Case C-495/21

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

12 August 2021

Referring court:

Bundesverwaltungsgericht (Germany)

Date of the decision to refer:

20 May 2021

Appellant on a point of law:

L. GmbH

Respondent in the appeal on a point of law:

Federal Republic of Germany

Subject matter of the main proceedings

Pharmaceutical law – Directive 93/42 – Article 1(2)(a) – Directive 2001/83 – Article 1(2)(a) and Article 2(2) – Definition of substance-based medical devices and medicinal products

Subject matter and legal basis of the request

Interpretation of EU law, Article 267 TFEU

Questions referred for a preliminary ruling

1. Can the principal intended action of a substance be pharmacological within the meaning of Article 1(2)(a) of Directive 93/42/EEC even if it is not based on a receptor-mediated mode of action and the substance is not absorbed by the human body but remains on and reacts with the surface of, for example, the mucosa? On what criteria should a distinction be drawn between

pharmacological and non-pharmacological means, in particular physico-chemical means, in such a case?

2. Can a product be regarded as a substance-based medical device within the meaning of Article 1(2)(a) of Directive 93/42/EEC if, according to current scientific knowledge, the mode of action of the product is open to debate and it is thus not possible to definitively determine whether the principal intended action is achieved by pharmacological or physico-chemical means?

3. In such a case, is the classification of the product as a medicinal product or as a medical device to be carried out on the basis of an overall assessment of its other properties and all other circumstances, or, in so far as it is intended to prevent, treat or alleviate diseases, is the product to be regarded as a medicinal product by presentation within the meaning of Article 1(2)(a) of Directive 2001/83/EC, irrespective of whether or not a specific medicinal effect is being claimed?

4. Does the primacy of the regime governing medicinal products also apply in such a case in accordance with Article 2(2) of Directive 2001/83/EC?

Provisions of European Union law relied on

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), last amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ 2007 L 247, p. 21), Article 1(2)(a) and Article (5)(c), Article 11(5) and point 13.3, letters (j) and (k) of Annex I

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ 2017 L 117, p. 1), recital 7 and Article 1(6)(b)

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 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 299, p. 1), Article 1(2)(a) and (b), Article 2(2) and Article 59(1)(c)(iii) and Article 59(e)

Succinct presentation of the facts and procedure in the main proceedings

1 The applicant is an undertaking that produces various pharmaceutical products. It places on the market as a medical device a product containing, inter alia, the same active substance as nasal drops, which it also markets. As regards the application

of the product, the package information leaflet reads as follows: ‘The preparation is suitable for use with irritation of the nasal mucosa caused by viral rhinitis. It also soothes irritation of the nasal mucosa and supports its regeneration during a cold.’ It is indicated ‘for supporting the treatment of colds’ and ‘for treating colds’. In order to justify classification as a Class I medical device, the technical documentation of January 2011 indicates that the preparation’s principal action on the nasal mucosa is achieved by physico-chemical means. It has an astringent effect. It causes the outermost cell layer of the nasal epithelium to contract, thereby reducing nasal secretions. Furthermore, due to the contraction of the outermost cell layer of the nasal epithelium, a change in the membrane lipids to a gel-like state, which could influence the penetration of DNA into the epithelial cell, is conceivable. A further component of the product also has a physico-chemical action, in so far as it forms an elastic film over the irritated nasal mucosa to prevent it drying out, thus soothing the nasal mucosa and supporting its regeneration.

2 By decision of 16 January 2014, the competent authority ruled that the preparation is a medicinal product requiring marketing authorisation. It fulfils the requirements of a medicinal product by function, since the principal intended action is achieved by pharmacological means. The product is also to be regarded as a medicinal product by presentation.

3 The authority dismissed the opposition brought against the abovementioned decision by decision of 14 October 2014. The action and the subsequent appeal were unsuccessful. The applicant is pursuing its claim by way of its appeal on a point of law.

