European Court of Justice, 15 November 2007, Commission v Germany (garlic extract powder capsule)

PHARMACEUTICAL LAW – FREE MOVEMENT

No medicinal product by presentation

- **Presentation in capsule form is the only aspect likely to suggest classification of the product as a medicinal product by presentation, however the capsule form is not exclusive to medicinal products**

No aspect of its packaging tends to make the product concerned resemble a medicinal product other than the photograph or of a head of garlic on the product's external packaging, as such an image also features on a number of products marketed as medicinal products in Germany. The photograph of a plant on the external packaging of a product is not, however, sufficient to inspire in a reasonably well-informed consumer confidence like that usually inspired by medicinal products. Therefore, presentation in capsule form is the only aspect likely to suggest classification of the prod-uct as a medicinal product by presentation. However, it must be recalled that, according to settle case-law, the external form given to a product, although it may serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product, cannot be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to medici-nal products would also be covered (see, to that effect, van Bennekom, paragraph 19, and Delattre, paragraph 38). As the Advocate General noted, in point 51 of her Opinion, the capsule form is not exclusive to me-dicinal products. A large number of foodstuffs are in fact offered for sale in that form in order to facilitate their ingestion by consumers. In that connection, it must be observed that Article 2(a) of Directive 2002/46 expressly refers, among the criteria used to define 'food supplement', to its presentation in capsule form. Con-sequently, that evidence alone is not sufficient to confer the status of medicinal product by presentation on the product concerned. In those circumstances, it must be held that the product concerned does not satisfy the criteria laid down in the first paragraph of Article 1(2) of Directive 2001/83. Therefore it cannot be classified as a medicinal product by presentation within the meaning of that directive.

No medicinal product by function

- **In those circumstances, it must be held that the product concerned, whose effect on physiological functions is no more than the effects of a foodstuff consumed in a reasonable quantity may have on those functions, does not have a significant effect on the metabolism and cannot, therefore, be classified as a products capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83.**

The legislation at issue is not necessary in order to protect consumer health

- **The obligation to obtain a marketing authorisation for a medicinal product before being able to market the disputed product on German territory may be regarded as in accordance with the principle of proportionality only if it is actually necessary to safeguard public health**

In those circumstances, the obligation to obtain a marketing authorisation for a medicinal product before being able to market the disputed product on German territory may be regarded as in accordance with the principle of proportionality only if it is actually necessary to safeguard public health. Such a restriction on the free movement of goods must therefore necessarily be based on a detailed assessment of the risk alleged by the Member State invoking Article 30 EC (see, to that effect, Commission v Denmark, paragraph 47, and Commission v France, paragraph 54). In this case, the Federal Republic of Germany merely refers to its arguments on the risks to health which derive from the preparation concerned in order to justify the restriction on the free movement of goods.As was stated in paragraphs 73 to 75 of this judgment, it must be recalled, first, that those arguments relate principally to the effect of garlic taken as a foodstuff and not specifically to those of the product concerned and, second, that such risks arose in very specific circumstances. The generic reference made by the Federal Republic of Germany to the risks that taking garlic may have for health in very specific circumstances is not sufficient, as the Advocate General observed in point 79 of her Opinion, to justify a measure such as making the product subject to the particularly strict procedure for a marketing authorisation for a medicinal product. Furthermore, the Member State, instead of making the product concerned subject to such a procedure, could have prescribed suitable labelling warning consumers of the potential risks related to taking this product. The protection of public health would thus have been ensured without such serious restrictions on the free movement of goods (see, to that effect, Case C-17/93 van der Veldt [1994] ECR I-3537, paragraph 19). It follows from the foregoing considerations that the Federal Republic of Germany has failed to prove that the legislation at issue is necessary in order to protect consumer health and that it goes no further than is necessary in order to achieve that aim. The decision of that Member State does not therefore satisfy the principle of proportionality. It follows from

all the foregoing considerations that, by classifying as a medicinal product a garlic preparation in capsule form not satisfying the definition of a medicinal product within the meaning of Article 1(2) of Directive 2001/83, the Federal Republic of Germany has failed to fulfil its obligations under Article 28 EC and Article 30 EC.

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European Court of Justice, 15 November 2007
(P. Jann, R. Schintgen, A. Borg Barthet, M. Ilešič and E. Levits)
JUDGMENT OF THE COURT (First Chamber)
15 November 2007 (*)
(Failure of a Member State to fulfil its obligations – Article 28 EC and Article 30 EC – Directive 2001/83/EC – Garlic preparation in capsule form – Preparation legally marketed as a food supplement in a number of Member States – Preparation classified as a medicinal product in the Member State of importation – Definition of 'medicinal product' – Obstacle – Justification – Public health – Proportionality)
In Case C-319/05,
ACTION under Article 226 EC for failure to fulfil obligations, brought on 19 August 2005,
Commission of the European Communities, represented by B. Stromsky and B. Schima, acting as Agents, with an address for service in Luxembourg,
applicant,
v
Federal Republic of Germany, represented by M. Lumma and C. Schulze-Bahr, acting as Agents,
defendant,
THE COURT (First Chamber),
composed of P. Jann, President of the Chamber, R. Schintgen, A. Borg Barthet (Rapporteur), M. Ilešič and E. Levits, Judges,
Advocate General: V. Trstenjak,
Registrar: B. Fülöp, Administrator,
having regard to the written procedure and further to the hearing on 19 April 2007,
after hearing the **Opinion of the Advocate General** at the sitting on 21 June 2007,
gives the following
Judgment
1 By its application, the Commission of the European Communities seeks a declaration from the Court that, by classifying as a medicinal product a garlic preparation in capsule form which does not fall under the definition of a medicinal product by presentation, the Federal Republic of Germany has failed to fulfil its obligations under Articles 28 EC and 30 EC.
Legal background
Directive 2001/83/EC
2 The second to the fifth recitals in the preamble to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67) state:
'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.
(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.
(4) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations of substances which are foods, animal feedingstuffs or toilet preparations), and such disparities directly affect the functioning of the internal market.
(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.'
3 Under Article 1(2) of Directive 2001/83, 'medicinal product' must be construed as meaning:
'Any substance or combination of substances presented for treating or preventing disease in human beings.
Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product …'
4 Article 2 of Directive 2001/83 provides:
'The provisions of this Directive shall apply to industrially produced medicinal products for human use intended to be placed on the market in Member States.'
5 According to Article 6(1) of Directive 2001/83:
'No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EEC) No 2309/93.'
Directive 2002/46/EC
6 Under Article 2(a) of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ 2002 L 183, p. 51), 'food supplements' means:
'… foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities'.
7 Under Article 2(b) of Directive 2002/46, 'nutrients' means the following substances:
'(i) vitamins;
(ii) minerals'.
8 Article 11 of Directive 2002/46 provides:
'(1) Without prejudice to Article 4(7), Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Arti-

cle 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive.
(2) Without prejudice to the EC Treaty, in particular Articles 28 and 30 thereof, paragraph 1 shall not affect national provisions which are applicable in the absence of Community acts adopted under this Directive.'

Regulation (EC) No 178/2002

9 According to Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), 'food' (or 'foodstuff') means:
'… any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.
…'.

10 Article 14(7) to (9) of Regulation No 178/2002 provide:
'7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe in so far as the aspects covered by the specific Community provisions are concerned.
8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.
9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.'

Pre-litigation procedure

11 The Commission received a complaint from an undertaking whose application for authorisation to import and market a garlic preparation in capsule form was refused by the Federal Ministry for Health on the ground that the product was not a foodstuff but a medicinal product.

12 The product concerned is marketed under the designation 'garlic extract powder capsule'. According to the information provided by the parties, it is an extract obtained using ethanol and incorporated in an excipient (lactose) for the technological purpose of spray drying. Each capsule contains 370 mg of garlic powder extract with an allicin content of between 0.95% and 1.05%, which is the equivalent of 7.4 g of fresh raw garlic.

13 After a lengthy informal exchange, the Commission sent a letter before action of 24 July 2001 to the Federal Republic of Germany in which it concluded that the classification of the garlic preparation concerned as a medicinal product on the basis of a justification such as that put forward when the complaint was being investigated was not compatible with the principle of free movement of goods under Article 28 EC and Article 30 EC and the relevant case-law. The Federal Republic of Germany replied to the letter of formal notice on 5 October 2001.

14 In its reasoned opinion of 17 December 2002, the Commission called on the Federal Republic of Germany to put an end, within two months of receiving the reasoned opinion, to the administrative practices according to which products composed of dried garlic powder which are clearly not labelled or presented as medicinal products are treated as such.

15 Since the Federal Republic of Germany, in its response to the reasoned opinion, stated that the classification of the product concerned as a medicinal product had been re-examined and had to be maintained, the Commission decided to bring the present proceedings.

The action

Arguments of the parties

16 The Commission observes, first of all, that, in addition to protecting human health, the Community provisions relating to medicinal products are intended to safeguard the free movement of goods, so that the interpretation of the provisions of Directive 2001/83 in general and of the term medicinal product in particular cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health.

17 The Commission then submits that, in order to classify the product concerned as a medicinal product by virtue of its function, account must be taken not only of the pharmacological effects but also the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (Case C-60/89 Monteil and Samanni [1991] ECR I-1547, paragraph 29).

18 With regard to the pharmacological effects, the Commission does not dispute the fact that the product in question may serve to prevent arteriosclerosis, but points out that that effect may be achieved by taking a dose equivalent to 4 g of raw garlic each day. Therefore, where a product which is claimed to be a medicinal product does nothing more than a conventional foodstuff, it is clear that its pharmacological properties are insufficient for it to be accepted as a medicinal product. According to the Commission, a product which has no more effect on the body than a foodstuff has not reached the threshold above which it must be regarded as a medicinal product by function. In other words, substances which do not have a significant effect on the body and strictly speaking modify the way in which it functions cannot be treated as medicinal products.

19 The Commission takes the view that the product concerned might at best be regarded as a food supplement within the meaning of Article 2(a) of Directive 2002/46, that is to say as a foodstuff which is a concentrated source of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form. It states, nevertheless, that the attempt to deny that the product concerned is a

foodstuff certainly does not justify its classification as a medicinal product.

20 As regards the classification of a product as a medicinal product by virtue of its presentation, the Commission submits that that must be done on a case-by-case basis according to the specific characteristics of the product. A product might 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 (**Case C-369/88 Delattre [1991] ECR I-1487, paragraph 41**).

21 The Commission states that, in this case, the preparation is not presented or recommended for treating or preventing disease, either on the label, on the information printed on the packaging, or in any other way. Neither can the product's external packaging be regarded as typical of medicinal products. The capsule form is the only specific characteristic of the product that relates to medicinal products, although external form alone cannot be an exclusive and decisive indicator. No other element in this case indicates that the product is a medicinal product by virtue of its presentation. The Commission takes the view that consumers know exactly what is contained in the capsules, namely garlic, which they know as a foodstuff. Consumers can also see that the product does not make reference to any therapeutic effect.

