

European Court of Justice, 15 January 2009, Hecht-Pharma v Bezirksregierung Lüneburg



PHARMACEUTICAL LAW

No medicinal product by function

- That that directive does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, without its being possible to exclude that possibility.

Concept of ‘medicinal product by function’

- That the characteristics of the manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail are still relevant to determining whether that product falls within the definition of a medicinal product by function.

Account taken of the content in active substances

- a product cannot be regarded as a medicinal product where, it is incapable of appreciably restoring, correcting or modifying physiological functions

That Article 1(2)(b) of Directive 2001/83 must be interpreted as meaning that, apart from the case of substances or combinations of substances intended for the purpose of making a medical diagnosis, a product cannot be regarded as a medicinal product within the meaning of that provision where, having regard to its composition – including its content in active substances – and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.

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European Court of Justice, 15 January 2009

(P. Jann, M. Ilešič, A. Tizzano, A. Borg Barthet and J.-J. Kasel)

JUDGMENT OF THE COURT (First Chamber)

15 January 2009 (*)

(Directive 2001/83/EC – Articles 1(2) and 2(2) – Concept of ‘medicinal product by function’ – Product in respect of which it has not been established that it is a medicinal product by function – Account taken of the content in active substances)

In Case C-140/07,

REFERENCE for a preliminary ruling under Article 234 EC from the Bundesverwaltungsgericht (Germany), made by decision of 14 December 2006, received at the Court on 12 March 2007, in the proceedings

Hecht-Pharma GmbH

v

Staatliches Gewerbeaufsichtsamt Lüneburg,

intervening party:

Vertreterin des Bundesinteresses beim Bundesverwaltungsgericht,

THE COURT (First Chamber),

composed of P. Jann, President of the Chamber, M. Ilešič, A. Tizzano, A. Borg Barthet (Rapporteur) and J.-J. Kasel, Judges,

Advocate General: V. Trstenjak,

Registrar: M.-A. Gaudissart, Head of unit,

having regard to the written procedure and further to the hearing on 24 April 2008,

after considering the observations submitted on behalf of:

– Hecht-Pharma GmbH, by C. Sachs, Rechtsanwältin,

– Staatliches Gewerbeaufsichtsamt Lüneburg, by H. Laackmann, acting as Agent,

– the Greek Government, by N. Dafniou, O. Patso-poulou and M. Apessos, acting as Agents,

– the Polish Government, by E. Ośniecka-Tamecka, T. Krawczyk and P. Dąbrowski, acting as Agents,

– the United Kingdom Government, by Z. Bryanston-Cross, acting as Agent, assisted by A. Henshaw, Barrister,

– the Commission of the European Communities, by B. Stromsky, B. Schima and G. Wilms, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 19 June 2008,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation 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 (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34), (‘Directive 2001/83’) and, in particular, Articles 1(2) and 2(2) thereof.

2 The reference has been made in the context of proceedings between Hecht-Pharma GmbH (‘Hecht-Pharma’) and the Staatliches Gewerbeaufsichtsamt Lüneburg (Public Authority for the Monitoring of Commercial Activities, Lüneburg) concerning the classification of a product called ‘Red Rice’ as a food additive or a medicinal product for the purposes of its marketing in German territory.

Legal framework

Community rules

3 Article 1(2) of Directive 2001/83, in its original version, provided that the term ‘medicinal product’ was to mean:

‘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 ...’

4 The present version of Article 1(2) of Directive 2001/83 provides that the term ‘medicinal product’ means:

‘(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis’.

5 Article 2(1) and (2) of Directive 2001/83 provides as follows:

‘1. This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.

2. 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 this Directive shall apply.’

6 Recitals 2, 3, 4 and 7 in the preamble to Directive 2004/27 state that:

‘(2) The Community legislation so far adopted has made a major contribution to the achievement of the objective of the free and safe movement of medicinal products for human use and the elimination of obstacles to trade in such products. However, in the light of the experience acquired, it has become clear that new measures are necessary to eliminate the remaining obstacles to free movement.

(3) It is therefore necessary to align the national laws, regulations and administrative provisions which contain differences with regard to the basic principles in order to promote the operation of the internal market while realising a high level of human health protection.

(4) The main purpose of any regulation on the manufacture and distribution of medicinal products for human use should be to safeguard public health. However, this objective should be achieved by means which do not hinder the development of the pharmaceutical industry or trade in medicinal products in the Community.

...

(7) Particularly as a result of scientific and technical progress, the definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medi-

nal products for human use. In order to take account both of the emergence of new therapies and of the growing number of so-called “borderline” products between the medicinal product sector and other sectors, the definition of “medicinal product” should be modified so as to avoid any doubt as to the applicable legislation when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products. This definition should specify the type of action that the medicinal product may exert on physiological functions. This enumeration of actions will also make it possible to cover medicinal products such as gene therapy, radiopharmaceutical products as well as certain medicinal products for topical use. Also, in view of the characteristics of pharmaceutical legislation, provision should be made for such legislation to apply. With the same objective of clarifying situations, where a given product comes under the definition of a medicinal product but could also fall within the definition of other regulated products, it is necessary, in case of doubt and in order to ensure legal certainty, to state explicitly which provisions have to be complied with. Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics, this Directive should not apply. It is also appropriate to improve the consistency of the terminology of pharmaceutical legislation.’

National legislation

7 Pursuant to Paragraph 69(1) of the Arzneimittelgesetz (Law on medicinal products), the competent German authorities are to take the necessary steps to eliminate infringements that have been confirmed or to prevent future infringements. They may, in particular, prohibit the placing on the market of medicinal products in the absence of the necessary authorisation or registration of such products.

The dispute in the main proceedings and the questions referred for a preliminary ruling

8 In September 2002, Hecht-Pharma, which operates a wholesale pharmaceutical business, marketed in Germany a product composed of fermented red rice under the name ‘Red Rice 330 mg Kapseln [capsules]’.

9 The capsules were marketed in plastic bottles which stated on their labels, inter alia: ‘Red Rice 330 mg, food supplement with fermented rice. One capsule corresponds to 1.33 mg of monacolin k’. The recommendations for use read as follows: ‘As food supplement, 1 capsule 1 - 3 times daily’.

10 By decision of 19 December 2002, the Bezirksregierung Lüneburg (District Administration, Lüneburg) prohibited Hecht-Pharma from marketing the product at issue in the main proceedings on the German market on the ground that it was a medicinal product that required a marketing authorisation but had not obtained any such authorisation.

11 Hecht-Pharma lodged a complaint against that decision with the Bezirksregierung Lüneburg. Since its complaint was rejected by decision of 11 June 2003, Hecht-Pharma brought an action against that decision before the Verwaltungsgericht (Administrative Court),

which dismissed the action by judgment of 28 April 2005.

12 In the view of the Niedersächsisches Oberverwaltungsgericht (Higher Administrative Court of Lower Saxony), which, by judgment of 23 March 2006, dismissed the appeal which Hecht-Pharma had brought before it against the judgment of the Verwaltungsgericht, the contested prohibition on marketing was justified by the fact that the product at issue in the main proceedings was a medicinal product.

13 The Niedersächsisches Oberverwaltungsgericht held that the legislation on medicinal products was applicable on the ground that the product in question could come within the scope of the definition of a medicinal product by function. It contained significant levels of monacolin K. That active substance is synonymous with lovastatin, an inhibitor of cholesterol synthesis which is contained, as an active substance, in a number of prescription medicinal products.

14 The Niedersächsisches Oberverwaltungsgericht concluded that the product at issue in the main proceedings was liable to lower excessively high cholesterol levels and therefore contribute to the realisation of a therapeutic objective. It added that inhibitors of cholesterol synthesis could also have serious, undesirable side-effects on the muscles and kidneys.

15 In the view of the Niedersächsisches Oberverwaltungsgericht, Hecht-Pharma could not rely on the fact that, having regard to the recommended dose, the product at issue in the main proceedings could not exert a pharmacological action. It held that it could not be concluded from the fact that the recommended dose amounts to a daily consumption of 1.33 to 4 mg of monacolin K, which is low in comparison with the daily consumption of 10 to 80 mg recommended for lovastatin, that monacolin K had no pharmacological effect.

16 The Niedersächsisches Oberverwaltungsgericht added that, even though the recommended daily dose represented a low level of consumption of monacolin K in comparison with the amount contained in prescription medicinal products, account had to be taken of the fact that preparations marketed as food supplements are as a rule taken unsupervised and in greater quantities than the recommended dose.

17 In addition, the Niedersächsisches Oberverwaltungsgericht pointed out that, since no pharmacological action had been demonstrated with certainty, the rule of doubt laid down in Article 2(2) of Directive 2001/83 ought to be applied. The application of that provision was not subject to the condition that the criteria governing the definition of a medicinal product be satisfied. It was sufficient that the product could come within the scope of the definition of a medicinal product.

18 Hecht-Pharma appealed on a point of law against the judgment of the Niedersächsische Oberverwaltungsgericht.

19 Having taken the view that resolution of the dispute called for an interpretation of Community law, the Bundesverwaltungsgericht (Federal Administrative Court) decided to stay the proceedings and to refer the

following questions to the Court for a preliminary ruling:

‘1. Does the rule of doubt in Article 2(2) of Directive 2001/83 ... mean that Directive 2001/83 ... applies to a product which could possibly be classified as a medicinal product but whose quality as a medicinal product has not been positively determined? What degree of probability, and hence what degree of elucidation of the facts, may be required in order to justify the application of Directive 2001/83 ...?’

2. Can a product which is not a medicinal product by presentation be regarded as a medicinal product by function within the meaning of Article 1(2) of Directive 2001/83 ... because of a component which can produce physiological changes in a certain dosage but whose dosage in the product to be assessed – if used as intended – is too low for that? Is this question to be allocated to the criterion of “pharmacological action” or the criterion of “modifying physiological functions” in human beings?

3. Are the characteristics of “the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail” (judgment in [[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 51]) stated in the case-law of the Court of Justice to be relevant, in addition to the pharmacological qualities, to classification as a medicinal product still relevant following the new definition of a medicinal product introduced by Directive 2004/27 ...?’

