On How to Assess a Medicinal Product By Function

*Kai Purnhagen**

Case C-27/08 BIOS Naturprodukte GmbH v. Saarland[1]

***Article 1(2) of Directive 2001/83** on the Community code relating to medicinal products for human use, as amended by Directive 2004/27 must, apart from the case of substances or combinations of substances intended for the purpose of making a medical diagnosis, be interpreted as meaning that a product which includes in its composition a substance which has a physiological effect when used in a particular dosage is not a medicinal product by function where, having regard to its content in active substances and under normal conditions of use, it constitutes a risk to health without, however, being capable of restoring, correcting or modifying physiological functions in human beings (...) (official headnote).*

I. Facts

The product, a preparation based on an Indian incense extract, is produced in India and imported into Austria, where it is marketed as a food product. In addition to various excipients, each tablet contains 400 mg of Indian incense extract. According to the information on the packaging, the recommended dosage is one tablet to be taken daily with a little liquid after a meal.

By decision of 23 January 2002, and pursuant to Paragraph 69(1) of the AMG (German Federal Drug Code), Saarland prohibited BIOS Naturprodukte from continuing to offer that product on the German market on the ground that it was a medicinal product which had not received prior marketing authorisation. Referring to comparable legislation in India, this decision placed the product in the category of medicinal products for which a marketing authorisation is required. BIOS Naturprodukte brought an action against that decision, submitting that the product in issue in the main proceedings is a food supplement and not a medicinal product. It argued before the Verwaltungsgericht (Administrative Court) that the product concerned is not a medicinal product by presentation, since it is expressly described as a food supplement on the packaging and no reference is made to any therapeutic or prophylactic effects. Neither is it a medicinal product by function, since the recommended daily dose of 400 mg has no pharmacological effect, as shown in the two expert reports it provided. BIOS Naturprodukte also indicated that, in line with the traditional use of incense extract as an aroma and a spice, the product concerned served a nutritional purpose.

By judgment of 20 May 2003, the Verwaltungsgericht dismissed the action on the ground that, in view of its purpose, the product at issue in the main proceedings was, in the perception of the trade, predominantly regarded as a medicinal product. By judgment of 3 February 2006, the Oberverwaltungsgericht (Higher Administrative Court) dismissed the appeal brought by BIOS Naturprodukte on the ground that the product in issue in the main proceedings was to be regarded as a medicinal product since it satisfies the definition of medicinal product set out in Article 1(2) of Directive 2001/83.

The Bundesverwaltungsgericht (Federal Administrative Court) took the view that there were two questions in the case in the main proceedings. The first was whether a product can be regarded as a medicinal product by function if it contains an ingredient capable, in a particular dose, of bringing about physiological changes, but nevertheless that product's dosage remains below that dose, in normal conditions of use. The second question was whether there was any risk to health linked to using a prod-

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1 Judgment of 30 April 2009.

** Editorial Hint: Article 1 No. 2 of Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, last amended by Directive 2004/27/EC, OJ L – 311, of 28 November 2004, pp. 67 – 128.

uct, but in insufficient doses, could result in that product having to be classified as a medicinal product. Taking the view that the resolution of the first question depended on the interpretation of Article 1(2) of Directive 2001/83, the Bundesverwaltungsgericht decided to delay the proceedings and to refer to the Court of Justice for a preliminary ruling on the following question:

"Is the definition of medicinal product in Article 1(2) of Directive 2001/83 ... to be interpreted to the effect that a product intended for human consumption and described as a food supplement is a medicinal product by function if it contains substances which pose a risk to health in the low dose contained in the product when the recommended intake printed on the packaging is observed, without being capable of producing therapeutic effects, but which have therapeutic effects in high doses?"

II. Judgment

(17.) By its question, the national court asks, essentially, whether Article 1(2) of Directive 2001/83 is to be interpreted as meaning that a product which includes in its composition a substance which has a physiological effect when it is used in a particular dosage is a medicinal product by function since, regard being had to its content in active substances and under normal conditions of use, it constitutes a risk to health without, however, being capable of restoring, correcting or modifying physiological functions in human beings.

(18.) First of all, it should be pointed out that, for the purpose of determining whether a product falls within the definition of a medicinal product by function for the purposes 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 (Case C-140/07 *Hecht-Pharma* [2009] ECR I-0000, paragraph 39).

(19.) It follows that products containing a substance which has 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 (*Hecht-Pharma*, paragraph 40).

(20.) The pharmacological, immunological or metabolic properties of a product constitute, in fact, 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 Article 1(2)(b) of Directive 2001/83, be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions (see, to that effect, Case C-319/05 *Commission* v *Germany* [2007] ECR I-9811, paragraph 59).