22 Finally, the Commission states that it is possible for Member States, under national law, to submit a product which is not a medicinal product within the meaning of Directive 2001/83 to the rules applying to medicinal products provided, however, that the measures to safeguard public health are proportionate (see Case C-387/99 Commission v Germany [2004] ECR I-3751, paragraph 72). In this case, the Federal Republic of Germany has not provided evidence that the prohibition on marketing the product concerned as a food supplement and the obligation to obtain authorisation for medicinal products are actually necessary for the protection of public health.

23 For its part, the Federal Republic of Germany submits that only the provisions of Community law specific to medicinal products apply to a product which satisfies equally well the conditions for classification as a foodstuff and the conditions for classification as a medicinal product (**Joined Cases C and-211/03, C-299/03 and C-316/03 to C-318/03 HLH Warenvertrieb and Orthica [2005] ECR I-5141, paragraph 43**). It submits that, according to the case-law of the Court, the priority accorded to the regime governing medicinal products follows from Article 2, third paragraph, subparagraph (d) of Regulation No 178/2002 and from Article 1(2) of Directive 2002/46, which both exempt medicinal products from the scope of the rules on foodstuffs and on food supplements. That interpretation is also confirmed by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83 (OJ 2004 L 136, p. 34) which inserts into Directive 2001/83 a new version of Article 2, according to paragraph 2 of which, in cases of doubt, where a product is also covered by other Community legislation – such as the rules governing foodstuffs – it is always the provisions of Directive 2001/83 that apply.

24 The Federal Republic of Germany submits that the garlic preparation in question is a medicinal product by function, primarily because it has pharmacological properties to which considerable importance is attached. In order to determine those pharmacological properties, the Federal Republic of Germany states that it is not only the effects of that preparation on health in general which is important, but also its pharmacological effectiveness (**Case C-112/89 Upjohn [1991] ECR I-1703, paragraph 17**). In this case, the product in question has therapeutic effects which prevent lesions occurring in the human body, and more specifically prevents arteriosclerosis. The Federal Republic of Germany relies on several studies and scientific reports in support of its argument.

25 In answer to the Commission's argument that the effects of the preparation concerned on arteriosclerosis are limited, the Federal Republic of Germany states that neither Directive 2001/83 nor the case-law of the Court indicates a 'materiality threshold' according to which a specific level of pharmacological effects has to be proven. Therefore, if pharmacological effectiveness is accepted in this case, it is irrelevant whether there is a slight or material reduction in the risk of arteriosclerosis.

26 The Federal Republic of Germany also submits that the origin of the substances cannot be decisive in order to define a medicinal product, and states that the Court has held that vitamins in a particular form and in high doses could be classified as medicinal products (see **Case 227/82 van Bennekom [1983] ECR 3883, paragraph 27**, and Commission v Germany, paragraph 56). The fact that vitamins also occur in many foodstuffs thus does not prevent their classification as medicinal products. The same must apply to garlic and allicin, the active substance contained in it. Therefore, it is ultimately irrelevant whether or not an active substance with pharmacological properties also occurs in a foodstuff.

27 The preparation concerned also has pharmacological properties that could cause health risks if taken (see Commission v Germany, paragraph 82). The fact that the consumption of certain other foodstuffs may also have negative effects on health cannot call into question the status of medicinal product. The Federal Republic of Germany states, however, that it is above all the pharmacological and/or therapeutic effects which play a crucial role.

28 With regard to the methods of use, the Federal Republic of Germany states that the fact that the product concerned is offered for sale in capsule form also

suggests that it should be classified as a medicinal product by function.

29 As to the definition of medicinal products by presentation, the Federal Republic of Germany submits that a product may be regarded as such if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product.

30 In this case the form of capsule used suggests that it is intended to be marketed as a medicinal product, although the Federal Republic of Germany accepts that the external form alone cannot be a decisive indicator for classification as a medicinal product (see Delattre, paragraph 38).

31 Furthermore, the Federal Republic of Germany points out that there are a large number of medicinal products containing active substances such as garlic bulb powder or oil on the German market, packaged in exactly the same way as the preparation concerned. The fact that they are all classified as medicinal products leans, according to commercial usage and consumer expectations, in favour of classification of the product in question as a medicinal product by virtue of its presentation.

32 The Federal Republic of Germany also infers from the case-law of the Court that the national authorities have a broad discretion when deciding classification (see HLH Warenvertrieb and Orthica, paragraph 56). The Commission has not satisfied the burden of proof as it has not established that the exercise of discretion by the German authorities in classifying the preparation concerned as a medicinal product was defective.

33 Alternatively, the Federal Republic of Germany states that in the event that the Court takes the view that the principle of free movement of goods is applicable and considers the classification of the product in question as a medicinal product to be a restriction on that principle, the decision is justified in any event in order to protect an overriding public interest, namely the protection of public health.

Findings of the Court

34 It is clear from Articles 2 and 6(1) of Directive 2001/83 that no industrially produced medicinal product may be placed on the market in a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State or an authorisation has been granted in accordance with Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1).

35 It follows that if a product produced industrially comes within the definition of medicinal product in Article 1(2) of Directive 2001/83, the obligation on the importer of that product to obtain a marketing authorisation in accordance with that directive prior to marketing it in the Member State of importation cannot in any event constitute a restriction on trade between Member States prohibited by Article 28 EC (see, to that effect, Case C-150/00 Commission v Austria [2003] ECR I-3887, paragraph 57).

36 Furthermore, although the essential purpose of Directive 2001/83 is to remove obstacles to trade in medicinal products within the Community, and although for that purpose Article 1 gives a definition of medicinal products, it nevertheless constitutes merely a first stage in the harmonisation of national legislation on the production and distribution of such products (see, to that effect, Commission v Austria, paragraph 58).

37 In those circumstances, so long as harmonisation of the measures necessary to ensure the protection of health is not more complete, it is difficult to avoid the existence of differences in the classification of products as medicinal products or foodstuffs between Member States. Thus, the fact that a product is classified as a foodstuff in another Member State cannot prevent it from being classified as a medicinal product in the Member State of importation, if it displays the characteristics of such a product (see HLH Warenvertrieb and Orthica, paragraph 56).

38 The fact remains that a product which satisfies the definition of 'medicinal product' within the meaning of Directive 2001/83 must be held to be a medicinal product and be made subject to the corresponding rules even if it comes within the scope of other, less stringent Community rules (see, to that effect, Case C-219/91 Ter Voort [1992] I-5485, paragraph 19 and the case-law cited).

39 In those circumstances it is appropriate to determine, first of all, whether the product concerned is a medicinal product within the meaning of Directive 2001/83.

40 Under the first subparagraph of Article 1(2) of Directive 2001/83, a medicinal product is '[a]ny substance or combination of substances presented for treating or preventing disease in human beings', and according to the second subparagraph thereof, '[a]ny substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings' is likewise to be considered a medicinal product.

41 The directive thus gives two definitions of medicinal product, one 'by presentation' and one 'by function'. A product is a medicinal product if it falls within either of those definitions (HLH Warenvertrieb and Orthica, paragraph 49).

42 In that connection, it must be observed that although the Commission expressly refers to the definition of medicinal product by presentation in its arguments, it makes no reference to the definition of medicinal product by function. In the grounds of its application, however, and throughout the pre-litigation procedure, the Commission formulated arguments relating to those definitions. In its defence, both in the pre-litigation procedure and in these proceedings, the Federal Republic of Germany also put forward arguments regarding those two definitions. Therefore, the Commission's application must be interpreted as deny-

ing the product the status of both medicinal product by presentation and medicinal product by function.

The definition of medicinal product by presentation

43 According to settled case-law, the term 'presentation' of a product must be interpreted broadly. It must be recalled, in that connection, that by basing its arguments on the criterion of the 'presentation' of the product, Directive 2001/83 intends to cover not only medicinal products having a genuine therapeutic or medical effect, but also those which are not sufficiently effective or do not have the effect which consumers would be entitled to expect from the way in which they are presented. The directive thereby intends to protect the consumer not only from harmful or toxic medicinal products, but also from a variety of products used instead of the proper remedies (van Bennekom, paragraph 17).

44 In that context, a product is 'presented for treating or preventing disease' within the meaning of Directive 2001/83 when it is expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation (see, to that effect, van Bennekom, paragraph 18, and Monteil and Samanni, paragraph 23).

45 In this case, it is clear from the file that the preparation concerned is not indicated or recommended as a product for treating or preventing disease, whether on the label, the information printed on the external packaging, or in any other way.

46 A product is also 'presented for treating or preventing disease' 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, having regard to its presentation, have the properties in question (see, to that effect, van Bennekom, paragraph 18, and Monteil and Samanni, paragraph 23).

47 In that regard, 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 proprietary medicinal products, having regard to the safeguards normally associated with their manufacture and marketing. Although the external form given to the product may serve as strong evidence of its classification as a medicinal product by presentation, the 'form' must be taken to mean not only the form of the product itself but also that of its packaging, which may, for reasons of marketing policy, tend to make it resemble a medicinal product (see, to that effect, van Bennekom, paragraph 19, and Monteil and Samanni, paragraph 24).

48 According to the information submitted to the Court, the product concerned is a garlic powder extract marketed in capsule form. On the product's external packaging there is, inter alia, a photograph of a head of garlic next to which are two capsules.

49 In that connection, the fact, relied on by the Federal Republic of Germany, that there are a large number of products containing active substances such as garlic bulb powder or oil on the German market, packaged in a similar manner to the product concerned and classified as medicinal products, is not sufficient to confer on that product the status of a medicinal product by presentation. The Federal Republic of Germany has not provided any specific evidence in support of that argument.

50 In those circumstances, taking account of the information before the Court, it must be held that no aspect of its packaging tends to make the product concerned resemble a medicinal product other than the photograph or of a head of garlic on the product's external packaging, as such an image also features on a number of products marketed as medicinal products in Germany. The photograph of a plant on the external packaging of a product is not, however, sufficient to inspire in a reasonably well-informed consumer confidence like that usually inspired by medicinal products.

51 Therefore, presentation in capsule form is the only aspect likely to suggest classification of the product as a medicinal product by presentation.

52 However, it must be recalled that, according to settle case-law, the external form given to a product, although it may serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product, cannot be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to medicinal products would also be covered (see, to that effect, van Bennekom, paragraph 19, and Delattre, paragraph 38).

