicinal Products or the Standing Committee for Foodstuffs or other special committees is not an appropriate way of avoiding differing classifications of the same product since the classification of products is not within the remit of those committees (and in any case their opinions are not binding on the Member States).
12. The second question relates in particular to the concept of medicinal products by virtue of presentation, as defined in the first subparagraph of Article 1(3) of Directive 65/65, pursuant to which "Any substance or combination of substances presented for treating or preventing disease in human beings or animals" is to be regarded as a medicinal product.
The Court has already given a ruling on that definition **in Van Bennekom**, in which it stated 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 ... but also whenever any averagely well-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". (13) This means that the directive in question is intended to "protect" consumers not only from harmful or toxic medicinal products but also from the various products presented as adequate remedies. And it is precisely for that reason that "the concept of the 'presentation' of a product must be broadly construed". (14) The Court also stated in the same judgment that the external form given to the product in question (including pills or capsules) may serve as strong evidence of the seller' s or manufacturer' s intention to market the product as a medicinal product, adding, however, that such evidence will not be conclusive "since otherwise certain food products which are traditionally presented in a similar form to pharmaceutical products would also be covered". (15)
It is specifically on the basis of the latter statement that the national court asks in particular whether a product extracted from a commonly consumed plant such as garlic must, in the absence of indications or recommendations showing it to be "medicinal", be regarded as such merely because of its external form, regard also being had to the fact that such presentation is permitted under the abovementioned Directive 85/573 in relation to chicory extracts, without the latter thereby coming within the concept of medicinal product "by virtue of presentation".
Let me say straight away that the reference to chicory extracts is of little relevance and in any event is not decisive, since that product, unless presented as being able to treat or prevent an illness, could certainly be brought within the category of food products which are traditionally (and often for eminently commercial reasons) presented in forms similar to those of medicinal products; and also precisely because it is covered by a specific provision applicable only to the product expressly mentioned.
With regard to the product at issue (garlic-based tablets) it should be recognized without more, as the Court has already held, that the criterion of the external form of the product cannot be the sole, decisive criterion for attributing curative properties to it and defining it as a medicinal product; and, even if I had no faith in the in-

tellectual qualities of the average consumer, I would not believe that a consumer, faced with a product such as the one at issue, would feel certain that he was being offered a product for the treatment of an illness, regardless of whether it is presented in the usual form of garlic or as tablets; and this applies a fortiori where, as in the present case, it is stated on the pack that the product is not medicinal, thus making it clear that the manufacturer does not intend to market it as a medicinal product.

It is not, therefore, a medicinal product by virtue of its presentation; nor, in principle, is it a medicinal product by virtue of its function, in the light of what I said earlier regarding products that are intended merely to enhance digestion: they do not change their nature, remaining essentially foodstuffs.

It is not beyond probability, however, that a Member State may, where a product is of a high concentration or becomes harmful when used to excess, regard it as a medicinal product and impose the requirement of prior authorization. In such circumstances it will be for the national court to ascertain, with the assistance of an expert if necessary, whether the classification is appropriate having regard to the available scientific knowledge.

13. In that connection, I would point out that where, as in the present case, a product is not a "proprietary medicinal product" within the meaning of Directive 65/65, it is clear that the imposition by the national legislature of the requirement of a prior authorization for marketing amounts, in the case of imported products, to a rule capable of hindering intra-Community trade directly or indirectly, actually or potentially, to use the well-known dictum in Dassonville. A further consequence is that, as the Court has also made clear on several occasions, (16) rules which hinder free movement may be "justified" under Article 36, on grounds of health, only where such rules are proportional and not excessive in relation to the requirement concerned and there are no alternative solutions which would allow the Member States to achieve the same aim with less disturbance of trade.

With particular reference to the issue of protection of health, the Court has stated on several occasions (17) that the Member States may, in the absence of harmonization at Community level and in so far as there are uncertainties in the present state of scientific research, decide what degree of protection of the health and life of humans is justified. Their discretion is not, however, absolute, nor are powers reserved to them: the Member States must be in a position - and the burden of proof falls on them - to justify the restrictions adopted by them on grounds of protection of health, in so far as the rules in question must be limited to what is necessary to achieve the lawfully pursued aim of protecting health. **In Van Bennekom**, the Court stated that "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". (18)

Consideration of that question, which is a matter for the national court, is extremely complex and delicate, in so far as there are uncertainties as to the critical threshold at which consumption of the products at issue might endanger health.