The questions referred to the Court

The first question

20 In its first question, the national court asks, essentially, whether Article 2(2) of Directive 2001/83 must be interpreted as meaning that that directive applies to a product in respect of which it has not been established that it is a medicinal product by function, without its being possible to exclude that possibility. It also seeks to determine, if need be, what degree of probability, and hence what degree of elucidation of the facts, is required in order to justify the application of Directive 2001/83.

21 First of all, it should be noted that both Article 2 of Directive 2001/83, in its original version, and Article 2(1) of Directive 2001/83 provide, essentially, that that directive applies to medicinal products for human use intended to be placed on the market in Member States and manufactured industrially.

22 The scope of Directive 2001/83 is thus limited to industrially-produced medicinal products, to the exclusion of products which do not fall under one or other of the definitions of a medicinal product contained in Article 1(2)(a) and (b) of that directive.

23 That conclusion is not invalidated by Article 2(2) of Directive 2001/83.

24 It is clear from recital 7 in the preamble to Directive 2004/27 that Article 2(2) was inserted into Directive 2001/83 in order to make clear that when a product falls within both the definition of a medicinal product and that of other regulated products, it must be

made subject to the provisions of Directive 2001/83. Thus, Article 2(2) of Directive 2001/83 starts from the premise that the product concerned satisfies the conditions for classification as a medicinal product (see, to that effect, *HLH Warenvertrieb and Orthica*, paragraphs 43 and 44).

25 It should be borne in mind in that regard that, contrary to the definition of medicinal product by presentation, the broad interpretation of which is intended to protect consumers from products which do not have the effectiveness which they are entitled to expect, the definition of medicinal product by function is designed to cover products the pharmacological properties of which have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions (**Case C-319/05 Commission v Germany [2007] ECR I-9811**, paragraph 61).

26 Thus, Directive 2001/83 does not apply to a product in respect of which it has not been established that it is a medicinal product within the meaning of Article 1(2)(b) of that directive, that is to say, a product in respect of which it has not been scientifically established that it is capable of restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or that it may be used to make a medical diagnosis.

27 That interpretation is corroborated by the case-law to the effect that the interpretation of the provisions of Directive 2001/83 – which is intended, in addition to protecting human health, to safeguard the free movement of goods within the Community – cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health (see, to that effect, *Commission v Germany*, paragraphs 62 and 71).

28 Moreover, it must be added that that interpretation does not cast doubt on the case-law to the effect that, as Community law stands, it is still possible that differences will continue to exist between Member States in the classification of products as medicinal products or as foodstuffs. It thus cannot be ruled out that one Member State may consider it established that a product is a medicinal product by function whereas another Member State may take the view that, according to current scientific knowledge, it has not been proved that that product is a medicinal product by function (see, to that effect, *HLH Warenvertrieb and Orthica*, paragraph 56).

29 Consequently, the answer to the first part of the first question is that Article 2(2) of Directive 2001/83 must be interpreted as meaning that that directive does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, without its being possible to exclude that possibility.

30 In the light of that answer, there is no need to reply to the second part of the first question.

The third question

31 In its third question, which it is appropriate to answer before the second, the national court seeks to

ascertain whether, following the amendment of the definition of a medicinal product by Directive 2004/27, Article 1(2)(b) of Directive 2001/83 must be interpreted as meaning that the characteristics of the manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail, laid down in the case-law of the Court, are still relevant in determining whether that product comes within the definition of a medicinal product by function.

32 In its case-law prior to the amendment of Directive 2001/83 by Directive 2004/27, the Court indicated that, for the purpose of determining whether a product falls within the definition of a medicinal product by function, 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, and *Commission v Germany*, paragraph 55).

33 As is apparent from recital 7 in the preamble thereto, the purpose of the amendments made by Directive 2004/27 to the definition of a medicinal product is to take account of the emergence of new therapies and of the growing number of so-called ‘borderline’ products. Also, in order to avoid doubts as to the applicable rules, the definition was made more precise and now specifies the type of action – pharmacological, immunological or metabolic – which a medicinal product must exert with a view to restoring, correcting or modifying human physiological functions.

34 That level of precision may have seemed necessary to the Community legislature inasmuch as physiological effect is not specific to medicinal products but is also among the criteria used for the definition of food supplements (*Commission v Germany*, paragraph 63).

35 By contrast, there is nothing in the amendments made to the definition of a medicinal product by Directive 2004/27 to indicate an intention to modify the criteria laid down in the case-law other than the need, in future, to take account of the immunological and metabolic properties of a product, in addition to its pharmacological properties.

36 Rather, Article 2(2) of Directive 2001/83, inserted by Directive 2004/27, confirms the approach adopted by the case-law by stating that ‘all its characteristics’ are to be taken into account in determining whether a product falls within the definition of a medicinal product.

37 The answer to the third question is therefore that Article 1(2)(b) of Directive 2001/83 must be interpreted as meaning that the characteristics of the manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail are still relevant to determining whether that

product falls within the definition of a medicinal product by function.

The second question

38 In its second question, the national court asks, essentially, whether Article 1(2)(b) of Directive 2001/83 is to be interpreted as meaning that a product may be classified as a medicinal product by function where, having regard to its composition – including its content in active substances – and if used as intended, it is incapable of restoring, correcting or modifying physiological functions. It also asks the Court whether the content in active substances of a product must be taken into account in assessing the capacity of the product to exert a ‘pharmacological action’ or its capacity to modify ‘physiological functions in human beings’.

39 First of all, it should be pointed out that it is apparent from paragraphs 32 and 33 of the present judgment that, for the purpose 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, immunological or metabolic 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.

40 It follows that products containing a substance having a physiological effect cannot automatically be classified as medicinal products by function unless the competent administration has made an assessment, with due diligence, of each product individually, taking account, in particular, of that product’s specific pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge.

41 In that regard, it should be borne in mind that the capacity to restore, correct or modify physiological functions should not lead to the classification as medicinal products by function of products 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 (see, to that effect, *Commission v Germany*, paragraph 60).

42 It follows that, apart from the case of substances or combinations of substances intended for the purpose of making a medical diagnosis, a product cannot be regarded as being a medicinal product by function where, having regard to its composition – including its content in active substances – and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions in human beings.

43 With regard to the second part of the national court’s second question, it must be pointed out that a product which may be used by, or administered to, human beings with a view, in particular, ‘to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic

action’ is a medicinal product by function within the meaning of Article 1(2)(b) of Directive 2001/83.

44 The distinction which the national court makes between the capacity to exert a pharmacological action and the capacity to modify physiological functions is therefore irrelevant for the purpose of classifying a product as a medicinal product by function.

45 Consequently, the answer to the second question is that Article 1(2)(b) of Directive 2001/83 must be interpreted as meaning that, apart from the case of substances or combinations of substances intended for the purpose of making a medical diagnosis, a product cannot be regarded as a medicinal product within the meaning of that provision where, having regard to its composition – including its content in active substances – and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.

Costs

46 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (First Chamber) hereby rules:

1. Article 2(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, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as meaning that Directive 2001/83, as amended by Directive 2004/27, does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, without its being possible to exclude that possibility.

2. Article 1(2)(b) of Directive 2001/83, as amended by Directive 2004/27, must be interpreted as meaning that the characteristics of the manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail are still relevant to determining whether that product falls within the definition of a medicinal product by function.

3. Article 1(2)(b) of Directive 2001/83, as amended by Directive 2004/27, must be interpreted as meaning that, apart from the case of substances or combinations of substances intended for the purpose of making a medical diagnosis, a product cannot be regarded as a medicinal product within the meaning of that provision where, having regard to its composition – including its content in active substances – and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.

OPINION OF ADVOCATE GENERAL

TRSTENJAK

delivered on 19 June 2008 (1)

Case C-140/07

Hecht-Pharma GmbH

v

Staatliches Gewerbeaufsichtsamt Lüneburg

(Reference for a preliminary ruling from the Bundesverwaltungsgericht (Germany))

(Directive 2001/83/EC, as amended by Directive 2004/27/EC – Pharmaceutical products – Concept of ‘medicinal product by function’ – Rule of doubt in Article 2(2) of Directive 2001/83/EC – Relevant criteria in determining whether a product is a medicinal product – Account to be taken of the intended dosage – Free movement of goods – Public health – Principle of proportionality)

I – Introduction

1. By its reference for a preliminary ruling pursuant to Article 234 EC the Bundesverwaltungsgericht (Federal Administrative Court) has referred three questions to the Court of Justice of the European Communities concerning the interpretation 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)

2. These questions have been raised in proceedings brought by Hecht-Pharma GmbH (‘the appellant’) contesting a decision of the Bezirksregierung Lüneburg (District Administration, Lüneburg, ‘the respondent’) prohibiting Hecht-Pharma from marketing a product, which was actually declared as a food supplement and known as ‘Red Rice’, on the ground that it was a medicinal product that required authorisation but had not been authorised.

3. The question at the centre of the legal dispute in the main proceedings is whether the product in question comes within the definition of a medicinal product and whether the respondent was entitled to proceed on the basis that it required authorisation. Consequently, the Court must here examine the criteria upon which the Member States’ authorities have to base their decision to apply the law on medicinal products and the degree of certainty necessary with regard to the pharmacological action of a product for the purpose of classifying it as a medicinal product.

II – Legal context

A – Community law

4. Under Article 1(2) of Directive 2001/83, the term ‘medicinal product’ referred to:

‘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.’

5. Directive 2004/27/EC (3) of the European Parliament and of the Council of 31 March 2004 has now amended this definition. It now reads as follows:

‘(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings, or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.’

6. Directive 2004/27 also reformulated Article 2 of Directive 2001/83 and introduced a new Article 2(2). Article 2(2) states:

‘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 this Directive shall apply.’

B – National law

7. Under Paragraph 69(1) of the German Arzneimittelgesetz (Law on medicinal products, ‘the AMG’), the competent authorities are required to take the necessary steps to eliminate infringements that have been confirmed and to prevent future infringements. They may, in particular, prohibit the placing on the market of medicinal products in, the absence of the necessary authorisation or registration of such products.

III – Facts and main proceedings

8. The appellant in the main proceedings operates a pharmaceutical wholesale business. In October 2002 the Arzneimittelkommission der deutschen Apotheker (Committee for medicinal products of German pharmacists) informed the Bezirksregierung Lüneburg (District Administration, Lüneburg) that the appellant had announced that from 1 September 2002 it would place on the market a product under the name ‘Red Rice 330 mg GPH Kapseln’ containing the active substance monacolin k. That substance is identical with lovastatin, a cholesterol synthesis inhibitor which is marketed in Germany as a prescription medicinal product.