53 As the Advocate General noted, in point 51 of her Opinion, the capsule form is not exclusive to medicinal products. A large number of foodstuffs are in fact offered for sale in that form in order to facilitate their ingestion by consumers. In that connection, it must be observed that Article 2(a) of Directive 2002/46 expressly refers, among the criteria used to define 'food supplement', to its presentation in capsule form. Consequently, that evidence alone is not sufficient to confer the status of medicinal product by presentation on the product concerned.

54 In those circumstances, it must be held that the product concerned does not satisfy the criteria laid down in the first paragraph of Article 1(2) of Directive 2001/83. Therefore it cannot be classified as a medicinal product by presentation within the meaning of that directive.

Definition of medicinal product by function

55 For the purposes of determining whether a product falls within the definition of a medicinal product by function within the meaning of Directive 2001/83, the national authorities, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (HLH Warenvertrieb and Orthica, paragraph 51).

56 In this case, in order to justify the classification of the product concerned as a medicinal product by

function, the Federal Republic of Germany relies essentially on its allicin content, its effect on blood pressure and lipid levels, the capsule form used and the risks related to its ingestion.

57 It is apparent from the file that the product in question is a garlic powder extract, the allicin content of which is between 0.95% and 1.05%, each capsule containing the equivalent of 7.4 g of fresh raw garlic. Allicin, the principal active ingredient, which is obtained from crushed garlic, is the result of the transformation of alliin, an amino acid naturally present in garlic, when it is mixed with the natural enzyme allinase.

58 Therefore, it must be held that, apart from the excipient into which the garlic extract was incorporated before being powdered, the product concerned is obtained entirely from garlic, and does not contain any substance which is not itself in garlic in its natural state.

59 The pharmacological properties of a product are the factor on the basis of which it must be ascertained, in the light of the potential capacities of the product, whether it may, for the purposes of the second subparagraph of Article 1(2) of Directive 2001/83, be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings (HLH Warenvertrieb and Orthica, paragraph 52).

60 Although, as the Advocate General observed in paragraph 58 of her Opinion, that definition is broad enough to include products which, although they are capable of having an effect on bodily functions have in fact another purpose, that criterion must not lead to the classification as a medicinal product by function of substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions (Upjohn, paragraph 22).

61 Contrary to the definition of medicinal product by presentation, whose broad interpretation is intended to protect consumers from products which do not have the effectiveness they are entitled to expect, the definition of medicinal product by function is designed to cover products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions.

62 Such an interpretation is in accordance with the aims of Directive 2001/83 which, as is clear from the second to the fifth recitals in the preamble, seeks to reconcile the aim of protection of public health with the principle of free movement of goods.

63 Furthermore, although only the provisions of Community law specific to medicinal products apply to a product which satisfies the conditions for classification a medicinal product, even if it comes within the scope of other, less stringent Community rules (see, to that effect, Delattre, paragraph 22, Monteil and Samanni, paragraph 17, Ter Voort, paragraph 19, and HLH Warenvertrieb and Orthica, paragraph 43), it must be stated, as is shown by a reading of Article 1(2) of Directive 2001/83 in conjunction with Article 2 of Directive 2002/46, that the physiological effect is not specific to medicinal products but is also among the criteria used for the definition of food supplements.

64 In those circumstances, and in order to preserve the effectiveness of that criterion, it is not sufficient that product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease.

65 That statement is even more relevant in the case of products which, in addition to being food supplements, are recognised as having beneficial effects on health. As the Advocate General observed, in point 60 of her Opinion, there are many products generally recognised as foodstuffs which may also serve therapeutic purposes. That fact is not sufficient however to confer on them the status of medicinal product within the meaning of Directive 2001/83.

66 In this case, the Federal Republic of Germany does not dispute that the physiological effects that it relies on, essentially with respect to the prevention of arteriosclerosis, may also be obtained by ingesting 7.4 g of garlic as a foodstuff. It is significant in that regard that the fact that the studies on which the Federal Republic of Germany bases its arguments relate both to the potential effects of ingesting garlic preparations in the form of capsules, powders or solutions, and to the potential effects of consuming garlic in its natural state.

67 It is also common ground that the disputed product does not have any additional effects as compared to those which derive from the consumption of garlic in its natural state and, as the Advocate General observed in point 62 of her Opinion, those effects should not be regarded as any greater than, or different from, those of other vegetable or animal products which are taken as part of the daily diet.

68 In those circumstances, it must be held that the product concerned, whose effect on physiological functions is no more than the effects of a foodstuff consumed in a reasonable quantity may have on those functions, does not have a significant effect on the metabolism and cannot, therefore, be classified as a products capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83.

69 Finally, and contrary to the Federal Republic of Germany's submissions, the fact that ingesting the product concerned could give rise to risks to health is not an indication that it is pharmacologically effective. It is clear from the case-law that the risk to health, although it must be taken into consideration in the classification of a product as a medicinal product by function, is none the less an autonomous factor (HLH Warenvertrieb and Orthica, paragraph 53).

70 The assessment of the potential risks related to the use of the product concerned must be undertaken in the context of Directive 2001/83 and in the light of the principles of Community law in general.

71 As the Commission has observed, the Community provisions relating to medicinal products must ensure, in addition to the protection of human health,

the free movement of goods, so that the interpretation of the provisions of Directive 2001/83 in general, and the definition of medicinal products in particular, cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health.

72 In this case, the Federal Republic of Germany cites cases of spontaneous post-operative bleeding occurring after excessive consumption of garlic as a foodstuff or in the form of a preparation, the suppression of the effects of certain anti-retroviral drugs and an interaction with some anticoagulants.

73 In that connection, it must be observed, first of all, that those risks arise from the absorption of garlic in general and not specifically from the ingestion of the disputed preparation.

74 Furthermore, it is clear from the examples cited by the Federal Republic of Germany that it is only the interaction with certain medicinal products or excessive intake of garlic or a garlic preparation in specific circumstances such as an operation that risks to health may arise.

75 As the Advocate General observed in point 65 of her Opinion, it is clear from those examples that the risks and contra-indications related to taking garlic preparations mentioned are limited and, more importantly, are no different from those linked to taking garlic as a foodstuff.

76 As regards the criterion for the method of use of the product concerned, it cannot be decisive in this case for the reasons set out in paragraph 53 of this judgment.

77 In those circumstances, it must be held, having regard to all its characteristics, that the product concerned cannot be classified as a medicinal product by function within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83.

78 It is clear from all the foregoing that the product concerned does not satisfy either the definition of medicinal product by presentation or the definition of medicinal product by function. Therefore, it cannot be classified as a medicinal product within the meaning of Directive 2001/83.

Infringement of Article 28 EC and Article 30 EC

79 It is now appropriate to ascertain whether, as the Commission submits, the requirement for a marketing authorisation as a medicinal product, as it appears from the decision taken by the Federal Republic of Germany, is a measure having equivalent effect to a quantitative restriction on imports prohibited by Article 28 EC.

80 The prohibition on measures having equivalent effect to quantitative restrictions, set out in Article 28 EC, covers all measures which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade (see, in particular, Case 8/74 Dassonville [1974] ECR 837, paragraph 5, and Commission v Austria, paragraph 81).

81 In this case, the Federal Republic of Germany's decision creates an obstacle to intra-Community trade in so far as the products concerned, legally marketed in other Member State as a foodstuff, can be marketed in Germany only after having been subjected to the authorisation procedure for the placing on the market of a medicinal product.

82 In that connection, the Federal Republic of Germany submits that its decision is justified by reasons relating to the protection of public health, in accordance with Article 30 EC.

83 Whilst Article 30 EC allows the maintenance of restrictions on the free movement of goods justified on grounds of the protection of the health and life of humans, which are fundamental requirements recognised by Community law, it must be recalled that that provision cannot be applied where Community directives provide for harmonisation of the measures necessary to achieve the specific objective which would be furthered by reliance upon it (see, to that effect, Case C-102/96 Commission v Germany [1998] ECR I-6871, paragraph 21).

84 In this case, it is not necessary to examine whether the product concerned may be classified as a food supplement within the meaning of Article 2 of Directive 2002/46 or as a foodstuff within the meaning of Article 2 of Regulation No 178/2002. It is sufficient to hold that, according to Article 11(2) of Directive 2002/46 and Article 14(9) of Regulation No 178/2002, in the absence of specific Community rules laid down in those provisions, national rules may be applied without prejudice to the provisions of the Treaty.

85 In those circumstances, it is appropriate to ascertain whether the German practice concerned may be justified on the basis of Article 30 EC.

86 In that connection, it must be recalled that it is for the Member States, in the absence of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research, to decide on their intended level of protection of human health and life and on whether to require prior authorisation for the marketing of foodstuffs, always taking into account the requirements of the free movement of goods within the Community (Case 174/82 Sandoz [1983] ECR 2445, paragraph 16; **van Bennekom, paragraph 37**; and Joined Cases C-158/04 and C-159/04 Alfa Vita Vassilipoulos and Carrefour-Marinopoulos [2006] ECR I-8135, paragraph 21).

87 However, in exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health; they must be proportional to the objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade (see Sandoz, paragraph 18, van Bennekom, paragraph 39; Case C-192/01 Commission v Denmark [2003] ECR I-9693, paragraph 45; and Case C-24/00 Commission v France [2004] ECR I-1277, paragraph 52).

88 Furthermore, since Article 30 EC provides for an exception, to be interpreted strictly, to the rule of free movement of goods within the Community, it is for the national authorities which invoke it to show in each case, in the light of national nutritional habits and

in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk for public health (Sandoz, paragraph 22; van Bennekom, paragraph 40; Commission v Denmark, paragraph 46; and Commission v France, paragraph 53).

89 Although, as was noted in paragraph 86 of this judgment, Community law does not, in principle, preclude a system of prior authorisation, it must however be stated that the issue of a marketing authorisation under Article 8 of Directive 2001/83 is subject to particularly strict requirements.

90 In those circumstances, the obligation to obtain a marketing authorisation for a medicinal product before being able to market the disputed product on German territory may be regarded as in accordance with the principle of proportionality only if it is actually necessary to safeguard public health.

91 Such a restriction on the free movement of goods must therefore necessarily be based on a detailed assessment of the risk alleged by the Member State invoking Article 30 EC (see, to that effect, Commission v Denmark, paragraph 47, and Commission v France, paragraph 54).

92 In this case, the Federal Republic of Germany merely refers to its arguments on the risks to health which derive from the preparation concerned in order to justify the restriction on the free movement of goods.

93 As was stated in paragraphs 73 to 75 of this judgment, it must be recalled, first, that those arguments relate principally to the effect of garlic taken as a foodstuff and not specifically to those of the product concerned and, second, that such risks arose in very specific circumstances.