Therefore, whilst it must again be stressed that the obstacles to the free movement of goods may be justified on the grounds of protection of health under Article 36 of the EEC Treaty, it must be added that that provision cannot be invoked to limit the marketing of products (whether or not described as medicinal) which undeniably present no direct or indirect danger to health.

Even if the national court were to determine - as it seems to have done in the present case - that such a product does not have and is not presented as having therapeutic or preventive properties, does not contain substances in a high concentration such as to make it a medicinal product and does not present any serious risk to health, it is clear that the requirement of prior authorization for such a product, when imported, is not justified under Article 36 of the Treaty.

I would add, finally, that an unavoidable precondition for reliance on Article 36 is that the restrictive measure must not constitute a means of arbitrary discrimination or a disguised restriction on trade: and that would be the case if it were found or demonstrated that products similar to those at issue are marketed in France, as contended by Mr Delattre, without being subject to the requirement of prior authorization.

14. The third question seeks to determine whether, under Community law, the Member States are empowered to create a sales monopoly for pharmacists and if so what the extent of that monopoly is - does it cover only medicinal products as defined in Directive 65/65 or does it extend to medicinal products as defined by each Member State?

As is expressly recognized in the second recital in the preamble to Directive 85/432, (19) the creation of a monopoly for the distribution of medicinal products is a matter for the Member States. Such a monopoly is not in principle linked with the Community legislation on medicinal products, in so far as the objectives and scope of the two sets of rules are different. The main purpose of Directive 65/65 is to subject proprietary medicinal products to the requirement of prior marketing authorization and it does not indicate which products are to be subjected to restrictive conditions as to distribution; still less does it make sales subject to the requirement of a medical prescription. The only Community limitation is, in principle, that such a sales system must not be incompatible with Article 30 et seq. of the Treaty.

Mr Delattre contends that rules on sales which prescribe a specific distribution network constitute a measure having an effect equivalent to a quantitative restriction and that such a restriction may not be regarded as justified when applied to products for the use of which the advice of a pharmacist is unnecessary. The Commission, on the other hand, expresses some doubt