9. The capsules in issue are marketed in plastic bottles with labels stating inter alia: Red Rice, 330 mg, food supplement with fermented rice. It is further stated: ‘One capsule contains 330 mg of red yeast rice corresponding to 1.33 mg of monacolin k’. The ingredients are stated to include 71% red rice powder. The recommendations for use read: ‘As food supplement, 1 capsule 1-3 times daily’.

10. On 4 December 2002 the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for medicinal products) issued a press release warning against the consumption of red rice products. With the simultaneous taking of red rice and medicinal products to reduce high cholesterol values, an increased risk of side-effects was to be feared; these could take the form in particular of damage to muscle tissue. On application by the Bezirksregierung Lüneburg, the Bundesinstitut stated that the product marketed by the appellant, on the basis of its predominant purpose, was a medicinal product within the meaning of Paragraph 2(1) of the AMG; the substances contained in the product were liable to influence the body or its condition.

11. The Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (Office for consumer protection and food safety of the Land of Lower Saxony) concluded in a report of 6 December 2002 that classification of the product as a food supplement, and hence as a foodstuff, was not justified. The reference on the packaging drew attention in particular to the ingredient monacolin k, which is not a nutrient but a therapeutically active substance.

12. By decision of 19 December 2002, the Bezirksregierung Lüneburg prohibited the appellant from marketing the product at issue in Germany. As grounds it stated that the product was a medicinal product and had not obtained the requisite authorisation. The appellant's objection was dismissed by the Bezirksregierung by decision of 11 June 2003.

13. By its application the appellant submitted that classification as a medicinal product is possible only if, on the basis of its dosage and recommended daily consumption, the product produces a pharmacological effect, which must be proved by the authorities, something which did not happen in the present case. The product marketed was, the appellant argued, fully in line with a series of other foodstuffs which also had a positive effect on cholesterol levels, such as margarine ('Becele') or salmon-oil capsules. Classification as a medicinal product, by contrast to its classification in Austria as a foodstuff, amounted, in the view of Hecht-Pharma, to an unlawful restriction on trade.

14. The Verwaltungsgericht (Administrative Court) dismissed the action by judgment of 28 April 2005. The appellant's appeal was dismissed by the Niedersächsisches Oberverwaltungsgericht (Higher Administrative Court of Lower Saxony) by judgment of 23 March 2006. While the product marketed by the appellant, the latter court found, did indeed fall within the currently valid concept of a food, it also satisfied the definition of a medicinal product.

15. That classification was, however, of no legal relevance here, since the precedence of the provisions of the law on medicinal products followed from Paragraph 2(2) of the Lebensmittel- und Futtermittelgesetzbuch (Food and Feedstuffs Code, 'the LFGB'), in conjunction with 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, (4) and Article 1 of Directive 2001/83 on medicinal products for human use, as amended by Directive 2004/27.

16. The product at issue was, the Niedersächsisches Oberverwaltungsgericht found, in all probability to be classified as a medicinal product by function. It contained a significant level of monacolin k. That active substance was synonymous with lovastatin, a well-known inhibitor of cholesterol synthesis. The substance lovastatin was contained as a pharmaceutically active component in a number of prescription medicinal products. Inhibitors of cholesterol synthesis and other medicinal products used to reduce fatty substances in

the blood could have serious side-effects on the muscles and kidneys. Risks and interactions of such substances were expressly pointed out in the package leaflets of medicinal products on the market for reducing cholesterol. Depending on dosage, monacolin k inhibited cholesterol production of the liver and thus lowered the cholesterol level of the blood in humans and stabilised fat metabolism. Taking the product at issue was therefore liable to lower high cholesterol values, which are regarded as a risk factor for the heart and the circulation, and so contributed to the fulfilment of a therapeutic purpose. That suggested that the product in question is a medicinal product by function.

17. The appellant could not rely on the fact that a pharmacological effect of the product at issue could be ruled out if the recommended consumption was followed. The recommended consumption led to a daily dose of 1.33 mg to 4 mg of monacolin k. That was indeed low when compared with the daily dose of 10 mg to 80 mg recommended for lovastatin. However, the appellant could not conclude from that that the product which it marketed had no pharmacological effect. What mattered was, rather, whether it was comparable with properly authorised medicinal products. Even if the daily dose, if the recommended consumption was followed, was low for the product at issue in comparison with prescription medicinal products, account had to be taken of the fact that preparations declared as food supplements were as a rule taken unsupervised and in greater quantities than recommended.

18. Since the pharmacological effect had not, however, been demonstrated with complete certainty, the rule of doubt in Article 2(2) of Directive 2001/83 came into play. Its application did not require it to be shown that the criteria governing the definition of a medicinal product had been satisfied. In accordance with the wording, it was sufficient that a product could fall within the definition of a medicinal product. The rule of doubt was designed to make it easier for the authorities to classify borderline products.

19. By its appeal on a point of law, the appellant argues that the Niedersächsisches Oberverwaltungsgericht erred in basing itself on the rule of doubt. It submits that that rule is intended merely to ensure that the law on medicinal products takes precedence over other provisions where the product in question is indubitably a medicinal product. It submits that that court wrongly assumed that the product in issue was or could be a medicinal product by function. If the recommended consumption is observed, the daily dose of monacolin k consumed is significantly below the quantity needed to achieve a pharmacological effect. The appellant submits that that court ought, if appropriate, to have had the point clarified by an expert.

IV – Questions referred

20. The Bundesverwaltungsgericht is unsure as to the correct interpretation of the Community-law provisions and has therefore stayed the proceedings and referred the following questions to the Court for a preliminary ruling:

(1) Does the rule of doubt in Article 2(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, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, mean that Directive 2001/83 applies to a product which could possibly be classified as a medicinal product but whose quality as a medicinal product has not been positively determined? What degree of probability, and hence what degree of elucidation of the facts, may be required in order to justify the application of Directive 2001/83?

(2) Can a product which is not a medicinal product by presentation be regarded as a medicinal product by function within the meaning of Article 1(2) of Directive 2001/83, as amended by Directive 2004/27, because of a component which can produce physiological changes in a certain dosage but whose dosage in the product to be assessed – if used as intended – is too low for that? Is this question to be allocated to the criterion of “pharmacological action” or the criterion of “modifying physiological functions” in human beings?

(3) Are the characteristics of “the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail” (judgment in [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 51) stated in the case-law of the Court of Justice to be relevant, in addition to the pharmacological qualities, to classification as a medicinal product still relevant following the new definition of a medicinal product introduced by Directive 2004/27?

V – Proceedings before the Court

21. The order for reference was received at the Court Registry on 12 March 2007.

22. The parties to the main proceedings, the Governments of the Hellenic Republic, the Republic of Poland and the United Kingdom, and the Commission submitted written observations within the period specified in Article 23 of the Statute of the Court of Justice.

23. Representatives of the parties to the main proceedings and of the Hellenic Republic, the Republic of Poland, the United Kingdom and the Commission presented oral submissions at the hearing held on 24 April 2008.

VI – Basic arguments of the parties

A – The first question

24. The appellant in the main proceedings proposes to the Court that the answer to the first question should be that the so-called rule of doubt in Article 2(2) of Directive 2001/83, as amended by Directive 2004/27, should apply only where it has been positively established that a product is a medicinal product. In other words, the product must satisfy the requirements laid down in Article 1 of Directive 2001/83, as amended by Directive 2004/27.

25. The respondent in the main proceedings proposes to the Court that the answer to the first question should be that the rule of doubt in Article 2(2) of Directive 2001/83, as amended by Directive 2004/27, refers

to any technically justified doubt on the part of the competent administrative authorities. It submits that the degree of elucidation of the facts arises from the national provisions which the national authorities are obliged to follow.

26. In relation to the first question, the Hellenic Republic takes the view that the product in issue should be classified as a medicinal product, to which Directive 2001/83 must be applied.

27. The Commission and the United Kingdom take the view that Article 2(2) of Directive 2001/83 must be interpreted as meaning that Directive 2001/83 is to be applied only to a product in respect of which it has been determined that, in the light of the current state of scientific knowledge, it has the characteristics of a medicinal product.

28. The Commission adds that the intention of the legislature in adopting Directive 2004/27 was, on the one hand, to define the concept of a medicinal product by means of a more precise definition of the type of effect which the medicinal product may have on physiological functions. On the other hand, it argues, the intention was to decree expressly that the provisions on medicinal products are to be applied to products which come within the definition of medicinal products, even if, in certain circumstances, those products could come within the definition of other regulated products, such as foods and food supplements. In those circumstances, however, the provisions concerning other regulated products would not apply.

29. The Republic of Poland takes the view that the rule of doubt in Article 2(2) of Directive 2001/83, as amended by Directive 2004/27, means that Directive 2001/83 may be applied to a product that might possibly be classified as a medicinal product where there is a justified scientifically-based assumption, based for example on clinical trials, epidemiological data, statements in academic writing etc., that a certain dosage of this product can produce a pharmacological, immunological or metabolic action, without it first being necessary to determine positively the product’s characteristics as a medicinal product, in other words, without it first being necessary to conduct a procedure in conjunction with an application for authorisation of the placing on the market of a medicinal product pursuant to Directive 2001/83, as amended by Directive 2004/27. It submits that the application of Article 2(2) must be supported by the criteria listed in the relevant directive, in particular in relation to evidence of the pharmacological action of the product, or in other words, the characteristic of its clinical effectiveness; it must be justified by means of available data and scientific evaluation.

30. The Republic of Poland further submits that that the ‘required degree of elucidation of the facts’ to justify the application of Directive 2001/83, as amended by Directive 2004/27, means a scientific evaluation giving reasons carried out with the necessary care by the authorities and a case-by-case assessment carried out on this basis, based on the criteria listed in Directive 2001/83, as amended by Directive 2004/27, in

particular in relation to the evidence of effectiveness. For this purpose, neither the conduct of a procedure for authorisation of the marketing of a medicinal product within the meaning of the above directive, nor the adoption of a decision on the relevant authorisation can be required. However, that does not mean that the decision in this matter is not subject to judicial review. It is impossible to fix a general and abstract rule, removed from an individual case, which determines the degree of probability of pharmacological action for all potential products and for the future.