(21.) 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 (*Hecht-Pharma*, paragraph 41).

(22.) When that assessment is being made, the normal conditions of use of the product in question should be taken into account (see, to that effect, Case C-150/00 *Commission* v *Austria* [2004] ECR I-3887, paragraph 75), and the fact that it is capable of having a significant physiological effect when used at a higher dosage than that indicated in the instructions or on the packaging is irrelevant in that regard.

(23.) It follows from the foregoing considerations 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 content and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions in human beings (see, to that effect, *Hecht-Pharma*, paragraph 42).

(24.) This conclusion is not invalidated by the fact that the product in question, under normal conditions of use, may involve a risk to health.

(25.) In that regard, it should be borne in mind, first, that the fact that the use of a product presents a risk to health is not an indication that it is pharmacologically effective. The risk to health, although it must be taken into consideration in the classification of a product as a medicinal product by function, is none the less an autonomous factor (see *Commission* v *Germany*, paragraph 69).

(26). Second, a risk to health is only one aspect of the product which must be taken into consideration by the competent national authorities for the purpose of assessing whether it is a medicinal product within the meaning of Article 1(2)(b) of Directive 2001/83, and cannot be the only determining factor (see, to that effect, *Commission* v *Austria*, paragraph 65).

(27.) Consequently, the answer to the question referred is that Article 1(2) of Directive 2001/83 must be interpreted as meaning that a product which includes in its composition a substance which has a physiological effect when used in a particular dosage is not a medicinal product by function where, having regard to its content in active substances and under normal conditions of use, it constitutes a risk to health without, however, being capable of restoring, correcting or modifying physiological functions in human beings.

III. Comment

The dividing line between medicinal products and foodstuffs in European law has caused huge debate in recent years. The first landmark decision in this respect was issued in 2007 on the question whether a garlic preparation in capsule form would be classified as either medicinal product or foodstuff,[2] and was then followed by the equally influential "*Hecht Pharma*" or "*Red Rice*" judgment in 2009.[3] The instant judgment connects both judgments with many other, more general judgments on the term "medicinal products" in recent years. Even though emphasising that decisions have to be taken on a case-by-case basis whether or not a product fulfils the criteria for a "medicinal product" in the sense of Article 1 No. 2 of Directive 2001/83/EC, it thereby also introduces a system of two tests that need to be conducted to resolve whether a product is a medicinal product or a foodstuff.

First, it has to be assessed whether each product individually has physiological effects in the sense of Article 1 No. 2 (b) of Directive 2001/83/EC. This is the case if the product has the capacity to restore, correct or modify physiological functions. When assessing these properties, the relevant Member State authority needs to take into consideration the '*product's specific pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge*'.

Second, these physiological effects have to affect the metabolism *significantly* and to *strictly* modify the way it functions. Unfortunately, the ECJ does not provide further clarification as to how these terms have to be interpreted. However, it clarifies that, when making this assessment the relevant authorities only have to take into account the normal use of the product. Such normal use is the use indicated in the instructions on the packaging. Possible harm resulting from a consumer's use of a higher dosage as instructed on the packaging is irrelevant for the classification.

This case hence follows a general trend in European risk regulation that systematises certain areas at European level.[4] Although the ECJ explicitly denies that this judgment has any systematising claim,[5] in fact it does nothing else. It collects and combines existing judgements in order to provide a general guideline to both Member State and European authorities on how they should exercise their margin of appreciation when enforcing Union law.

As Member State enforcement of European regulation is a typical feature of risk regulation, in theory the ECJ has only very limited powers to intervene in issues directly relating to Member State supervision. However, the ECJ is increasingly governing the administrative procedures of Member State institutions by interpreting European legal terms in a procedural, systematising way. The ECJ therefore does not interfere in the administrative procedures directly, but it does set certain tight benchmarks for the exercise of the Member State authority's enforcement of European risk regulation.

2 Case-C-319/05, *Commission v. Germany* [2007| ECR I-09811.

3 Case C-140/07, *Hecht-Pharma GmbH v. Staatliches Gewerbeaufsichtsamt Lüneburg*, [2009] ECR (judgment of 15 January 2009), see also the commentary of Müller, Rolf-Georg, "Grundfragen des Arzneimittelbegriffs und der Zweifelsregelung", *Neue Zeitschrift für Verwaltungsrecht* (2009), pp. 425 *et sqq*.

4 See Purnhagen, Kai, "Systematisation in European Risk Regulation" (forthcoming PhD thesis, on file at the European University Institute in Florence from 2011 on).

5 Para. 19 "cannot automatically be classified as medicinal products by function unless the competent administration has made an assessment". This is clearer in the German version, where instead of 'automatically' the term as 'systematisch' is used.