94 The generic reference made by the Federal Republic of Germany to the risks that taking garlic may have for health in very specific circumstances is not sufficient, as the Advocate General observed in point 79 of her Opinion, to justify a measure such as making the product subject to the particularly strict procedure for a marketing authorisation for a medicinal product.

95 Furthermore, the Member State, instead of making the product concerned subject to such a procedure, could have prescribed suitable labelling warning consumers of the potential risks related to taking this product. The protection of public health would thus have been ensured without such serious restrictions on the free movement of goods (see, to that effect, Case C-17/93 van der Veldt [1994] ECR I-3537, paragraph 19).

96 It follows from the foregoing considerations that the Federal Republic of Germany has failed to prove that the legislation at issue is necessary in order to protect consumer health and that it goes no further than is necessary in order to achieve that aim. The decision of that Member State does not therefore satisfy the principle of proportionality.

97 It follows from all the foregoing considerations that, by classifying as a medicinal product a garlic preparation in capsule form not satisfying the definition of a medicinal product within the meaning of Article 1(2) of Directive 2001/83, the Federal Republic of Germany has failed to fulfil its obligations under Article 28 EC and Article 30 EC.

Costs

98 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the Federal Republic of Germany has been unsuccessful, the latter must be ordered to pay the costs.

On those grounds,

the Court (First Chamber)

hereby:

1. Declares that, by classifying as a medicinal product a garlic preparation in capsule form not satisfying the definition of a medicinal product within the meaning of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, the Federal Republic of Germany has failed to fulfil its obligations under Article 28 EC and Article 30 EC;

2. Orders the Federal Republic of Germany to pay the costs.

OPINION OF ADVOCATE GENERAL
TRSTENJAK
delivered on 21 June 2007 1(1)
Case C-319/05
Commission of the European Communities
v
Federal Republic of Germany
(Failure of a Member State to fulfil obligations – Article 226 EC – Free movement of goods – Measures having equivalent effect – Directive 2001/83/EC – Meaning of the term 'medicinal product' – National administrative practice according to which a garlic preparation in capsule form is classified as a medicinal product)

I – Introduction

1. The present case is based on an action for failure to fulfil obligations brought by the Commission pursuant to Article 226 EC against the Federal Republic of Germany, by which it asks the Court of Justice to declare that by classifying as a medicinal product a garlic preparation in capsule form which does not fall under the definition of a medicinal product by presentation under Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, (2) the Federal Republic of Germany has failed to fulfil its obligations under Articles 28 and 30 EC.

2. The dispute thus hinges on whether the garlic preparation in question falls under that definition or whether it is to be regarded as a food supplement within the meaning of Article 2(a) of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the

laws of the Member States relating to food supplements. (3)

II – Legal framework

1. Primary Community law

3. Article 28 EC prohibits quantitative restrictions on imports between Member States and all measures having equivalent effect.

4. Under Article 30 EC, prohibitions or restrictions on imports are permitted where they are justified on grounds of public security and the protection of health and life of humans, provided they neither constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

2. Directive 2001/83/EC

5. Recitals 2 to 5 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use state:

'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

(4) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations of substances which are foods, animal feedingstuffs or toilet preparations), and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.'

6. Under Article 1(2) of Directive 2001/83/EC, medicinal products means:

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

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.'

7. Article 6(1) of that directive provides:

'No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EEC) No 2309/93.'

3. Directive 2002/46/EC

8. Under Article 2(a) of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, food supplements are:

'foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities'.

III – Pre-litigation procedure

9. The Commission took action following a complaint lodged by an undertaking whose application pursuant to Paragraph 47a of the Law on foodstuffs and consumer products (Lebensmittel- und Bedarfsgegenständegesetz; the 'LMBG') for the adoption of a decision of general application on the importation and marketing of a garlic preparation in capsule form was refused by the Federal Ministry of Health on the ground that the product was not a foodstuff, but a medicinal product.

10. The product in question is marketed under the designation 'Knoblauch-Extrakt-Pulver-Kapsel' ('garlic extract powder capsule') or 'Knoblauch-Zwiebel-Pulver' ('garlic bulb powder'). According to the information available to the Court, it is an extract obtained using ethanol, which is cultivated on a medium (lactose) for the technological purpose of spray drying. The product is composed of carbohydrates, proteins and fats, as well as trace elements and vitamins.

11. After a lengthy informal exchange, on 24 July 2001 the Commission sent a letter of formal notice to the Federal Republic of Germany in which it concluded that the classification of garlic bulb powder in capsule form as a medicinal product on grounds such as those chosen in the case of the complaint is incompatible with the principles of the free movement of goods under Article 28 EC and Article 30 EC and the relevant case-law. The German Government replied to the letter of formal notice on 5 October 2001.

12. In its reasoned opinion of 19 December 2002, the Commission called on the Federal Republic of Germany to put an end to the administrative practice according to which products which consist of dried powdered garlic and which are clearly not labelled or presented as medicinal products are treated as medicinal products.

13. The Federal Government replied by letter of 14 March 2003. It reported that the classification of the product in question as a medicinal product had been re-examined and had to be maintained.

IV – Proceedings before the Court of Justice and forms of order sought by the parties

14. In its application, which was lodged at the Court Registry on 19 August 2005, the Commission claims that the Court should declare that by classifying as a medicinal product a garlic preparation in capsule form which does not fall under the definition of a medicinal product by presentation under Article 1(2) of Directive 2001/83, the Federal Republic of Germany has failed to fulfil its obligations under Articles 28 and 30 EC. It also claims that the Court should order the Federal Republic of Germany to pay the costs.

15. In its defence, lodged on 11 November 2005, the German Government claims that the Court should dis-

miss the action as unfounded and order the Commission to pay the costs.

16. The written phase of the proceedings concluded following submission of the reply on 3 February 2006 and the rejoinder on 7 April 2006.

17. At the hearing, held on 19 April 2007, the representatives of the Commission and of the Federal Republic of Germany confirmed their respective positions.

V – Submissions of the parties

18. The Commission points out, first of all, that, in addition to protecting human health, the Community rules on medicinal products are intended to safeguard free movement of goods, with the result that the interpretation of the rules contained in the directive in general and of the term 'medicinal product' in particular cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health.

19. As regards the question of classification as a medicinal product by function, in addition to the pharmacological effects of the product in question, consideration must also be given to the methods for use, the extent of dissemination, awareness among consumers and the risks that might be associated with usage.

20. With regard to pharmacological effects, the Commission does not dispute that the product in question may serve to prevent arteriosclerosis, although the same effect could be achieved simply by taking four grams of raw garlic each day. If a product which is claimed to be a medicinal product does nothing more than a conventional foodstuff, this shows that its pharmacological properties are not sufficient for it to be accepted as a medicinal product. According to the Commission, a product that has no further effects does not go far enough to be a medicinal product by function.

21. The product could at most be a food supplement within the meaning of Article 2(a) of Directive 2002/46, that is to say a foodstuff which contains substances with a nutritional or physiological effect, alone or in combination, marketed in dose form. Nevertheless, the attempt to deny that the products in question are foodstuffs certainly does not justify their classification as medicinal products.

22. With regard to the classification of a product as a medicinal product by presentation, this question must be clarified on a case-by-case basis, having regard to the specific characteristics of the product. A product may be regarded as a medicinal product by 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, but it is not in itself conclusive.

23. In the present case, the product is not presented or recommended for treating or preventing disease either on the label, on the information printed on the packaging, or in any other way. The external packaging of the product cannot be regarded as typical of medicinal products. The capsule form is the only specific characteristic of the product that relates to medicinal products. However, this external form alone cannot be a decisive indicator. In other respects too, there is nothing in the present case to suggest that the product is a medicinal product by presentation. Consumers know exactly what is contained in the capsules, namely garlic, which they know as a foodstuff. They can also see that the product does not make reference to any therapeutic effect.

24. Lastly, whilst Member States cannot be prevented, in their national law, from making a product which is not a medicinal product within the meaning of Directive 2001/83 subject to the rules applying to medicinal products, the measures to safeguard public health must be proportionate. In the present case, however, the German authorities have not shown that the prohibition on marketing the product in question as a food supplement and the obligation to obtain a marketing authorisation for medicinal products are actually necessary for the protection of the health of the population.

25. The German Government claims that Community law provides that the regime governing medicinal products takes priority over the provisions on foodstuffs and food supplements. According to the case-law of the Court of Justice, the priority accorded to the regime governing medicinal products follows from Article 2, third paragraph, (d) of Regulation No 178/2002 and from Article 1(2) of Directive 2002/46, which both exempt medicinal products from the scope of the rules on foodstuffs and on food supplements. (4) That interpretation is confirmed by Directive 2004/27/EC, by which a revised Article 2 was inserted into Directive 2001/83, under paragraph 2 of which, in cases of doubt, where a product is also covered by other Community legislation – such as the rules governing foodstuffs – the provisions of the directive on medicinal products apply.

26. It then takes the view that the garlic preparation in question is a medicinal product by function, primarily because it has pharmacological properties to which considerable importance is attached. The product in the present case has therapeutic effects which prevent pathological changes in the human body and in particular prevent arteriosclerosis. In support of its view, the German Government relies on various reports and scientific articles.

27. With regard to the Commission's argument that the effects of the preparation on arteriosclerosis are limited, the Federal Government states that neither the directive on medicinal products nor the case-law of the Court of Justice indicates a 'materiality threshold' beyond which a specific level of pharmacological effects has to be proven. If, then, the pharmacological effectiveness is taken to exist, it is irrelevant whether there

is a slight or material reduction in the risk of arteriosclerosis.

28. Classification as a medicinal product cannot depend on the origin of the substances and the Court has ruled that in certain large doses vitamins may be classified as medicinal products. (5) The fact that vitamins also occur in many foodstuffs thus does not prevent their classification as medicinal products. The same must apply to garlic and to allicin, the active substance contained in it. It is therefore ultimately irrelevant whether or not an active substance with pharmacological properties also occurs in a foodstuff.

29. The preparation at issue also has pharmacological properties because it could cause health risks if taken. The fact that the consumption of certain other foodstuffs may also have negative effects on health nevertheless cannot call into question their status as medicinal products. Above all, however, the pharmacological and therapeutic effects play a crucial role.

30. With regard to the methods for use, the German Government claims that the fact that the product in question is offered for sale in capsule form essentially suggests that it is a functional medicinal product. The Federal Government states that a product may be regarded as a medicinal product by presentation if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product. In the present case the capsule form used suggests that it is intended to be marketed as a medicinal product even if the external form alone cannot be a decisive indicator for classification as a medicinal product.

31. Furthermore, there are numerous medicinal products with active substances such as garlic bulb powder on the market in Germany which are packaged in exactly the same way as the preparation at issue in the main proceedings. The fact that they are all classified as medicinal products suggests that, according to the established view and consumer expectations, the comparable product at issue is also a medicinal product by presentation.