Succinct presentation of the reasoning in the request for a preliminary ruling

4 The success of the action hinges on the way in which the scope of the rules governing medicinal products and medical devices are to be defined with respect to each other. There is a need for clarification with regard to the concept of ‘pharmacological’ means within the meaning of Article 1(2)(a) of Directive 93/42 (first question referred), how a product is to be classified when it cannot be clarified whether the principal intended action is achieved by pharmacological or physico-chemical means (second question referred), under what conditions a product placed on the market by the manufacturer as a Class I medical device is to be regarded as a medicinal product by presentation within the meaning of Article 1(2)(a) of Directive 2001/83 (third question referred) and whether the rule of priority for the law on medicinal products as set out in Article 2(2) of Directive 2001/83 also applies to medicinal products by presentation (fourth question referred).

5 In the case of a declaratory decision such as that at issue in the present case, the relevant date for assessing the factual and legal situation is the conclusion of the administrative procedure, meaning that Directive 93/42 applies in the present case.

The first question referred

6 Pursuant to Article 1(5)(c) of Directive 93/42 (and Article 1(6)(b) of subsequent Regulation 2017/745), in deciding whether a product falls under the Medical Devices Directive (2001/83/EC) or under the provisions that apply to medical devices, particular account is to be taken of the principal mode of action of the product. The scope of the provisions must then be clearly defined with respect to one another (see also recital 7 of Regulation 2017/745).

7 A definition of pharmacological action is necessary in order to clarify whether the principal mode of action of a product is achieved by pharmacological means. In accordance with the case-law of the Court of Justice, the guidelines issued by the European Commission – and thus in particular what is known as the 'Borderline Guideline' (European Commission, Medical Devices: Guidance Document, MEDDEV 2.1/3 rev 3, point A.2.1.1) – may be a useful reference in this respect. Under that provision, a pharmacological action is to be understood as an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response or blocks the response of another agent. The Court of Justice has held that a substance the molecules of which do not interact with a human cellular constituent may nevertheless, by means of its interaction with other cellular constituents present within the user's organism, such as bacteria, viruses or parasites, have the effect of restoring, correcting or modifying physiological functions in human beings. It follows that it is not a priori inconceivable that a substance the molecules of which do not interact with a human cellular constituent may constitute a medicinal product within the meaning of Article 1(2)(b) of Directive 2001/83 (judgment of 6 September 2012, *Chemische Fabrik Kreussler*, C-308/11, EU:C:2012:548, paragraph 31 and 32). The reaction triggered by an active substance, which is not based on a receptor-mediated mode of action and in which the substance is not absorbed by the human body, but remains on the surface – for example of mucosa – cannot thus be classified a priori as a non-pharmacological action. The formation of a 'precipitation membrane' resulting from the interconnection of the active substance with the mucosal proteins, as assumed by the defendant, could therefore be regarded as a pharmacological means.

The second question referred

8 In accordance with the binding factual findings made in the judgment of the appellate court, according to current scientific knowledge, it is not possible to clarify whether the principal intended action of the product is achieved by pharmacological or physico-chemical means. In such a case, it is not clear how and according to what criteria classification is to be made to a category of product.

9 The fact that Article 1(5)(c) of Directive 93/42 does not preclude other criteria from being taken into account could argue against a solution based on the principles of the burden of proof. Accordingly, it is instead necessary to take into

consideration only ‘in particular’ the principal mode of action of the product. If this cannot be clarified, the legislation should therefore not exclude recourse to other criteria. On the contrary, all of the characteristics of the product could then be taken into account, such as the significance of the action on human physiological properties or the potential risks to the health of the user. As in the decision as to whether a product falls under the definition of a medicinal product, an overall assessment of the product could then be carried out on a case-by-case basis. The classification of a product under the term ‘medical device’ would therefore be possible even if its non-pharmacological action cannot be positively established.

The third question referred

10 Under Article 1(2)(a) of Directive 2001/83, any substance or combination of substances presented for treating or preventing disease in human beings is a medicinal product (known as a medicinal product ