JUDGMENT OF THE COURT (First Chamber)

15 January 2009 *

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,

* Language of the case: German.

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. Patsopoulou 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 medicinal 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.**

[Signatures]