32. The German Government also infers from the Court's case-law that in deciding on the classification of the product the national authorities have a broad discretion. (6) The Commission has not satisfied the burden of proof on it and cannot show that the exercise of discretion by the German authority, according to which the preparation is to be classified as a medicinal product, has been defective.

33. In the alternative, the Federal Republic of Germany claims, in the event that the Court takes the view that free movement of goods is applicable and considers the classification decision to be a restriction, that the decision was justified in order to protect an overriding public interest, namely to safeguard public health.

VI – Legal assessment

1. Introductory remarks

a) Harmonisation as a result of a balancing act by the legislature

34. The term 'medicinal product' does not appear in the EC Treaty. Nevertheless, the law governing medicinal products is governed and regulated to a considerable extent by Community law. EC law on medicinal products – like Community law on foodstuffs – was developed on the basis of the rules governing the free movement of goods. Medicinal products are included among the goods which form part of trade between Member States. However, they are products which, because of fundamental health dangers, require extraordinary precautions to be taken to guarantee the safety of the population. (7)

35. These measures are taken by the Member States, according to the modern view, as part of the State duty to protect health in pursuance of a fundamental State duty to provide protection. However, as long as and in so far as there are different national views on the necessary degree of protection and the appropriate methods for providing the level of safety, such rules are barriers to trade and thus almost classic cases of measures having equivalent effect to quantitative restrictions on imports within the meaning of Article 28 EC. (8) Under Article 30 EC they are justified only if they serve actual grounds of protection of health and are proportionate.

36. However, the harmonisation of the law on medicinal products at Community level is intended to remove precisely those justified barriers to trade with a view to establishing a single market as an area without internal borders. That aim is served by the secondary legislation, based first on Article 94 EC, then on Article 95 EC, to approximate national law on medicinal products, whereby, initially, terms such as medicinal product were defined for the purposes of Community law, the necessary material safety standards were approximated, and measures were taken in relation to the labelling of medicinal products and the facilitation and guaranteeing of the mutual recognition of national measures in the field of the law on medicinal products. A qualitatively new step was taken with the establishment of the uniform Community authorisation procedure. (9)

37. Harmonisation is carried out above all by means of directives which, according to the objective of Community law on medicinal products, essentially seek to safeguard public health. (10) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community. (11) The objectives of protection of health and free movement of goods are therefore both to be attained and must therefore be balanced. (12) Accordingly, harmonising directive 2001/83 should be regarded as the result of a balancing act by the legislature involving two Community objectives.

b) The meaning of the term 'medicinal product' under Community law

38. The Community legislature is free, within the limits laid down by the Treaty, to determine the extent of harmonisation. Full harmonisation of certain areas of the law on medicinal products therefore does not leave any room for separate national measures. With full harmonisation, the definition of 'medicinal product' in Article 1(2) of Directive 2001/83 is to be regarded as exhaustive, with the result that in describing products

as 'medicinal products' the Member States are bound by that definition. (13) The competent national administrative authorities are therefore forbidden to bring products within the definition of medicinal products if, on the basis of objective criteria, they are not such products. (14)

39. If, however, the adoption of a decision of general application on the importation and marketing of a product is refused on the ground that it constitutes a medicinal product, even though the elements of the definition of medicinal product under Community law are not satisfied, that official action must be regarded as a failure to comply with the prescribed definition and thus an infringement of Community law in so far as that official action is based on an administrative practice. (15) Such an infringement inevitably gives rise to national liability on the part of the Member State in question.

40. In the present case, the Commission's complaint is directed against an administrative practice on the part of the German authorities whereby products which consist of dried powdered garlic are treated as medicinal products.

41. The definition of 'medicinal product' under Directive 2001/83, just like the old definition in Directive 65/65/EEC, consists of two parts. A substance is a medicinal product if it is presented for treating or preventing disease in human beings (definition 'by presentation'). It is also to be regarded as a medicinal product if it may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings (definition 'by function'). A product is a medicinal product under Community law if it comes within one or other of those two definitions.

42. It should be noted in this connection that I expressly concur with the restrictive interpretation of the term 'medicinal product' under Directive 2001/83 advocated by Advocate General Geelhoed in his Opinion in HLH Warenvertrieb and Orthica. (16)

3. As Advocate General Geelhoed rightly argues in point 36 of his Opinion in HLH Warenvertrieb and Orthica, there are three objections to too broad an interpretation and application of the definition of medicinal product. First of all, the concept of 'medicinal product' would cease to have any differentiating effect if it were to include products whose properties and action did not justify their being classified as such. This would harm rather than serve the interests of human health. Secondly, it could result in the specific Community regulations for certain categories of food – containing provisions relating to the particular risks of the products – losing their regulatory object, like, in this case, Directive 2002/46 on food supplements. Thirdly, a 'stealthy' extension of the scope of Directive 2001/83 to include extraneous products would be detrimental to the free movement of goods.

44. Indications of a more restrictive interpretation of the term 'medicinal product' can be seen in the case-law. On the one hand, there is agreement that the legislation for medicinal products must be more stringent than for foodstuffs because particular dangers may be associated with their use. (17) On the other hand, the Court requires, for a product to be classified as a medicinal product, that there must be sufficient certainty that products which are claimed to have an effect as a medicinal product actually have that effect. (18) Logically, the existence of both the particular dangers and the effect as a medicinal product must be examined using information based on sound scientific research.

45. In my opinion, these considerations must be taken into account in the legal examination of the question, which is relevant to the present action for failure to fulfil obligations, whether the contested garlic preparation satisfies the criteria for classification of a product as a medicinal product, i.e. whether the classification made by the Federal Ministry of Health is consistent with Community law.

46. With regard to the possible limits of the judicial review of decisions of national authorities by the Court of Justice, it must be pointed out that under Community law the authorities concerned must enjoy a wide measure of discretion in performing duties which call for technical and scientific analyses. The Court concluded from this fact that the decision-making freedom of national authorities is subject only to a limited judicial review. In particular, the Community judicature may not substitute its assessment of the facts for that made by the authority in question. At the same time, however, the Court stressed that it had the tasks of examining the accuracy of the findings of fact and law made by that authority. (19) As a result, it is entirely within the power of the Community Courts, in an action for failure to fulfil obligations like the present case, to examine whether the elements of the definition of the term 'medicinal product' are satisfied in the individual case. It must therefore be examined below whether the garlic preparation at issue is a medicinal product within the meaning of the first subparagraph of Article 1(2) of Directive 2001/83.

47. Let me point out, moreover, that, as the Court has consistently held in proceedings under Article 226 EC, it is for the Commission to prove an alleged infringement of Community law. (20) In this case, therefore, it is primarily for the Commission to demonstrate and establish that the German Government misapplied Directive 2001/83, notwithstanding the discretion conferred on it, by wrongly treating the garlic preparation in question as a medicinal product. Of course, this does not preclude the Member State concerned from having to cooperate in the production of evidence by plausibly demonstrating, as the Court has stated in its case-law, on the basis of the results of international scientific research, that a given product is a medicinal product for the purposes of Directive 2001/83. (21) If the Commission wishes to contest the data furnished by the Member State, it must do so on the basis of equally reliable data.

2. Medicinal product by presentation

48. According to the case-law of the Court of Justice, the criterion of 'presentation' is designed to catch

not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or do not have the effect which consumers would be entitled to expect from the way in which they are presented. (22) This part of the definition of the term 'medicinal product' under Community law covers both 'genuine' medicinal products and preparations which do not have any pharmaceutical active substance and thus, from an objective perspective, cannot have any medical effect. As a result, according to case-law, the consumer is intended to be protected 'not only from harmful or toxic medicinal products, but also from a variety of products used instead of the proper remedies'. (23) For that reason, the notion of the 'presentation' of a product has thus far been given a broad interpretation.

49. It must be assumed that a product is presented for treating or preventing disease within the meaning of Directive 2001/83 not only when it is expressly 'presented' or 'recommended' as such, possibly by means of labels, leaflets or oral representation, 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, having regard to its presentation, have the properties in question. (24) Reference must therefore be had to the intended use designated by the manufacturer, which is apparent to the consumer. (25)

50. According to the papers in the case, the contested product manufactured by Piddimax is a garlic extract powder which is sold in capsule form, each capsule containing the equivalent of 7.4 g of fresh, raw garlic. It is clear from the label, which was submitted with the application for the adoption of a decision of general application, that one capsule contains 370 mg of highly concentrated allicin-containing garlic extract powder.

51. I must concur with the Commission's view that, apart from the capsule form in which the garlic preparation is marketed, there is nothing to suggest that it should be classified as a medicinal product by presentation. It should be borne in mind that, according to the case-law, the external form, such as a tablet, pill or capsule, may serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product. Such evidence cannot, however, be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to pharmaceutical products would also be covered. (26) In fact, at present the capsule form has probably lost importance for possible classification as a medicinal product, especially since many food supplements as well as many dietetic foodstuffs are offered for sale in capsule, gelatine and tablet form, just like medicinal products. (27) Simply making reference to the marketing form would not take sufficient account of the fact that, for example, elements which were previously typical of medicinal products have become established on the market in food supplements in the interests of customer orientation and for reasons of expediency. (28) In addition, it is undoubtedly often essential for reasons of quality and practicability to offer food supplements for sale packaged in capsule form. It must therefore be assumed that an averagely well-informed consumer has now accepted the fact that this form is no longer specifically for medicinal products. The marketing of the contested garlic preparation in capsule form does not therefore automatically allow it to be classified as a medicinal product.

52. Furthermore, the fact that a 'dosage' and not a 'portion of the product recommended for daily consumption', as referred to in Article 6(3)(b) of Directive 2002/46, is indicated on the packaging cannot make the contested garlic preparation a medicinal product either. As the Commission rightly argues, that directive mentions elsewhere 'dose form' and 'recommended daily dose', which suggests that the terms 'dosage' and 'portion of the product recommended for daily consumption' essentially describe the same thing. Irrespective of terminological differences, a dosage cannot be the crucial factor in distinguishing between medicinal products and foodstuffs, as an appropriate maximum limit may prove to be necessary for the protection of health even in the case of certain foodstuffs which are not to be regarded as medicinal products.

53. Consequently, the contested garlic preparation does not satisfy the definition of the term 'medicinal product' by presentation under the first subparagraph of Article 1(2) of Directive 2001/83. Neither is the manner in which it is packaged typical of medicinal products, nor can the conclusion be drawn, on the basis of particular characteristics or indications from the manufacturer, that the manufacturer had the intention of marketing the garlic preparation as a medicinal product.