as to whether a limitation on the marketing of medicinal products, deriving from the creation of a sales monopoly for pharmacists, can be regarded as incompatible with Article 30, since it is a measure that is applied without distinction to both domestic and imported products, and states that in any event it is justified by the objective of protection of health.
It is therefore necessary, by way of preliminary, to establish whether trading rules of the kind at issue add up to a measure equivalent to a quantitative restriction within the meaning of Article 30.
Let me say first of all that a measure which reserves the sale of a category of products to specified persons in specified places may constitute a measure having equivalent effect, in the sense defined by the Court in the well-known Dassonville judgment, (20) since they are trading rules "capable of hindering, directly or indirectly, actually or potentially, intra-Community trade".
In particular, rules such as those at issue, which confine sales to a restricted distribution network, may affect imports both by reducing the actual volume of sales and by causing prices to rise.
That said, I must nevertheless point out that such rules, and indeed all the rules on sales, apply without distinction to both domestic and imported products. Moreover, they do not impose an absolute prohibition on sales, with the result that, in principle, the marketing of imported products is not made more difficult than that of domestic products.
In fact, such obstacles to free movement do not arise, in such cases, from a disparity between national laws but rather from the very existence of the laws in question, in so far as their existence bears no relation to the fact that the Member State from which they originate prohibits sales of them otherwise than through pharmacies or, conversely, authorizes such sales. (21)
The relevant case-law of the Court may at first sight appear to have adopted divergent approaches. In some cases, the Court has held that it is necessary to examine the allegedly imperative requirement, in line with the course taken in the famous Cassis de Dijon case, in order to establish whether the means used to attain that end are proportionate in relation to the aim pursued, as well as necessary, in the sense that that objective could not be achieved by another means which interfered to a lesser extent with Community trade. (22) In other, apparently similar cases, it seems that no link with imports was attributed to rules of that kind. But on closer examination it is apparent that there are few examples of the latter approach and, moreover, that they derived from the fact that the Court considered that the rules at issue did not have an impact on the marketing of the product at a significant stage as far as intra-Community trade was concerned; (23) or that they did not affect marketing of the same product by other methods; (24) or, finally, that the product could be marketed through alternative channels. (25)
15. In the case of the monopoly enjoyed by pharmacies, on the other hand, it is clear that the products in question cannot be marketed otherwise than through pharmacies and the fact that one and the same product may be confined to sales in pharmacies in one Member State and authorized to be sold through other outlets in another Member State together with the fact that, in principle, it is not impossible for one Member State to extend the pharmacists' monopoly to products that are certainly not medicinal products, in itself makes it unacceptable for that Member State not to have to justify such rules under Article 36.
Returning to the present case, I shall merely point out that here too the imperative requirement relied on in order to justify the obstacles to free movement by both the Commission and the Member States which submitted observations is the protection of health.
Health is without doubt intrinsically deserving of protection at Community level and therefore that objective is, in principle, lawful. It is obvious that national legislation which limits the sale of medicinal products to specialized businesses (pharmacies) and to qualified professional persons (pharmacists) seeks to safeguard health, since the products in question are, by definition, linked with health.
The decisions of the Court to which I referred earlier support the view that, in view of the nature of the rules at issue, it is incumbent on the national authorities to show that the sale of the products in question otherwise than through pharmacies constitutes a "genuine risk to health".
Having said that, I can do no less than draw attention to the inconsistency which would afflict the entire system if it were to be concluded that a Member State should, in each instance, justify the decision to reserve to pharmacists the sale of products classified as "proprietary medicinal products" within the meaning of Directive 65/65. And although, as I have already pointed out, the aim of the directive in question is certainly not to subject medicinal products to a restricted distribution network, it is nevertheless true that, where a product falls within the Community definition of proprietary medicinal products, that product must, because of its intrinsic properties, be recognized as one which may possibly affect health, with the result that its consumption must be subject to special safeguards. Indeed, the adoption of a Community definition of medicinal products, implying in principle that a particular product is to be classified in the same way in all the Member States and, in particular, that the nature of the product in question is such that it may have an impact on health, renders it lawful and also logical that, as far as such "medicinal products" are concerned, the Member States should be lawfully entitled to grant pharmacists a monopoly.
On the other hand, for products which do not fall within the Community definition of proprietary medicinal products (whether they are medicinal products under the legislation of one or more Member States or are products of a different kind), a pharmacists' monopoly on sales obviously cannot be justified in absolute terms.
In fact, it will be necessary to establish in each individual case that the product in question is such that it presents risks to health and, in particular, that the pres-

ence of a pharmacist is essential when it is sold. That applies with greater force where, as has been contended in the present case with regard to the "La Vie Claire" and "Vitamin System" products, similar products of domestic manufacture are marketed otherwise than through pharmacies: discrimination which, let it be remembered, renders Article 36 of the Treaty inapplicable.

16. In its last question, the national court asks whether the products referred to in Annex I to Directive 74/329 may be subjected to trade restrictions by the Member States.

The answer is clearly negative but - and it hardly needs saying - only in the case of emulsifiers, stabilizers, thickeners and gelling agents which may be used in foodstuffs. Let me explain: the directive in question harmonized the provisions on certain agents used in the preparation of foodstuffs. This implies that it is only when they are used as such that the Member States are wholly precluded from restricting their marketing (other than in the cases referred to in Article 5 of that regulation).

The fact that guar gum (a product covered by the directive in question) is the only component of "Zero 3" raises the presumption that the national court, in submitting that question, took it for granted that "Zero 3" was not a medicinal product. Admittedly, the fact that the substance in question is allowed to be used - what is more, without any quantitative limitation - in food products cannot be regarded as indicating that that substance is harmless or, at the same time, that it is a product which does not in itself have any particular therapeutic characteristics.

That said, I would point out that the foregoing general observations and the answers to the first two questions are such as to provide the national court with the necessary criteria to establish whether "Zero 3" is a medicinal product or a food product. Needless to say, if the national court finds that it is not a medicinal product, the problem of any restrictions imposed on the marketing of guar gum would fall to be examined in relation to Articles 30 and 36 of the Treaty (see paragraph 13).