B – The second question

31. The appellant in the main proceedings submits that a physiological change is a normal function of the human body and is accordingly not pathological. In relation to the first part of the second question, it asserts that for every medicinal product it depends on the dosage in which it is administered. A product cannot be regarded as being a medicinal product by function if, in the intended dosage, it does not produce a pharmacological action as a medicinal product because it does not exceed the threshold of the minimum effective dose.

32. The respondent in the main proceedings proposes that the answer to the second question referred should be that a product which is not a medical product by presentation can be regarded as a medicinal product by function within the meaning of Article 1(2) of Directive 2001/83, as amended by Directive 2004/27, irrespective of the dosage. Further, it submits that the recommended dosage for a food supplement product cannot be conclusive for the purpose of evaluating an active pharmaceutical ingredient which is on the market, or could come onto the market, in a higher concentration as a medicinal product.

33. The Hellenic Republic considers that a product may be a medicinal product either as a result of its presentation or as a result of its effects. The dosage is immaterial inasmuch as the desired or actual effect is decisive (something that is apparent only from clinical studies, that is, when a medicinal product is involved). Moreover, the term ‘substance’ in Article 1(3) of Directive 2001/83 is defined very broadly and covers all cases in which the ‘substance’ operates or is presented in the manner indicated in Article 1(2) of the directive in relation to ‘medicinal product’.

34. It submits that, since the Food Supplements Directive does not refer to restoring, correcting or modifying physiological functions, but rather to the normal development of the human organism and maintenance of good health, both in conjunction with the abovementioned assumption in favour of a medicinal product in cases of doubt and on the basis that establishing positive lists of substances for food supplements is envisaged, it is clear that the distinguishing criteria of ‘pharmacological action’ or ‘modifying physiological functions’ in human beings proposed in the second question are irrelevant. It is sufficient if one of the two criteria is satisfied.

35. The Republic of Poland takes the view that a product which is not a medicinal product by presentation may be regarded as a medicinal product within the

meaning of Article 1(2) of Directive 2001/83, as amended by Directive 2004/27, by virtue of a component which in certain dosages can restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action (prevention or cure of illnesses), but the dosage of which in the product to be assessed – if used as intended – is too low for that, only if, according to scientific data, the present state of scientific knowledge or the experience of the competent authorities, the daily consumption of that substance may be associated with a risk to human life or health, for example due to interactions with other products or because of side-effects. However, in cases of doubt such a product cannot be treated as being a medicinal product by function if it does not have any effect and at the same time falls clearly within the definition of a product other than a medicinal product.

36. It submits that it is always necessary to make an assessment on a case-by-case basis in relation to the product and the substance it contains, both on the basis of information and documentation provided by the manufacturer and on the basis of other available scientific data, in particular concerning interactions and side-effects which, according to the present state of scientific knowledge and the experience of the competent authorities, can be produced by a certain dose.

37. The United Kingdom and the Commission refer to the case-law of the Court, and in particular to the judgment in *Van Bennekom* (Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraphs 26 to 29), in which the Court held that vitamins could not, as a general rule, be regarded as medicinal products, since they were consumed only in small quantities. However, the Court drew a distinction between, on the one hand, vitamins and, on the other, vitamin or multi-vitamin preparations, stating that the latter were generally used in large doses for therapeutic purposes in combating certain diseases other than those resulting from vitamin deficiency.

38. The United Kingdom proposes that the answer to the second question should be that a product which is not a medicinal product by presentation can be regarded as a medicinal product by function within the meaning of Article 1(2) of Directive 2001/83, as amended by Directive 2004/27, because of a component which can produce physiological changes in a certain dosage, but the dosage of which in the product to be assessed – if used as intended – is too low for that. It should be regarded as a medicinal product by function, if consideration of the relevant factors as a whole leads to the conclusion that the product is used in or administered to human beings ‘with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action’. The significance of dosage cannot be confined to the criterion of pharmacological effect.

39. The Commission proposes that the second question referred should be answered to the effect that a product can be regarded as a medicinal product by function within the meaning of Article 1(2) of Directive

2001/83, as amended by Directive 2004/27, only if, due to its dosage when used as intended, it is capable of appreciably influencing physiological functions by exerting a pharmacological, immunological or metabolic action.

C – The third question

40. In relation to the third question the appellant in the main proceedings takes the view that the term ‘medicinal product’ was re-defined by Directive 2004/27. It argues that it was the intention of the Community legislature that the term ‘medicinal product’ should be construed more objectively than had previously been the case. The characteristics of ‘the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail’ could not be decisive for the purposes of the classification of a product as a medicinal product. Such divergent assessments on the basis of these criteria are not necessary either from the point of view of protection of health. If a product is presented as a medicinal product without having a corresponding effect, it comes within the first limb of the medicinal product definition in Directive 2001/83, as amended by Directive 2004/27. However, if a product is shown to have a pharmacological effect, then the second limb of the definition is fulfilled, namely that of the medicinal product by function, with the result that the consumer is also protected.

41. The respondent in the main proceedings submits that the answer to the third question should be that the characteristics of ‘the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail’ are still relevant.

42. The Hellenic Republic takes the view that the abovementioned criteria – taken into account in the alternative – remain extremely relevant characteristics, since the primary reason for the adoption of detailed rules by the Community legislature for products which are connected with public health must be considered to be to ensure a high level of protection of consumers’ health in accordance with the corresponding requirements of the Treaty.

43. The Republic of Poland proposes that the third question referred should be answered to the effect that, following the new definition of a medicinal product introduced by Directive 2004/27, taking into account the case-law of the Court, the starting point for the classification of a product as a medicinal product by the national authorities must be the definition of ‘medicinal product’ in Directive 2001/83, as amended by Directive 2004/27, in relation to the pharmacological, immunological or metabolic action, or to the making of a medical diagnosis. In addition to that, the authorities must take into account the general characteristics of the product which continue to be relevant (‘the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail’ – judgment in *HLH Warenvertrieb and Orthica*) and the features which are listed in detail in Directive 2001/83, as amended by Directive 2004/27, such as, for example, the risk of side-effects, the efficacy of the product as determined by clinical trials, risks related to

use of the medicinal product, the risk-benefit balance and the presentation of the product.

44. The United Kingdom and the Commission propose that the answer to the third question should be that, for the purpose of classifying a product as a medicinal product, the characteristics of the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail are also determinant in view of the definition in Article 1(2) of Directive 2001/83, as amended by Directive 2004/27.

45. In relation to that point, the Commission states that the amendment of Directive 2001/83 by Directive 2004/27 merely specified more precisely the possible effects of a product for the purpose of its classification as a medicinal product. While not being constituent parts of the legal definition of a medicinal product, the other aspects which the Court took into account in its judgments concerning the legal position prior to the amendment of Directive 2001/83 are, in the Commission’s view, unaffected by that amendment.

VII – Legal appraisal

A – Introductory comments

46. The legal demarcation of foodstuffs, food supplements and medicinal products has always been problematic, but is of great significance for legal practice, since substantively different legal provisions apply to each of these categories of products. (5) A product which is subject to the law on foodstuffs must be dealt with in a fundamentally different way, from a legal perspective, to a product which comes under the law governing medicinal products. The food supplements which are flooding the market are particularly susceptible to this problem, since it is not unusual for them to be classified as medicinal products on the basis of the health-promoting properties attributed to them.

47. An attempt may be made to make the necessary differentiation with the aid of legal definitions which are laid down in the applicable Community-law provisions. Whilst Directive 65/65/EEC introduced a uniform Community-wide definition for medicinal product as early as in 1965, the concept of foodstuff was harmonised only in 2002 by Regulation (EC) No 178/2002 (6) and the concept of food supplement shortly afterwards by Directive 2002/46/EC. (7) However, even since harmonisation of the concepts, distinguishing between them precisely is sometimes associated with considerable difficulties, due not least to the fact that these legal definitions overlap. Consequently, the Community legislature again attempted to address this problem of distinguishing between these concepts by adopting Directive 2004/27. In particular, the latter directive changed the content of the legal definition of medicinal product by function in Article 1(2) of Directive 2001/83 and in Article 2(2) of Directive 2001/83 introduced a new provision in relation to the applicability of the legal provisions on medicinal products in the event of doubts as to classification.

48. The questions referred by the Bundesverwaltungsgericht which are to be examined below, concern, *inter alia*, both the Community-law definition of a me-

dicinal product by function and the normative significance of the so-called rule of doubt.

B – The first question

1. Meaning of the rule of doubt in Article 2(2) of Directive 2001/83

49. The key feature of the main proceedings is that the product in issue was not definitively classified by the national authorities and courts as a medicinal product by function, but only classified as being such ‘in all probability’. It can be seen from the order for reference that, according to German administrative practice and case-law, in order for a product to be classified as a medicinal product the positive determination of that product’s characteristics as a medicinal product is not required but a degree of probability is regarded as sufficient. The legal view taken by the Niedersächsisches Oberverwaltungsgericht in the main proceedings is based in particular on the rule of doubt in Article 2(2) of Directive 2001/83.

50. By contrast, the Bundesverwaltungsgericht, in its role as a national court of appeal on points of law, casts doubt on whether that interpretation is correct, since in its opinion it would lead to a significant extension of the scope of the law on medicinal products, without conclusively clarifying whether the product concerned is indeed a medicinal product.

51. In my opinion, the Bundesverwaltungsgericht’s concerns are entirely justified. The interpretation favoured by the appellate court amounts in fact to regarding Article 2(2) of Directive 2001/83 as a rule of presumption or a rule of evidence, under which a certain degree of probability suffices for the purpose of accepting, in an individual case, that a product has the characteristics of a medicinal product by function. (8) However, no support can be found in Community law for such an interpretation of the rule of doubt.

52. Rather, the spirit and purpose of the provision and the intention of the Community legislature, documented both in the recitals and in the legislative history of Directive 2004/27, suggest that Article 2(2) of Directive 2001/83, as amended by Directive 2004/27, is designed to anchor statutorily the precedence, established in the Court’s case-law, of the legal provisions governing medicinal products law provisions over the legal provisions relating to foodstuffs or food supplements. In this respect the law governing medicinal products constitutes a *lex specialis vis-à-vis* the law governing foodstuffs and food supplements.