54. The two parts of the definition of the term 'medicinal products' under Community law cannot, however, be viewed as rigorously distinct. As the Court stated in van Bennekom, (29) a substance which is endowed with properties 'for treating or preventing disease in human beings or animals' within the meaning of the first part of the Community definition, but which is not 'presented' as such, falls within the scope of the second part of the Community definition of a medicinal product.

3. Medicinal product by function

55. The definition of a medicinal product by function laid down in the second subparagraph of Article 1(2) of Directive 2001/83 is to be understood as encompassing only substances or combinations of substances which may be administered to human beings with a view to modifying physiological effects. That definition of the term 'medicinal product' covers products which, actually or according to their claimed effects, can affect the body in such a way that they modify considerably the way in which it functions. (30)

56. In its case-law, the Court has mentioned the following criteria which may be used to determine whether a product falls under this part of the definition: its composition, its pharmacological properties – to the extent to which they can be established in the present state of scientific knowledge – the manner in which it is

used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail. (31) However, the Court has left open how those characteristics are to be assessed and has not yet provided any definition of 'pharmacological properties', except for stating that those properties include the 'effect on health in general'. (32)

57. In my opinion, the criterion of the pharmacological properties (33) is of crucial importance because it is an objective characteristic which can be established only on a case-by-case basis by means of a thorough technical/scientific examination. The need for a clear definition of pharmacological properties is particularly evident in cases like the present one, which concern the classification of products which, in addition to their status as foodstuffs, are recognised as having health-promoting effects.

58. As Advocate General Tesauro rightly stated in Delattre, (34) the wording 'restoring, correcting or modifying physiological functions' contained in the second subparagraph of Article 1(2) of Directive 2001/83 is formulated in broad terms in order to extend to those products which, although without doubt inherently able to affect physiological functions, have an essentially nutritional purpose. I have already argued elsewhere that such an interpretation ultimately promotes neither the protection of health nor the free movement of goods. (35) Nor can that be the intention of the Community legislature. Concurring with the proposals made by Advocate Generals Geelhoed (36) and Tesauro, (37) I therefore take the view that the concept of a medicinal product by function must be interpreted restrictively. (38) Accordingly, the definition should cover only products with scientifically identifiable pharmacological properties. It should not be sufficient for the product merely to have physiological and nutritional effects. Rather, I consider that it must either be intended to prevent or treat disease, have relevant health risks or secondary effects which are detrimental to health, or have an excessive effect on physical functions. (39)

59. The German Government essentially justifies the classification of the product as a medicinal product by reason of its high allicin content which, according to its own information, has a two to four times higher concentration of active substances than the scientifically recommended daily dose. It argues that for that very reason the product is not a substance which should be treated in the same way as the foodstuff garlic, but rather a highly concentrated garlic extract obtained using ethanol which is cultivated on a medium (lactose). It sees evidence of pharmacological properties first of all in garlic's effects in lowering blood pressure and lipid levels, which makes the preparation a suitable means for preventing general hardening of the arteries (general arteriosclerosis).

60. At this point, I believe that it should be pointed out that the legal assessment to be conducted by the Court must not be restricted to the health-promoting effect which garlic has as a foodstuff in the present state of scientific knowledge. Many products which are clearly foodstuffs according to the established view may also objectively serve therapeutic purposes. (40) On the basis of the restrictive interpretation of the definition of 'medicinal product' advocated here, the question must be asked whether the contested product in itself offers any additional benefit compared with garlic in its natural form.

61. On this question I tend to concur with the view taken by the Commission that the product in question in the present case is not a medicinal product. The literature on which the German Government relies in its defence explains the effect of the foodstuff garlic, which can be achieved through consumption of that foodstuff, but also by taking garlic preparations in the form of capsules, powders or solutions. (41) On closer examination the contested preparation proves to be nothing more than a concentrate of the natural active substance allicin, whose physiological effects can simply be achieved by taking a larger amount of the foodstuff garlic.

62. Whilst it is recognised that the use of garlic has a positive effect on the human body, its effect should not be regarded as any greater or different from that of other vegetable or animal products which are taken as part of the daily diet. As the Commission argues in its application, that effect can also be achieved by using other foodstuffs and by adopting a certain diet. For example, sea fish such as salmon, tuna, herring and sardines contain omega-3 fatty acids, which also reduce the risk of arteriosclerosis. In addition, vitamin C, vitamin E and the mineral selenium are important and can all be taken as part of normal foodstuffs, but also as food supplements.

63. I do not believe that the arguments put forward by Federal Government are conclusive enough to take the view that the product should be classified as a medicinal product 'by function' since the effects of such a preparation are not such as to prevent the risk of arteriosclerosis entirely. As can be seen from the letter from the German Government of 14 March 2003, which is Annex 4 to the application, apart from the active substance allicin the contested preparation does not contain any substances that could be classified as vitamins, minerals or other substances with a nutritional or physiological effect. (42)

64. In any case, any effect of a foodstuff in reducing risks or promoting health must not automatically lead to classification as a medicinal product, otherwise the Member States would be free to impede trade specifically in those valuable foodstuffs and thus withhold them from consumers. It is clear that such a consequence is directly contrary to the objectives of free movement of goods.

65. It is equally difficult to understand the German Government's reference to the risks associated with the use of garlic. In so far as it refers to reports of spontaneous and post-operative bleeding, to possible interactions with the HIV medication Saquinavir and with certain medicinal products which stem blood clotting, the objection must be raised that the risks concerned are associated with taking garlic in general

and are not to be attributed specifically to the preparation. As the Commission rightly notes, it is not unusual for an individual's state of health possibly to require a certain diet to be observed, such as eating food that is low in salt or avoiding alcoholic drinks. Since those secondary effects occur very rarely and only where there is a certain inherited or situation-specific susceptibility, they should not really be regarded as relevant health risks or secondary effects which are detrimental to health within the meaning of the case-law. In addition, a possible health risk is just one of many factors which the competent national authorities have to take into account in classifying a product as a medicinal product 'by function'. (43)

66. The German Government's argument that an established view has been formed with regard to highly concentrated garlic preparations must also be rejected. That view fails to recognise that under Community law, to determine whether a product should be classified as a medicinal product, the national authorities must work on a case-by-case basis. (44) The blanket reference to an established view with regard to garlic products in general, for which no further evidence is given, does not relieve it of that duty. Furthermore, the Court has already held that consumers' conceptions are likely to evolve in the course of the establishment of the internal market. (45) National rules must not result in certain consumer habits becoming entrenched in a way that would run counter to the establishment of the internal market.

67. All in all, therefore, the product does not fall within the definition of the term 'medicinal product' under Community law in accordance with Article 1(2) of Directive 2001/83.

68. Since the contested garlic preparation does not satisfy any of the legal definitions of 'medicinal product' contained in Article 1(2) of Directive 2001/83 and does not therefore fall within the scope ratione materiae of that provision, it is not necessary to comment on whether and to what extent the regime governing medicinal products takes priority over the rules on foodstuffs and food supplements. (46) The submissions made by the Federal Government in that regard must therefore be rejected as irrelevant in this case.

4. Applicability of the Treaty provisions on the free movement of goods

69. The product could at most be a food supplement within the meaning of Article 2(a) of Directive 2002/46, that is to say a foodstuff the purpose of which is to supplement the normal diet and which is a concentrated source of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form. However, the garlic preparation in question is not composed of the nutrients listed in Article 2(b) of Directive 2002/46 (vitamins and minerals) and is not therefore covered by the scope ratione materiae of that rule.

70. Under the eighth recital of Directive 2002/46, the Member States may, until such specific Community rules are adopted and without prejudice to the provisions of the Treaty, apply national rules concerning nutrients or other substances with nutritional or physiological effect used as ingredients of food supplements, for which no specific Community rules have been adopted.

71. In the absence of harmonisation in that sector, the Treaty provisions concerning free movement of goods therefore form the basis for assessing the compatibility of the classification of the product as a medicinal product by the German authorities.

5. Unjustified restriction of the free movement of goods

72. Under Article 28 EC, quantitative restrictions on imports and all measures having equivalent effect are prohibited between Member States. Measures having equivalent effect to a quantitative restriction are all rules and measures enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-community trade. (47)

73. The decision of 8 June 2000, by which the contested garlic product was refused authorisation as a food supplement in connection with the application under Paragraph 47a of the LMBG, is a national measure within the meaning of Article 28 EC. According to the grounds of the decision, the garlic product marketed lawfully in another Member State is regarded as a medicinal product in the Federal Republic of Germany. It may not therefore be marketed in Germany as a foodstuff or food supplement, but would have to be authorised as a medicinal product. That requirement is capable of impairing intra-Community trade in the product in question. It therefore constitutes a prohibited measure having equivalent effect.

74. The Court has stated that in default of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research, Member States may, in certain conditions, restrict on the basis of Article 30 EC the marketing of foodstuffs lawfully marketed in another Member State on grounds of the protection of the health and life of humans. (48) However, the measures taken by the Member States in relation to that product in order to safeguard public health must be proportionate. (49)

75. It is for the national authorities which invoke protection of public health to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk to public health. (50) The burden of justification is heavier for the Member State in question, the higher the legal and factual requirements for marketing a product. It should be pointed out in this connection that the issue of a marketing authorisation under Article 8 of Directive 2001/83 is subject to strict requirements. (51)

76. Under these circumstances, the prohibition on marketing the product in question as a foodstuff and the obligation to obtain a marketing authorisation for medicinal products are regarded as proportionate only if

they are actually necessary for the protection of the health of the population.

77. The German Government takes the view that the restriction of free movement of goods is in any case justified in order to protect an overriding public interest, namely to safeguard public health. In this respect it refers to its submissions on the health risks stemming from the preparation. (52)

78. As has already been explained, those arguments clearly relate to the effects of the foodstuff garlic, whilst they fail entirely to examine the contested preparation on a case-by-case basis. For example, the German Government does not clearly distinguish between the physiological effects resulting from the consumption of large quantities of garlic and from taking garlic preparations. In the letter from the German Government of 5 October 2001 to the Commission, reference is made to the foodstuff and the product to some extent indiscriminately, for example in connection with possible secondary effects such as gastrointestinal complaints, allergic reactions and slight lowering of blood pressure.

79. However, Article 30 EC may be relied on only if there actually exists a danger to the interest to which the Member State in question refers. (53) According to case-law, even if a situation of danger does not have to have been proven beyond scientific doubt, a substantiated and comprehensible case must be made in this regard. (54) Against the background of the high justification requirements which the Community legislature and the Court has imposed on the Member States, the mere blanket reference by the German Government to possible health risks which may arise from the consumption of garlic under very specific living conditions cannot be sufficient to justify such a drastic measure as the refusal of market access.