17. In the light of the foregoing considerations, I therefore propose that the Court give the following answers to the questions referred to it by the Tribunal de Grande Instance, Nice:

(1) Only proprietary medicinal products, as defined by Directive 65/65, are subject to the obligation on the part of the Member States to make their release on to the market subject to prior authorization. In the case of imported products which, in the assessment of the national court, do not fall within the definition of proprietary medicinal products in so far as they do not have properties for the treatment or prevention of pathological conditions but merely affect natural physiological conditions such as hunger, tiredness, digestion and itching, limitations on marketing, which are incompatible with Article 30 of the Treaty, may be justified under Article 36 only if they are necessary for effective protection of health and do not constitute arbitrary discrimination.

(2) If the national court finds that a product is not a medicinal product, by virtue either of its presentation or its function, and does not, on the basis of verifiable scientific knowledge, present any risk to health, the requirement of a prior marketing authorization for imported products is incompatible with Article 30 and is not justified under Article 36.

(3) The creation of a sales monopoly for pharmacists is a matter for the Member States; except, in principle, in the case of products which are proprietary medicinal products within the meaning of Directive 65/65, the extension of that monopoly to other products (whether or not classified as medicinal products), where they are imported, is justified by the requirement of the protection of health where the presence of a pharmacist is necessary when such products are sold.

(4) Directive 74/329 precludes the Member States from imposing restrictions on the free movement of the products referred to in Annex I thereto only where they are used for the purposes specified in the directive. Any restrictions imposed on the marketing of guar gum, when it is not used for the purposes envisaged in that directive, must therefore be examined the light of Article 30 et seq. of the Treaty.

(*) Original language: Italian.

(1) First and second Council Directives (65/65 and 75/319) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (Official Journal, English Special Edition 1965-1966, p. 20, and OJ 1975 L 147, p. 13).

(2) The national court refers in particular to certain provisions of the following directives:

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, p. 169);

Council Directive 74/329/EEC of 18 June 1974 on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (OJ L 189, p. 1);

Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters (OJ L 229, p. 1);

Council Directive 85/573/EEC of 19 December 1985 which amends Council Directive 77/436/EEC on the approximation of the laws of the Member States relating to coffee extracts and chicory extracts (OJ L 372, p. 22).

(3) See Articles L.512, L.596 and L.601 of the Code de la Santé Publique.

(4) By virtue of Article L.511 of the Code de Santé Publique, all anti-smoking products are treated as medicinal products.

(5) Case 227/82, [1983] ECR 3883.

(6) Judgment in Case 35/85 Procureur de la République v Tissier [1986] ECR 1207, paragraph 22.

(7) See the judgments **in Van Bennekom** and Tissier, both cited earlier.

(8) Council Directive on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ 1979 L 33, p. 1.).
(9) OJ 1989 L 186, page 27. That directive replaced Directive 77/94 (OJ 1977 L 26, page 55).
(10) Annex I to the directive in question contains a (non-exhaustive) list of groups of products covered by it (including, in fact, food products with low or reduced energy values intended to control weight and foods for diabetics) for which the adoption of directives is envisaged with a view to achieving complete harmonization of the applicable national laws.
(11) Supra, paragraph 26.
(12) Supra, paragraph 29.
(13) Supra, paragraph 18.
(14) Ibid., paragraph 17.
(15) Ibid., paragraph 19.
(16) The most recent example is Case C-42/90 Bellon [1990] ECR I-4863.
(17) See the judgments in Case 174/82 Sandoz [1983] ECR 2445 and Case 178/84 Commission v Germany [1987] ECR 1227.
(18) Supra, paragraph 40.
(19) Council Directive 85/432 of 15 September 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy (OJ 1985 L 253, p. 34).
(20) Case 8/74, [1974] ECR 837.
(21) See in that regard the Opinion of Mr Advocate General Van Gerven of 29 June 1989 in Case C-145/88 B & Q [1989] ECR 3865.
(22) See to that effect the judgments in Case 382/87 Buet [1989] ECR 1235 and Case C-145/88 B & Q [1989] ECR 3851.
(23) Judgment in Case 155/80 Oebel [1981] ECR 1983, paragraphs 19 and 20.
(24) Judgment in Case 75/81 Blesgen [1982] ECR 1211, paragraph 9.
(25) Judgment in Case C-23/89 Quietlynn [1990] ECR I-3059.
Translation