53. Since the judgments in *Delattre* (9), *Monteil* and *Samanni* (10) and *Ter Voort*, (11) the Court has expressed the view in its established case-law that a product which is presented as possessing therapeutic or prophylactic properties, or which is intended to be administered with a view to restoring, correcting or modifying physiological functions, 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. The Court mostly recently issued a reminder of this in its judgment of 15 November 2007 in Case C-319/05 *Commission v Germany*. (12)

54. By means of the application of the strict provisions on medicinal products to those products which cannot be classified beyond all doubt because, as a result of their objectively determined qualities, they could also be classified as foodstuffs, food supplements or even as cosmetic products, account is taken of the objective pursued by Directive 2001/83 of protecting public health. This case-law reflects the awareness that the use of medicinal products is associated with particular risks. (13) Consequently, only those Community-law provisions which specifically apply to medicinal products apply to a product which fulfils both the criteria for a food supplement and those for a medicinal product.

55. As evidence of the fact that Article 2(2) of Directive 2001/83 enshrines statutorily the precedence to be accorded to the provisions on medicinal products and is not, for instance, to be conceived as a rule of presumption or a rule of evidence, *HLH Warenvertrieb* and *Orthica* (14) may be cited, in which the Court expressly referred to that provision. (15) In that case the Court first of all referred to the abovementioned case-law on the precedence of the legal provisions on medicinal products and then, to confirm its reasoning, cited the rule of doubt introduced by Directive 2004/27. It may be concluded from this, as Advocate General Geelhoed (16) correctly stated in his Opinion in the same case, that Article 2(2) of Directive 2001/83 merely explicitly states what is already valid law pursuant to the legislation and the case-law.

56. This rule of precedence also supplements the provisions contained in the Community-law provisions on foodstuffs and food supplements, which exclude from their scope of application all those products which must be categorised as medicinal products, regardless of whether they also fulfil the conditions of the relevant directive. This applies, for instance, to Article 2(d) of Regulation No 178/2002 (17) with regard to the distinction between foodstuffs and medicinal products, and to Article 1(2) of Directive 2002/46, (18) which relates to the distinction between food supplements and medicinal products.

57. This conclusion is further confirmed by recital 7 in the preamble to Directive 2004/27. According to that recital, the introduction of the rule of doubt is evidently a reaction to the fact that scientific and technical progress has resulted in an increase in the number of so-called ‘borderline’ products between the medicinal product sector and other sectors. From the perspective of the law on medicinal products, this concerns products coming fully within the definition of a medicinal product but which possibly also come within the definition of other regulated products. (19)

58. The intention of the legislature in adopting Directive 2004/27 was, on the one hand, to state the concept of a medicinal product more precisely by means of a more detailed definition of the type of effect that the medicinal product may have on physiological functions. On the other hand, for the purposes of ensuring legal certainty, an indication was to be expressly given that the provisions on medicinal products must be

applied to products which fall within the definition of medicinal products. In such cases the provisions relating to other regulated products do not apply, even if the medicinal product might also correspond to the definition of those other products.

59. In this respect one must concur with the view expressed by the Bundesverwaltungsgericht in paragraph 23 of the order for reference that, in particular, the second sentence of recital 7 in the preamble to Directive 2004/27 assumes that the criteria for a medicinal product are satisfied, while doubts arise only as a result of the additional classification in other areas of law. This understanding of the concept of doubt forms the basis of Article 2(2) of Directive 2001/83. By contrast, it is clearly not intended to mean the doubt which results from an inadequate determination of the characteristics as a medicinal product, for instance due to the authorities' lack of scientific knowledge. (20)

60. The Bundesverwaltungsgericht acknowledges difficulties in interpretation in view of the formulation used in the seventh sentence of recital 7. That sentence states that Directive 2001/83 should not apply where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics. As the Bundesverwaltungsgericht correctly states, that formulation cannot be found in the text of Article 2(2) of Directive 2001/83, as amended by Directive 2004/27. However, in my opinion it is not relevant to the case to be decided here.

61. As the Commission correctly observes, referring to the legislative process which led to the adoption of Directive 2004/27, (21) the wording of the seventh sentence of the seventh recital amounts to nothing more than a clarification of the fact that, in cases where it is entirely clear that a product is, for instance, a foodstuff, a food supplement or a cosmetic product, the national authorities should not regard themselves as compelled also to examine whether it possesses the characteristics of a medicinal product if there is no evidence pointing in that direction. In other words, this formulation means that the rule of doubt should apply only in cases of doubt and not if a product is clearly to be categorised in one or other product group. (22) In this respect there is no contradiction between the recitals in the preamble to Directive 2004/27 and the wording of the rule of doubt introduced into Directive 2001/83.

62. It follows that Article 2(2) of Directive 2001/83, as amended by Directive 2004/27, does not introduce any rule of presumption or rule of evidence, but merely enshrines in statutory form the principle of the precedence of the law governing medicinal products which has long been recognised in the case-law of the Court. (23)

2. The requirement that characteristics as a medicinal product be positively determined

63. Regarding the remainder of the question, as to whether classification as a medicinal product requires a positive determination of characteristics as a medicinal product, I would like to recall, as previously in my Opinion of 21 June 2007 in *Commission v Germany*,

(24) that in order for a product to be classified as a medicinal product, the Court requires that there must be sufficient certainty that products in respect of which it is claimed that they have an effect as medicinal products actually do have that effect. The existence of both the particular dangers and the effect as a medicinal product must be examined by reference to information based on sound scientific research.

64. In accordance with settled case-law, (25) in order to determine whether a product should come within the definition of a medicinal product by function within the meaning of Directive 2001/83, the competent national authorities, subject to judicial review, are obliged to work on a case-by-case basis, having regard to all of the product's characteristics, 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.

65. Against the background of this clear case-law, the national authorities are required to apply the legislation on medicinal products only where, in the light of the present state of scientific knowledge, they have positively determined that the product in question is indeed a medicinal product. (26) With regard to the requisite degree of elucidation of the facts, it is to be required that the review of the characteristics as a medicinal product must be based upon the present state of scientific knowledge. (27)

66. In so far as uncertainties persist in the present state of scientific research, (28) it is for the Member States, in the absence of harmonisation, to decide what degree of protection of health and life of humans they intend to ensure, having regard, however, to the requirements of the free movement of goods within the Community and whether they require prior authorisation for placing foodstuffs on the market. (29) That discretion relating to the protection of health is particularly significant where it is shown that uncertainties continue to exist in the current state of scientific research as to certain substances, which are not as a general rule harmful in themselves, but which may have particular harmful effects if taken to excess as part of general nutrition, the composition of which cannot be foreseen or monitored. (30)

67. This conclusion may also be justified on the basis of a teleological interpretation of Community law. It best corresponds to the aim of Community law on medicinal products to ensure the free movement of goods by establishing an internal market for medicinal products but at the same time safeguarding the best possible protection of public health. (31) The strict law on medicinal products, and in particular the requirement for authorisation in order to place a medicinal product on the market pursuant to Article 6(1) of Directive 2001/83, constitutes a barrier to trade which is justified on grounds of public health. (32) It attempts to harmonise the free movement of goods and the protection of public health in such a way that both aims can be achieved as far as possible. A balancing of these aims,

taking into account the principle of proportionality, would not sanction a measure constituting an obstacle to the marketing of a product on the basis of mere suspicion of a pharmacological effect or where the probability of such an effect has not been established in detail. On the contrary, the practical implementation of both of these aims would be severely impaired.

68. At the same time, I would like to recall the disadvantages which result from an overly extensive interpretation and application of the definition of medicinal product, particularly in my opinion in the event of an incorrectly supported application of the definition which is not based on adequate scientific knowledge. First of all, the concept of 'medicinal product' would cease to have any distinguishing force if it were to include products the properties and action of which did not justify such classification. This would harm, rather than serve, the interests of human health. Secondly, it could result in the specific Community rules governing certain categories of food – containing provisions relating to the particular risks of the products – losing their regulatory purpose; one thinks, in the present case, of Directive 2002/46 on food supplements. Thirdly, a 'creeping' extension of the scope of Directive 2001/83 to include extraneous products would be detrimental to the free movement of goods. (33)

69. Accordingly, in the interests of achieving, as far as possible, the free movement of goods and the protection of public health, a positive determination, by scientific means, that a product has the characteristics of a medicinal product must always be required. (34)

C – The second question

1. The intended dosage as an assessment criterion

70. In asking the second question, the Bundesverwaltungsgericht in essence seeks to determine whether the existence of any amount of a component, which can produce physiological changes in a certain dosage, results in a product which contains this component being a medicinal product by function.

71. The definition of medicinal product by function in Article 1(2)(b) of Directive 2001/83 should be understood as meaning that it only includes those substances or combinations of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. This concept of medicinal product includes products with real or advertised effects which can affect the body by appreciably modifying the way in which it functions. (35) As explained above, (36) the competent national authorities, subject to judicial review, are obliged to verify this on a case-by-case basis having regard to all of the characteristics of the relevant product, including the manner in which it is used.

72. Logically it would be necessary for the competent national authorities also to have to base their assessment on the dosage recommended by the manufacturer, since the manner in which the product is to be used can be seen from the recommended dosage.

73. As the Bundesverwaltungsgericht, the United Kingdom Government and the Commission correctly observe, important conclusions may be drawn from the case-law of the Court on the classification of vitamin preparations, which assist in answering the second question referred.

74. First of all in *Van Bennekom* (37) the Court held that vitamins may not, as a general rule, be regarded as medicinal products since they are only consumed in small quantities. However, the Court then emphasised that vitamin or multi-vitamin preparations are sometimes used, generally in large doses, for therapeutic purposes in combating certain diseases other than those of which the morbid cause is a vitamin deficiency. Consequently, the Court concluded that in such cases it is beyond dispute that the vitamin preparations are medicinal products. In so doing the Court saw itself as being confronted with the particular situation that, in the state of scientific knowledge at the time, it was impossible to specify the level of concentration above which such a vitamin preparation would fall within the Community definition of a medicinal product. (38) The Court therefore decided that the classification of a vitamin as a medicinal product within the meaning of the definition of a medicinal product by function must be carried out on a case-by-case basis, having regard to the pharmacological properties of each such vitamin to the extent to which they have been established in the present state of scientific knowledge.