80. The German Government has not therefore shown that the issue of a marketing authorisation for the garlic preparation in question as a medicinal product was necessary to safeguard public health, especially since warnings for those who suffer allergies or those who have an inherited or situation-specific susceptibility to certain diseases are perfectly conceivable as a less onerous measure than a general marketing prohibition. (55)

81. To apply the requirements governing authorisation as a medicinal product to the contested garlic preparation therefore constitutes an unjustified restriction on the free movement of goods.

VII – Costs

82. Under Article 69(2) of the Rules of Procedure, in treaty infringement proceedings the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the Federal Republic of Germany has been unsuccessful, it must be ordered to pay the costs.

VIII – Conclusion

83. On the basis of the foregoing considerations, I propose that the Court:

(1) declare that by classifying as a medicinal product a garlic preparation in capsule form which does not fall under the definition of a medicinal product by presentation under Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, the Federal Republic of Germany has failed to fulfil its obligations under Articles 28 and 30 EC.

(2) order the Federal Republic of Germany to pay the costs.

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1 – Original language: German.

2 – OJ 2001 L 311, p. 67.

3 – OJ 2002 L 183, p. 51.

4 – Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 HLH Warenvertrieb and Orthica [2005] ECR I-5141, paragraph 43.

5 – Case C-387/99 Commission v Germany [2004] ECR I-3751, paragraph 56, and Case 227/82 van Bennekom [1983] ECR 3883, paragraph 27.

6 – HLH Warenvertrieb and Orthica (cited in footnote 4 above, paragraph 43).

7 – Clement, C., 'La notion de médicament en droit communautaire de la santé', Les petites affiches, 1995, No 12, p. 20, states that medicinal products are not ordinary goods since they are used to combat diseases, pains and other complaints. At the same time, however, he points out the risks associated with taking medicinal products by drawing attention to the widely held view that 'the more effective a medicinal product is, the more harmful it is'.

8 – Streinz/Ritter, J., in: Dauses, M. (ed.), Handbuch des EU-Wirtschaftsrechts, C. V., paragraph 2; Winter, B., Die Verwirklichung des Binnenmarktes für Arzneimittel, Berlin 2004, p. 77; Cadeau, E./Richeux, J.-Y., 'Le juge communautaire et le médicament: libre circulation des marchandises et protection de la santé publique', Les petites affiches, 1996, No 7, p. 9, regard national rules and administrative practices that are liable to hinder trade in pharmaceutical products between Member States as measures having equivalent effect to quantitative restrictions on imports within the meaning of Article 28 EC.

9 – A medicinal product is given access to the market only if it has undergone the specified authorisation procedure and the competent authority has granted authorisation for the marketing of the medicinal product. Authorisation of a medicinal product is necessary in order to guarantee the safety of consumers dealing with medicinal products and to protect them against ineffective and harmful medicinal products. Nevertheless, the guarantee of a high level of protection in dealings with medicinal products must be attained by means which will hinder trade in pharmaceutical products within the Community as little as possible. Differences between the national authorisation rules have a direct effect on the establishment and functioning of the internal market. For these reasons, the creation of uniform Community authorisation proce-

dures was an important concern for the Community. There are now three possible ways a medicinal product can be authorised in the European Union: the central authorisation which applies throughout the Union, the decentralised authorisation for several Member States, and a purely national authorisation, although the material authorisation criteria for all procedures are the same: authorisation of a medicinal product is refused if the examination of the authorisation documents reveals that the medicinal product does not have the indicated composition in terms of kind and quantity, if the therapeutic effectiveness is absent or insufficiently substantiated, or if the medicinal product is harmful when used as directed (see Winter, B., loc. cit. (footnote 8), p. 77-94).

10 – Second recital in the preamble to Directive 2001/83/EC.

11 – Third recital in the preamble to Directive 2001/83/EC.

12 – In Case C-83/92 Pierrel [1993] ECR I-6419, paragraph 7, the Court observed that, in Community law, proprietary medicinal products are the subject of a series of highly detailed harmonisation directives aiming at the gradual attainment of the free movement of these products in the Community, while at the same time safeguarding public health. Along similar lines, see also Cadeau, E./Richeux, J.-Y., loc. cit. (footnote 8), p. 4. According to Fraguas Gadea, L., 'La libre circulación de medicamentos', Noticias de la Unión Europea, 2000, No 184, p. 57, and Petit, Y., 'La notion de médicament en droit communautaire', Revue de droit sanitaire et social, 1992, 28th year, No 4, p. 572, the Community legislature has pushed forward with harmonisation in order to strike a fair balance between the requirements of public health and free movement of goods. In the view of the authors, free movement of goods could also be described in a broader sense as a project to build a common European market in medicinal products.

13 – See Opinion of Advocate General Geelhoed in HLH Warenvertrieb and Orthica (judgment cited in footnote 4, point 34).

14 – Ibid., point 54.

15 – HLH Warenvertrieb and Orthica (cited above in footnote 4, paragraph 42). The Court has held that for an administrative practice to constitute a measure prohibited under Article 30 EC that practice must show a certain degree of consistency and generality. See Case 21/84 Commission v France [1985] ECR 1355, paragraphs 13 and 15, Case C-187/96 Commission v Greece [1998] ECR I-1095, paragraph 23, and Case C-185/96 Commission v Greece [1998] ECR I-6601, paragraph 35.

16 – See Opinion of Advocate General Geelhoed in HLH Warenvertrieb and Orthica (judgment cited in footnote 4, point 35).

17 – Case C-219/91 Ter Voort [1992] ECR I-5485, paragraph 19, Case C-60/89 Monteil and Samanni [1991] ECR I-1547, paragraph 16, and Case C-369/88 Delattre [1991] ECR I-1487, paragraph 21.

18 – Case C-112/89 Upjohn I [1991] ECR I-1703, paragraph 23. According to Doepner, U./Hüttebräuker, A., 'Abgrenzung Arzneimittel/Lebensmittel – die aktuelle gemeinschaftsrechtliche Statusbestimmung durch den EuGH', Wettbewerb in Recht und Praxis, 2005, Vol. 10, p. 1199, there are a number of decisions which highlight the fact that previously the Court has in some cases clearly opposed efforts made by the Member States to advocate an extension of the national regime for medicinal products to ambivalent products. By way of an example the authors mention the judgment in Case C-387/99 Commission v Germany [2004] ECR I-3751, paragraphs 56-57, in which the Court made clear that in accordance with settled case-law, to determine whether a certain product should be classified as a medicinal product, the national authorities must work on a case-by-case basis, having regard to all of its characteristics. In particular the authorities must ascertain that it is intended to restore, correct or modify physiological functions and that it may thus have an effect on health in general.

19 – In its judgment in Case C-120/97 Upjohn II [1999] ECR I-223, paragraph 34, the Court held, with reference to the case-law cited therein, that where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to limited judicial review in the course of which the Community judicature may not substitute its assessment of the facts for the assessment made by the authority concerned. Thus, in such cases, the Community judicature must restrict itself to examining the accuracy of the findings of fact and law made by the authority concerned and to verifying, in particular, that the action taken by the authority is not vitiated by a manifest error or misuse of powers and that it clearly did not exceed the bounds of its discretion.

20 – Opinion of Advocate General van Gerven in Case C-290/90 Commission v Germany [1992] ECR I-3317, point 5, and the judgments in Case 97/81 Commission v Netherlands [1982] ECR 1819, paragraph 6, Case 323/87 Commission v Italy [1989] ECR 2275, paragraph 19, and Case 290/87 Commission v Netherlands [1989] ECR 3083, paragraph 11. See also in this sense Case C-290/90 Commission v Germany [1992] ECR I-3317, paragraph 20, and Case C-24/00 Commission v France [2004] ECR I-1277, paragraph 72.

21 – Delattre (cited in footnote 17 above, paragraph 32)

22 – Upjohn I (cited in footnote 18 above, paragraph 16) van Bennekom (cited in footnote 5 above, paragraph 17). The Upjohn I case concerned Minoxidil, which had been developed in the early 1960s as a medicinal product for the treatment of arterial hypertension and on account of its secondary effects was marketed under a different name as a treatment for natural baldness. The national referring court had to decide whether that product was a medicinal product or a cosmetic product. The van Bennekom case concerned highly concentrated vitamin preparations which were presented as medicinal products (in the form of tablets, pills and capsules).

23 – Upjohn I (cited in footnote 18 above, paragraph 16) and Case 227/82 van Bennekom (cited in footnote 5 above, paragraph 17).
24 – van Bennekom (cited in footnote 5 above, paragraph 18) and Monteil and Samanni (cited above in footnote 17, paragraph 23).
25 – Köhler, H., 'Die Abkehr vom Anscheinsarzneimittel – Neue Ansätze zur Abgrenzung von Arzneimittel und Lebensmittel', Zeitschrift für das gesamte Lebensmittelrecht, 1999, Vol. 5, p. 609.
26 – van Bennekom (cited in footnote 5 above, paragraph 19).
27 – By judgment of 10 January 1995 (file reference I ZR 209/92), the Bundesgerichtshof (Federal Court of Justice) ruled – contrary to the view taken by the lower court – that a garlic preparation marketed in capsule form, even though it was presented for cooking and seasoning, had to be classified not as a foodstuff, but as a medicinal product. The grounds cited for the Bundesgerichtshof's decision were, first of all, the effect of the active substance contained in garlic in lowering blood pressure and cholesterol and, secondly, the form, which was typical of medicinal products (gelatine capsules, blister strips). That ruling has met with criticism in specialist literature. For example, Köhler, H., loc. cit. (footnote 25), p. 606, pointed out that many food supplements as well as many dietetic foodstuffs are offered for sale in capsule, gelatine and tablet form, just like medicinal products, with the result that consumers have now accepted that that form is not specifically for medicinal products. Köhler, H., 'Die neuen europäischen Begriffe und Grundsätze des Lebensmittelrechts', Gewerblicher Rechtsschutz und Urheberrecht, 2002, Vol. 10, p. 852, takes the view that the capsule form is irrelevant since the van Bennekom judgment, or at least it is now. Consequently, the garlic preparation would not be classified as a medicinal product in his view.
28 – See Klein, A., 'Nahrungsergänzung oder Arzneimittel?', Neue Juristische Wochenschrift, 1998, Vol. 12, p. 793. The author criticises the use of outmoded definition criteria by the Bundesgerichtshof in the abovementioned judgment. In his view, in any decision the courts must take account of any changes of circumstances which may have occurred on the market, such as the marketing of products and the expectations of consumers. As evidence of this need he cites the example of vitamin preparations, which were used from an early stage as food supplements and are particularly popular among consumers, and which have helped to create a situation where a product is not necessarily regarded as a medicinal product if it has been made in the same way as medicinal products once were. He considers that the classification of a garlic preparation as a medicinal product on the basis of its marketing form as capsules alone is not compatible with the factual situation, especially since it is essential for reasons of quality and practicability to offer food supplements for sale packaged in capsule form. Hagenmeyer, M., 'Die Nahrungsergänzung – ein Lebensmittel in der Grauzone', Zeitschrift für das gesamte Lebensmittelrecht, 1998, Vol. 3, p. 367, refers, with regard to the typically medicinal forms formerly offered, that the view is still encountered that preparations in capsule form are generally medicinal products. However, the view is beginning to become established that the capsule form taken by a product – above all as gelatine capsules in blister strips – tablets, powders etc. must be irrelevant to its status as a food supplement.
29 – van Bennekom (cited in footnote 5 above, paragraph 22) and Upjohn I (cited in footnote 18 above, paragraph 18).
30 – Upjohn I (cited in footnote 18 above, paragraph 18).
31 – van Bennekom (cited in footnote 5 above, paragraph 29), Monteil and Samanni (cited in footnote 17 above, paragraph 29), Upjohn I (cited in footnote 18 above, paragraph 23), Case C-290/90 Commission v Germany (cited in footnote 20 above, paragraph 17), and Case C-387/99 Commission v Germany (cited in footnote 5 above, paragraph 57).
32 – Upjohn I (cited in footnote 18 above, paragraphs 17 and 22) and Case C-387/99 Commission v Germany (cited in footnote 5 above, paragraph 58). Upjohn I concerned the classification of a hair growth aid as a medicinal product or a cosmetic product. The Court made clear that the definition of medicinal product does not serve to include substances such as certain cosmetics which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions. In Commission v Germany the Court ruled that classification as a medicinal product of a vitamin preparation which is based solely on the recommended daily amount of the vitamin it contains, namely the amount which potentially covers the requirements for that vitamin of all persons in good health in the population group under consideration, does not fully satisfy the requirement for a classification on the basis of the pharmacological properties of each vitamin preparation.
33 – Originally developed by the Court with a view to the classification of products as functional medicinal products, the notion of 'pharmacological action' is incorporated into the definition of functional medicinal product alongside the notions of 'immunological' and 'metabolic' action by amending Directive 2004/27/EC and has thus become a definitional element expressly laid down by law.
34 – Opinion of Advocate General Tesauro in Delattre (judgment cited in footnote 17 above, point 9). Petit, Y., loc. cit. (footnote 12), p. 573, also points out that that definition is so broadly formulated that, on the basis of its wording, it can be equally applicable to medicinal products, foodstuffs or cosmetics.
35 – See point 43.
36 – See Opinion of Advocate General Geelhoed in HLH Warenvertrieb and Orthica (judgment cited in footnote 4, point 35).
37 – Opinion of Advocate General Tesauro in Delattre (judgment cited in footnote 17 above, point 9). In that Opinion, Advocate General Tesauro stated that that definition 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.

38 – The restrictive interpretation concerns the unwritten definitional element of 'pharmacological properties' developed by the Court of Justice. Doepner, U./Hüttebräuker, A., loc. cit. (footnote 18), p. 1201 to 1203, complain that there has not yet been a substantive definition or a clarification of the criterion created by the Court itself. A definition of the substance and the scope of this concept either by the Court or by the Community legislature is needed because it is an essential definitional criterion. They fear that a uniform assessment of ambivalent products (products in the grey area between foodstuffs and medicinal products) could lead the national authorities generally to accept products as medicinal products, which would not really be appropriate for many of the products concerned and would not be necessary under Community law or make sense in terms of health or domestic economic policy. The call made by the authors for clarification of the definition of functional medicinal product therefore essentially amounts to a restrictive interpretation of the legal definition contained in the second subparagraph of Article 1(2) of Directive 2001/83. Clement, C., loc. cit. (footnote 7), p. 19, 22, criticises the absence of more reliable assessment criteria and the broad formulation of the term 'medicinal product'. He also advocates a restrictive interpretation by the courts.

39 – Using the definition adopted by Köhler, H., loc. cit. (footnote 26), p. 849.

40 – See also Köhler, H., loc. cit. (footnote 27), p. 850, who classifies among foodstuffs which serve therapeutic purposes herbal teas and other medicinal herbs, including grated carrots to combat intestinal parasites or garlic to prevent arteriosclerosis. He believes that it is absurd to classify them as medicinal products because of their therapeutic function alone.

41 – Breithaupt-Grögler, K./Ling, M./Boudoulas, H./Belz, G., 'Protective Effect of Chronic Garlic Intake on Elastic Properties of Aorta in the Elderly', Circulation, 1997, p. 2654; Koscielny, J./Klüßendorf, D./Latza, R./Schmitt, R./Radtke, H./Siegel, G./Kiesewetter, H., 'The antiatherosclerotic effect of Allium sativum, Atherosclerosis, 1999, p. 237'.

42 – According to the papers in the case, the contested product contains between 0.95 and 1.05 per cent natural allicin. Chemically, the product is composed of carbohydrates, proteins and fats, as well as trace elements and vitamins, which could not, according to the German Government, in themselves be classified as vitamins, minerals or other substances with a nutritional or physiological effect.

43 – See Case C-150/00 Commission v Austria [2004] ECR I-3887, paragraph 65, Case C-387/99 Commission v Germany (cited in footnote 31 above, paragraph 57) and HLH Warenvertrieb and Orthica (cited in footnote 4 above, paragraph 53), according to which a risk to public health is only one aspect of the product which must be taken into consideration by the competent national authorities.

44 – Case 227/82 van Bennekom (cited in footnote 5 above, paragraph 40) and HLH Warenvertrieb and Orthica (cited in footnote 4, paragraphs 30 and 51).

45 – Case 178/84 Commission v Germany [1987] ECR 1227, paragraph 32.

46 – Nor is it necessary to comment on the 'rule of doubt' introduced into Article 2(2) of Directive 2001/83 only later by amending Directive 2004/27/EC (OJ 2004 L 136, p. 34), according to which, in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of that directive shall apply. Klaus, B., 'Leitfaden zur Abgrenzung von Lebensmitteln und Arzneimitteln in der Rechtspraxis aller EU-Mitgliedstaaten auf Grundlage der gemeinschaftsrechtlich harmonisierten Begriffsbestimmungen', Zeitschrift für das gesamte Lebensmittelrecht, 2004, Vol. 5, p. 574, points out that cases of doubt in distinguishing medicinal products from other categories of product, including foodstuffs, might not be properly resolved even using such a 'rule of doubt', as provided for in the current version of Article 2(2) of Directive 2001/83. There is a danger that by applying that clause it might be accepted prematurely that a substance or product is subject to the rules governing medicinal products. However, this would lead to very inappropriate results particularly with regard to the distinction with foodstuffs since, because of the broad scope of the definition of 'medicinal product', foodstuffs would theoretically be covered by that definition in many cases. Because of the uncertainties inherent in the 'rule of doubt', the way is opened for national interpretations which ultimately decide when classification doubts exist. In the author's view, preference should have been given to the approach originally taken by the European Parliament, where the distinction problem was facilitated by a clear wording of the legal definitions.

47 – Case 8/74 Dassonville [1974] ECR 837, paragraph 5, and Case 120/78 Rewe-Zentral ('Cassis de Dijon') [1979] ECR 649, paragraph 14. The establishment and maintenance of free movement of goods within the Community requires not only the removal of customs barriers, but also the elimination of all other restrictions on trade. For that reason, alongside quantitative restrictions, Articles 28 and 29 EC also prohibit measures having equivalent effect. These are 'all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-community trade'. In the view of Oppermann, T., Europarecht, 3rd edition, Munich 2005, p. 416, this broad 'Dassonville formula' makes clear that it is sufficient for the national measure to be capable of impeding trade and no actual fall in imports has to be proven. Nor is there any need for an intention to restrict trade or for the restriction to be appreciable.

48 – See HLH Warenvertrieb and Orthica (cited in footnote 4 above, paragraph 42) and Case C-192/01 Commission v Denmark [2003] ECR I-9693, paragraph 68. Both judgments develop earlier case-law under which reliance on Article 30 EC is not possible from the outset where the Community itself has laid down definitive Community legislation to protect the legal interests in question, for example by a directive or regulation. See, for example, Case 5/77 Denkavit [1977] ECR 1555 paragraphs 33/35. Cadeau, E./Richeux, J.-Y., loc. cit. (footnote 8), p. 8, also point out that recourse to Article 30 EC in Community law on medicinal products is possible only in cases of incomplete harmonisation.

49 – Case 72/83 Campus Oil [1984] ECR 2727, paragraph 37.

50 – Case C-387/99 Commission v Germany (cited in footnote 5 above, paragraph 72).

51 – In Case C-387/99 Commission v Germany (cited in footnote 5 above, paragraphs 74 to 76), the Court stated, with regard to the requirements for authorisation of vitamin preparations as medicinal products under Article 4 of Directive 65/65, which are essentially the same as those under Article 8 of Directive 2001/83, that the issue of marketing authorisation for medicinal products is subject to particularly strict requirements. In order to obtain a marketing authorisation, the person responsible for placing the product on the market is to attach various particulars and documents, including qualitative and quantitative particulars of all the constituents of the medicinal product, a brief description of the method of preparation, therapeutic indications, contra-indications and side-effects, posology, pharmaceutical form, method and route of administration and expected shelf life, description of control methods employed by the manufacturer, results of physico-chemical, biological or microbiological tests, pharmacological and toxicological tests, and clinical trials. Moreover, the person responsible for placing the product on the market is to provide proof that the manufacturer is authorised in his own country to produce medicinal products.

52 – See point 65.

53 – Epiney, A., Kommentar des Vertrages über die Europäische Union und des Vertrages zur Gründung der Europäischen Gemeinschaft (edited by Christian Calliess/Matthias Ruffert), Neuwied 1999, Article 30, paragraph 23; Cadeau, E./Richeux, J.-Y., loc. cit. (footnote 8), p. 9, 10, therefore take the view that a Member State cannot rely successfully on the justification of safeguarding public health if the danger in question is only potential and not real.

54– See Case C-17/93 van der Veldt [1994] ECR I-3537, paragraph 17, according to which the fact that there is a risk to consumers is sufficient to make legislation of the kind at issue compatible with the requirements of Article 30 EC. However, the risk must be measured, not according to the yardstick of general conjecture, but on the basis of relevant scientific research.

55 – Account is taken of those requirements in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ 2000 L 109, p. 29). It provides inter alia for certain product information to be indicated, such as the list of ingredients, the quantity of certain ingredients or categories of ingredients, and any special storage conditions or conditions of use. According to the eighth recital in the preamble to the directive, detailed labelling, in particular giving the exact nature and characteristics of the product which enables the consumer to make his choice in full knowledge of the facts, is the most appropriate since it creates fewest obstacles to free trade.