75. On the basis of this argumentation, in *Commission v Germany* (39) the Court ruled incompatible with Community law a national administrative practice under which vitamin preparations which were legally manufactured or placed on the market in other Member States as food supplements were automatically classified as medicinal products if they exceeded three times the daily amount recommended by the *Deutsche Gesellschaft für Ernährung* (German Food Association). In relation to this finding it was decisive that the three-fold rule was automatically applied by the national authorities, without any assessment being made on a case-by-case basis by reference to the different vitamins added or to the risk associated with taking them. (40)

76. It appears important to me to draw attention to the fact that in the judgments cited above the Court examined the varying effect of vitamins entirely based on the respective dosage and clearly refrained from allocating vitamins to a particular category of products – namely medicinal products – solely on the basis of their potentially harmful effects. The Court's findings thus confirm my view that it is not possible to draw scientifically accurate conclusions in relation to a product's characteristics as a medicinal product without taking into account the respective intended dosage. (41)

77. In addition, it is necessary to take into account that, in classifying a product, the principle of proportionality, as a general principle of Community law, is of special significance, particularly because in settled case-law since *Sandoz* (42) the Court has stated (43) that, 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 in proportion to the objective thus pursued, and the measures chosen to attain that objective must be those which are least restrictive of intra-Community trade.

78. With particular regard to the justification for a requirement of authorisation to placing food supplements on the market, the Court ruled in *Van Bennekom* (44) that it is for the national authorities to demonstrate in each case that a national provision which restricts the free movement of goods is necessary and, in particular, to show that the marketing of the product in question creates a serious risk to health. The greater the legal and factual requirements for marketing a product, the heavier will be the burden of justification for the Member State in question. 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. (45)

79. In light of the foregoing, I conclude that it is contrary to both the assessment criteria applied by the Court since *Van Bennekom* and to the principle of proportionality for a national authority to classify a particular product as a medicinal product without its being possible to specify with certainty the level of concentration above which that product exceeds the threshold of a foodstuff and is to be regarded as a medicinal product.

80. Any other interpretation would ultimately amount to relieving the national authorities of the obligation to assess the pharmacological effect on a case-by-case basis, since they could in any event rely on a possible risk to health caused by consumption in greater quantities in order to find that that product has the characteristics of a medicinal product. (46) This simplified and undifferentiated consideration of the pharmacological qualities of the respective product would not merely take insufficient account of the special features of the individual case. It would also be incompatible with Community law, since it would be contrary to the aims of free movement of goods and the protection of public health which the Community law on medicinal products seeks to pursue. It would restrict the free movement of goods even though it might be certain that the pharmacological effect would not be achieved if the product was used as intended. Such a restriction would not be justifiable from the perspective of the protection of public health.

2. Criterion of ‘pharmacological action’

81. Against the background of the amendment of Directive 2001/83 by Directive 2004/27, the *Bundesverwaltungsgericht* asks whether this question should be allocated to the criterion of ‘pharmacological action’ or to the criterion of ‘modifying physiological functions in human beings’.

82. The characteristic of a ‘pharmacological action’ refers to one of the criteria which have already been mentioned, (47) which may, according to the case-law of the Court, be taken into account in order to ascertain

whether a product falls within the definition of a medicinal product by function. (48) As a result of the new definition introduced by Article 1(1)(a) of Directive 2004/27, in addition to the criterion of immunological and metabolic action, the issue of whether a substance or combination of substances is capable of ‘restoring, correcting or modifying physiological functions’ has become a factor recognised by the Community legislature for the assessment. However, in embodying this characteristic in positive law, Directive 2004/27 has not in itself brought about a change in the legal position. Rather, the amendment to the wording is significant only in terms of clarification, since it reproduces the pre-existing legal situation.

83. The second part of the second question referred essentially seeks a determination as to whether the Member States’ authorities and courts are required, in assessing the immunological and metabolic action of a product, also to consider the intended dosage. Consideration of the dosage is first of all supported by the fact that, according to the wording of Article 1(2)(b) of Directive 2001/83, the three types of action rank equally. Further, no scientific reasons can be provided for the theory that the intended dosage is a criterion which is relevant solely to the assessment of the pharmacological action of a product.

84. Having regard to the fact that the Court’s case-law, and in particular the principle of proportionality, as a general legal principle of Community law, demand that, in assessing a product’s characteristics as a medicinal product, the pharmacological effect, which is dependent on the intended dosage, must be taken into account, I am of the opinion that it is absolutely mandatory to take this criterion also as a basis for assessing the immunological and metabolic action of a product.

D – The third question

85. Finally, the *Bundesverwaltungsgericht* seeks to determine whether, as a consequence of the new definition of a medicinal product introduced by Directive 2004/27, the characteristics of ‘the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail’ are no longer relevant to this definition.

86. With the exception of the appellant in the main proceedings, all of the parties before the Court argue that these characteristics are still relevant following the new definition of a medicinal product in Article 1(2) of Directive 2001/83. That legal point of view appears preferable to me, taking into account the spirit and purpose of those characteristics, the wording of the new definition of medicinal product by function and also the legislative intention of the Community legislature as expressed in the recitals in the preamble to Directive 2004/27.

87. The abovementioned characteristics constitute further criteria which are relevant in addition to the characteristic of ‘pharmacological properties’, which the Court has to date, in its settled case-law, (49) applied to the assessment of the question whether a particular product should be classified as a medicinal product by function. At the same time, the Court

clearly did not intend to regard this list of criteria as exhaustive, particularly since it proceeded on the basis of the national authorities' duty, in the context of the case-by-case assessment, to take into account 'all characteristics' of the product, 'particularly' those expressly mentioned. It should also be explained that the Court also regarded the risk that the use of the product at issue may entail for health as an autonomous factor. (50) 88. However, there is no reason to conclude that the new definition of a medicinal product, and in particular the inclusion of the concept of 'pharmacological action' in Article 1(2)(b) of Directive 2001/83, would have been intended to replace the other characteristics developed in the case-law. On the contrary, it is apparent from recital 7 in the preamble to Directive 2004/27 that the new definition was intended merely to specify the type of action that the medicinal product may exert on physiological functions. The enumeration of actions was also intended to make it possible to cover medicinal products such as gene therapy, radiopharmaceutical products and certain medicinal products for topical use. 89. There is just as little ground for an argument, which the appellant in the main proceedings advances, to turn away from the previous case-law on the basis that the new definition allegedly makes the definition of a medicinal product by function more objective. This submission must be examined in the context of the grounds upon which the Court has supported its settled case-law in relation to the relevant assessment criteria. 90. The Court originally justified the relevance of the characteristics of 'the manner in which it is used', the 'extent of its distribution' and its 'familiarity to consumers' on the basis of the broad, subjectively conceived definition of a medicinal product by function in the preceding directive, namely Directive 65/65. (51) The Court has previously expressed the opinion that the aim of protecting health, pursued by the legislature in adopting the directive, required the expression 'with a view to restoring, correcting or modifying physiological functions' to be understood in such a broad sense as to include not only products which have a real effect on physiological functions, but also those which do not have the advertised effect. Accordingly, the Court concluded from this finding that the authorities may also prevent the placing of such products on the market in order to protect consumers. 91. While it is necessary, on the one hand, to accept the appellant's argument that, in deleting the words 'intended to' and 'with a view to', the definition of a medicinal product by function appears, at first glance, to have been made more objective, on the other hand it overlooks the fact that these subjective components have been replaced in Article 1(2)(b) of Directive 2001/83, as amended by Directive 2004/27, by the subjective term 'with a view to...'. (52) Consequently, it must be assumed that the Community legislature merely intended to undertake an editorial reformulation of the definition of a medicinal product by function but not to make any substantive change to the position in law. (53) Accordingly, whilst not expressly identified in the directive's definition of medicinal product, the

other aspects which the Court takes into account in its settled case-law for the purposes of assessing the quality of a medicinal product by function are clearly unaffected by this amendment.

92. In the light of the foregoing, the answer to the third question referred must be that the characteristics of the 'the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail' stated in the case-law of the Court of Justice to be relevant, in addition to the pharmacological qualities, to classification as a medicinal product are still relevant following the new definition of a medicinal product introduced by Directive 2004/27.

VIII – Conclusion

93. In the light of the foregoing, I propose to the Court that the answers to the questions referred by the Bundesverwaltungsgericht should be as follows:

(1) Article 2(2) of Directive 2001/83/EC, as amended by Directive 2004/27/EC, must be interpreted as meaning that Directive 2001/83 may be applied only to a product in respect of which it has been positively established, in the light of current scientific knowledge, that it is a medicinal product.

(2) A product may be regarded as a medicinal product by function within the meaning of Article 1(2) of Directive 2001/83, as amended by Directive 2004/27, only if, on the basis of its recommended dosage, it is capable of appreciably modifying human physiological functions by exerting a pharmacological, immunological or metabolic action.

(3) The manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail are still relevant to classification as a medicinal product even in the light of the definition in Article 1(2) of Directive 2001/83, as amended by Directive 2004/27.

1 – Original language: German.

2 – OJ 2001 L 311, p. 67.

3 – OJ 2004 L 136, p. 34.

4 – OJ 2002 L 31, p. 1.

5 – See Klein, A., 'Nahrungsergänzung oder Arzneimittel?', *Neue Juristische Wochenschrift*, 1998, volume 12, p. 791, and Leca, A., 'Droit pharmaceutique', third edition, Marseille 2006, p. 150, which suggest that this distinction plays a not inconsiderable role in almost all areas of law. In civil law for example, it is decisive in relation to the prospects of success of competition cases. Would-be competitors or monitoring organisations will usually seek interlocutory injunctions to prevent the distribution and advertising of a product which is not clearly definable. In such cases the merits of the application for an injunction will usually depend on the legal categorisation of the product at issue. At a national level, the law governing foodstuffs and medicinal products will also contain rules for penalising infringements as summary or even criminal offences. Finally, the distinctions are also relevant in administrative law. In particular, the law governing the

safety of medicinal products provides the competent supervisory authorities with an array of intervention powers by which they can take decisive steps merely on the basis of a suspicion that an unauthorised medicinal product may have been placed on the market.

6 – 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).

7 – 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).

8 – This view is evidently shared by some German-language academic writers, to whom the Bundesverwaltungsgericht refers in its order for reference. In general, the issue of the function of the rule of doubt in Article 2(2) of Directive 2001/83 is controversial. For an interpretation as a rule of presumption or a rule of evidence, see Dettling, H.-U, ‘Physiologische, pharmakologische und toxikologische Wirkung – Ein Beitrag zur Abgrenzung von Lebensmitteln, Arzneimitteln und gefährlichen Stoffen (Teil 1)’, *Lebensmittel & Recht*, 2007, part 1, p. 8, who takes the view that, with regard to the rule of doubt in Article 2(2) of Directive 2001/83, it is sufficient for the requirement for the status of a substance or a preparation of substances as a medicinal product that it is not obviously unsuited to achieving an actively useful effect. Kraft, F./Röcke, T., ‘Auswirkungen der neuen Zweifelsregelung in Article 2(2) der Arzneimittelrichtlinie 2001/83/EG auf die Einstufung von Grenzprodukten als Lebens- oder Arzneimittel’, *Zeitschrift für das gesamte Lebensmittelrecht*, 2006, part 1, p. 34, take the view that the rule of doubt is equivalent to a rule on the burden of proof. The authority applying the law need not be entirely certain whether it has to deal with a medicinal product or with a foodstuff. However, it is bound under the provision to apply the provisions governing medicinal products legal provisions even though it is not entirely certain.

9 – Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 22.

10 – Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547, paragraph 17.

11 – Case C-219/91 *Ter Voort* [1992] ECR I-5485, paragraph 19.

12 – Case C-319/05 *Commission v Germany* [2007] ECR I-9811, paragraphs 38 and 63.

13 – In my Opinion in *Commission v Germany*, cited above, point 44, I referred to the fact that the legislation governing medicinal products must necessarily be more stringent than that governing foodstuffs in view of the particular dangers which may be associated with their use.

14 – Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 *HLH Warenvertrieb and Orthica* [2005] ECR I-5141, paragraphs 43 to 45). In that case, in order to support its theory that ‘the provisions of Community

law specific to medicinal products [must be applied] to a product which satisfies equally well the conditions for classification as a foodstuff and the conditions for classification as a medicinal product’, the Court refers to the judgment in *Ter Voort*. The Court regards this interpretation as being confirmed by Directive 2004/27, which introduced the abovementioned rule of doubt in Article 2(2) of Directive 2001/83.

15 – Meisterernst, A., also agrees: ‘Mit dem Wissen wächst der Zweifel’, *Zeitschrift für das gesamte Lebensmittelrecht*, 2007, part 3, p. 393; in his view HLH Warenvertrieb and Orthica appears rather to support the view that the rule of doubt should not be taken as a rule of evidence but only as a rule that the law on medicinal products takes precedence in the event that a product actually meets in full the definition of a medicinal product and also that of one of the other product categories, for example that of foodstuffs or cosmetic products.

16 – Opinion of Advocate General Geelhoed in *HLH Warenvertrieb and Orthica*, point 52.

17 – Article 2(d) of Regulation No 178/2002 states: “‘Food’ shall not include [for the purposes of that regulation]: medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC”. Köhler, H., ‘Die neuen europäischen Begriffe und Grundsätze des Lebensmittelrechts’, *Gewerblicher Rechtsschutz und Urheberrecht*, 2002, part 10, p. 845, infers from the exclusion of medicinal products from the scope of application of that directive that foodstuffs and medicinal products are mutually exclusive categories. He submits that a product can be either a medicinal product or a foodstuff, but not both at the same time. In addition, fulfilling the medicinal product requirements represents a more specific requirement than fulfilling that relating to foodstuffs. If a product is to be classified as a medicinal product, it is at the same time clear that it cannot be a foodstuff. The author considers his opinion to be confirmed in Article 2(2) of Directive 2001/83, a provision which, he submits, serves to determine the scope of application of Directive 2001/83. However, the author considers this rule of precedence to have already been enshrined in the older (in terms of legislative history) negative rule contained in Article 2(d) of Regulation No 178/2002.

18 – Article 1(2) of Directive 2002/46 states as follows: ‘This Directive shall not apply to medicinal products as defined by 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.’

19 – The version of Article 2(2) of Directive 2001/83 originally proposed by the Commission read: ‘Whenever a substance or combination of substances falls within the definition of “medicinal product”, the provisions of this Directive shall apply, even in cases where the substance or combination of substances falls also within the scope of other Community legislation.’ (Commission Proposal of 26 November 2001 for a Directive of the European Parliament and of the Council amending Directive 2001/83 on the Community code

relating to medicinal products for human use, COM[2001] 404 final). In the justification for its proposal the Commission stated that it was necessary, in view of the growing number of so-called 'borderline products', to modify the definition of 'medicinal product' 'so as to avoid any doubt as to the applicable legislation, when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products'. The Commission considered that taking into account the characteristics of pharmaceutical legislation, provision should be made that such legislation should apply. In its report on the Commission's proposal, the European Parliament (Session document A5-0340/2002, Amendments 18-23) of 9 October 2002 proceeded on the basis of a 'hierarchy of legislation on medicinal products'. It stated that according to this hierarchy, in cases of doubt whether a product is a medicinal product, the legislation on medicinal products was to apply.

20 – On this note see also Büttner, T., 'Die Zweifelsregelung enthebt nicht der Prüfung, ob ein Medicinal product vorliegt', *Zeitschrift für das gesamte Lebensmittelrecht*, 2006, part 6, p. 774, who is of the opinion that the term 'case of doubt' means that a product fulfils both the requirements of another product category and the requirements of a medicinal product. Since the requirements for both product categories are fulfilled, doubt arises as to the classification of the product.

21 – The formulation in the seventh sentence of the seventh recital of Directive 2004/27 stems from a concern raised by the European Parliament, which proposed, in its amendments in relation to the Commission's original proposal (Report of 9 October 2002, Session document A5-0340/2002, Amendments 18-23), *inter alia*, exclusion clauses for food, medical devices and cosmetics. These exclusion clauses were intended to close regulatory loopholes. However, the Commission was of the opinion that such exclusion clauses would not have been compatible with the device of enshrining the precedence of the medicinal product regime, on which it based its proposal. The Commission was accordingly not prepared to incorporate it in the text of its amended proposal for a directive. Instead, it proposed a reformulation of the seventh recital (amended proposal for a Directive of the European Parliament and of the Council of 3 April 2003 amending Directive 2001/83 on the Community code relating to medicinal products for human use (COM[2003] 163 final, p. 11, 12), which the Council ultimately adopted (Common Position [EC] No 61/2003 of 29 September 2003 (2003/C 297 E/02)).

22 – Meisterernst, A., cited above (footnote 15), p. 393, is of the opinion that the seventh sentence, which is based on the premises that a product clearly falls within the definition of other product groups, here only represents a supposed contrast to the second sentence of recital 7. It is merely intended that the rule of doubt should only apply in cases of doubt and not if a product clearly falls to be categorised in one or other product group. According to Büttner, T., cited above (footnote

20), p. 771, recital 7 in the preamble to Directive 2004/27 corresponds exactly in terms of content to the wording of Article 2(2) of Directive 2001/83. Büttner argues that recital 7 says nothing other than that, where there is a clear classification of a product under the definition of another product group, the law on medicinal products should not apply. In the same way, Article 2(2) of Directive 2001/83 provides that the rule of doubt may actually apply only in cases of doubt. Accordingly, there is no contradiction between the recitals and the wording of Article 2(2) of Directive 2001/83.

23 – Groß, T., in 'Neues zur Abgrenzung zwischen Lebensmitteln und Arzneimitteln', *Europäische Zeitschrift für Wirtschaftsrecht*, 2006, part 6, p. 175, also agrees and explains, referring to the legislative history of Directive 2004/27, that the provision, the text of which states that, where there are difficulties in classifying a product, in the event of doubt a product should be classified as a medicinal product, reflects the case-law of the Court. According to Schroeder, W., 'Die rechtliche Einstufung von Nahrungsergänzungsmitteln als Lebens- oder Arzneimittel – eine endlose Geschichte?', *Zeitschrift für das gesamte Lebensmittelrecht*, 2005, part 4, p. 421, the rule of doubt is merely declaratory in nature and does not change the position in law, pursuant to which a product which can be defined as both a foodstuff and a medicinal product, must primarily be considered in accordance with the law on medicinal products. In the view of Peigné, J., 'La réforme de la législation pharmaceutique communautaire', *Revue de droit sanitaire et social*, 2004, No 3, p. 580, the provision in Article 2(2) of Directive 2001/83 is consistent with the previous case-law on the precedence of the law relating to medicinal products.

24 – See my Opinion in *Commission v Germany* (cited in footnote 13), point 44.

25 – Judgments in *Commission v Germany* (cited in footnote 12), paragraph 55; *Case C-387/99 Commission v Germany* [2004] ECR I-3751, paragraph 57; *Case C-112/89 Upjohn* [1991] ECR I-1703, paragraph 23; *Case C-290/90 Commission v Germany* [1992] ECR I-3317, paragraph 17; *Monteil and Samanni* (cited in footnote 10), paragraph 2; and *Case 227/82 Van Bennekom* [1983] ECR 3883, paragraph 29. See Doepner, U./Hüttebräuer, A., 'Abgrenzung Arzneimittel/Lebensmittel – die aktuelle gemeinschaftsrechtliche Statusbestimmung durch den EuGH', *Wettbewerb in Recht und Praxis*, 2005, part 10, p. 1199, who conclude, with reference to this case-law, that to some extent the Court clearly wants to discourage attempts by Member States to advocate an expansion of the respective national regimes governing medicinal products in order to cover ambivalent products.

26 – Reinhart, A., in 'Zur Abgrenzung Arzneimittel/Lebensmittel im Lichte der BasisVO und des gemeinschaftsrechtlichen Arzneimittelbegriffs', *Zeitschrift für das gesamte Lebensmittelrecht*, 2005, part 4, pp. 510-512, correctly refers to the fact that the rule of doubt under Article 2(2) of Directive 2001/83, as amended by Directive 2004/27, is a confirmation of

the previous case-law. He argues that the rule of doubt may only apply once all of the circumstances of the individual case have been comprehensively considered and it has been positively determined that the product comes within both the medicinal product definition and the definition of foodstuff (or another product). In order to apply this provision it is not sufficient if, although a pharmacological effect cannot be excluded, it cannot ultimately be confirmed either. Classification as a foodstuff can only be rejected – and in cases of demarcation vis-à-vis medicinal products, classification as a medicinal product can only be affirmed – if the existence of a medicinal product within the meaning of the Community Code for human medicinal products has been positively established. In the opinion of Gorny, D., 'Funktionelle Nahrungsergänzungsmittel im Schnittpunkt der Begriffe Arzneimittel, Lebensmittel und Zusatzstoffe', *Zeitschrift für das gesamte Lebensmittelrecht*, 2005, part 1, p. 124, a very careful comprehensive consideration of all the characteristics of the product to be assessed is required. The rule of doubt, it is argued, applies only once a product may be both a foodstuff in the form of a functional food supplement and a medicinal product.

27 – Klein, A., cited above (footnote 5), p. 795, calls for the objective determination of the function of a product within the context of a scientific review. In the opinion of Callens, S., *Chapters on pharmaceutical law, Antwerp/Groningen/Oxford 2000*, pp. 9 and 10, a product's characteristics as a medicinal product must be capable of being determined on the basis of the present state of scientific knowledge.

28 – The national authorities remain free to invoke the precautionary principle in certain cases, in which, after an evaluation of the information available, the possibility of effects which are harmful to health is established, but there is still scientific uncertainty (see in relation to this the Communication from the Commission of 2 February 2000 on the applicability of the precautionary principle, COM[2000] 1 final). This allows interim risk-management measures to be taken in order to ensure the high level of protection of health chosen for the Community, until further scientific information is available for a more comprehensive risk assessment. The steps to be taken must, however, be proportionate and may not have a greater impact on the free movement of goods than is necessary to achieve the high level of protection of health chosen for the Community, regard being had to technical and economic feasibility and other factors which it is considered need to be taken into account in view of the relevant facts of the case. The precautionary principle has found its way into food law through its express inclusion in Article 7 of Regulation (EC) No 178/2002.

29 – Judgments in Case 174/82 Sandoz [1983] ECR 2445, paragraph 16; Van Bennekom (cited in footnote 25), paragraph 37; Case C-192/01 Commission v Denmark [2003] ECR I-9693, paragraph 42; Case C-24/00 Commission v France [2004] ECR I-1277, paragraph 49; and Commission v Germany (cited in footnote 25), paragraph 68.

30 – Judgments cited in Footnote 29: Sandoz (paragraph 17), Commission v Denmark (paragraph 43), Commission v France (paragraph 50); and Commission v Germany (paragraph 69).

31 – As I stated in my Opinion in Commission v Germany (cited in footnote 13), points 34 to 37), the harmonising effect achieved by the Community law on medicinal products should be regarded as the result of a balancing act by the legislature between the objectives of free movement of goods and protection of health. Both objectives are therefore to be attained and must therefore be balanced. In Pierrel (Case C-83/92 Pierrel [1993] ECR I-6419, paragraph 7), the Court established 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 those products in the Community, while at the same time safeguarding public health. On this note see also 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. 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 promoted harmonisation in order to achieve a fair balance between the needs of public health and the free movement of goods. The latter could, in the view of the authors, also be described in a broader sense as a project to establish a common European market for medicinal products.

32 – Consequently, a national practice which requires the grant of a marketing authorisation for medicinal products in order to place food supplements on the market constitutes a measure having an effect equivalent to a quantitative restriction on imports, within the meaning of Article 28 EC, which may nevertheless be justified on grounds of public health pursuant to Article 30 EC (see, to that effect, Cases C-150/00 Commission v Austria [2004] ECR I-3887, paragraphs 81 to 83, and Van Bennekom (cited in footnote 25), paragraph 33).

33 – See my Opinion in Commission v Germany (cited in footnote 13), point 43. See also the Opinion of Advocate General Geelhoed in HLH Warenvertrieb and Orthica (cited in footnote 16), point 36.

34 – According to Büttner, T., cited above (footnote 20), p. 751, 761, the precedence of the law on medicinal products does not relieve the authorities from the obligation to actually examine in detail whether a substance has a pharmacological effect and therefore is or is not a medicinal product by function. The author refers both to the disadvantages of an unduly extensive interpretation and application of the concept of a medicinal product for the free movement of goods and the protection of health and to the criminal-law consequences of marketing a product which is considered to require authorisation but which has not, however, been authorised. In his opinion, those responsible for marketing a product would have to anticipate criminal law

sanctions although it had never actually been established whether the product in fact fulfilled the requirements for a medicinal product. He argues that this is not compatible with the specific principle of criminal procedure ‘in dubio pro reo’ or with the clarification principle applicable in the German law of administrative procedure. Against this, however, Kraft, F., „Klare Worte zur Zweifelsregelung“, *Zeitschrift für das gesamte Lebensmittelrecht*, 2006, part 6, p. 750, who, on the one hand, interprets the rule of doubt in Article 2(2) of Directive 2001/83 to the effect that it does not require a positive determination that a product has the characteristics of a medicinal product, but allows residual doubt, but, on the other hand, refers to the risk that the rule of doubt could be used as a pretext to classify a product as a medicinal product prematurely on the basis of an unclear factual situation.

35 – Upjohn (cited in footnote 25), paragraph 18.

36 – Point 64 of this Opinion.

37 – Van Bennekom (cited in footnote 25), paragraphs 26 and 27.

38 – Van Bennekom, paragraph 28.

39 – Commission v Germany (cited in footnote 25), paragraphs 77 to 83.

40 – See Commission v Germany (cited in footnote 25), paragraph 79. In that case the Court criticised the fact that the automatic nature of this administrative practice made it impossible to identify and assess a real risk to public health, which would have required a detailed assessment on a case-by-case basis of the effects which the addition of the vitamins in question might entail. In Commission v Denmark (cited in footnote 29), paragraph 56, the Court criticised an administrative practice under which enriched foodstuffs lawfully produced or marketed in other Member States could be marketed in Denmark only if it was shown that such enrichment with nutrients corresponded to a need in the Danish population.

41 – Also of this Opinion: Dettling, H.-U., cited above (footnote 8), p. 8, who takes into account the actual dosage. He refers to that fact that in many substances and preparations derived from substances different effects may be produced depending on the dosage and that harmful side effects had to be faced with almost all medicinal products. In his opinion, in order for a product to be considered to be a medicinal product, its useful modifying effect on bodily functions, in the actual dosage, combination, pharmaceutical form and application, had to be the main effect of the substance or the preparation made from substances. Similarly also Büttner, T., cited above (footnote 20), p. 762, who states that the dosage of a substance is decisive. Büttner states that it is true that a number of vitamins, minerals and other substances have authorisations as medicinal products. However, from this it cannot be concluded that, as a matter of principle, a therapeutic purpose and a pharmacological effect have to be assumed. On the contrary, this writer argues that an exact differentiation must be made according to the dosage from which authorisation as a medicinal product was granted. Kraft, F., cited above (footnote 34), p. 751, states that the

mere fact that a substance is contained in an authorised medicinal product is not in itself sufficient to justify the assumption that, as a matter of principle, a food supplement containing this substance has pharmacological effects. This applied in particular to ‘dual-use’ substances, which, depending on the dose administered, could be used for either nutritional-physiological or medicinal purposes.

42 – Sandoz (cited in footnote 29), paragraph 71.

43 – Van Bennekom (cited in footnote 25), paragraph 39; Commission v Denmark (cited in footnote 29), paragraph 45; Commission v France (cited in footnote 29), paragraph 52; and Commission v Germany (cited in footnote 25), paragraph 71.

44 – Van Bennekom (cited in footnote 25), paragraph 40.

45 – See my Opinion in Commission v Germany (cited in footnote 13), point 75. In Commission v Germany (cited in footnote 25), paragraphs 74 to 76, in relation to the conditions for the authorisation of vitamin preparations as medicinal products pursuant to Article 4 of Directive 65/65, which substantially correspond to those of Article 8 of Directive 2001/83, the Court stated that the issue of a marketing authorisation for medicinal products is subject to particularly strict requirements. Accordingly, in order to obtain a marketing authorisation, the person responsible for placing the product on the market must attach various particulars and documents to the application, 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 must provide proof that the manufacturer is authorised in its own country to produce medicinal products.

46 – In the view of Büttner, T., cited above (footnote 20), p. 765, the national court may not be excused from its duty to examine whether a product demonstrates a pharmacological effect, and specifically on the basis of the actual recommended daily dosage.

47 – See point 64 of this Opinion.

48 – The Court has, however, left open how those characteristics are to be assessed and has so far not provided any definition of pharmacological properties, except for stating that those properties include the ‘effect on health in general’. I referred to this in my Opinion in Commission v Germany (cited in footnote 13), point 56. Thus, the Court most recently held in Commission v Germany (cited in footnote 12), paragraph 59, referring to HLH Warenvertrieb and Orthica (cited in footnote 14), paragraph 52, that 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.

49 – See point 64 of this Opinion and the case-law cited in footnote 25.

50 – HLH Warenvertrieb and Orthica (cited in footnote 14), paragraph 53, and Commission v Austria (cited in footnote 32), paragraphs 64 and 65.

51 – See in particular Upjohn (cited in footnote 25), paragraph 20, in which the Court referred to the wording of the legal definition of a medicinal product by function in Directive 65/65. Pursuant to that definition, those products had to be regarded as medicinal products on the basis of their function ‘which are intended to restore, correct or modify physiological functions and which may thus have an effect on health in general’. The Court decided that the fact that the provision uses the expression ‘with a view to’ means that the definition of a medicinal product may include not only products which have a real effect on physiological functions but also those which do not have the advertised effect, thereby enabling public authorities to prevent the marketing of such products in order to protect consumers.

52 – This subjective term features in several language versions. German: ‘um ... zu’; English: ‘with a view to’; French: ‘en vue ... de’; Spanish: ‘con el fin de’; Italian: ‘allo scopo di’; Dutch: ‘om ... te’; Portuguese: ‘com vista a’.

53 – See Groß, T., cited above (footnote 23), pp. 174 and 175, who also refers to the subjective expression ‘with a view to’ in Article 1(2)(b) of Directive 2001/83, as amended by Directive 2004/27. Schroeder, W., cited above (footnote 23), pp. 420 and 422, assumes that the new definition of medicinal product by function does not change the previous legal position. Peigné, J., cited above (footnote 23), p. 581, clearly also proceeds on the basis of a broad interpretation of the definition of medicinal product by function.
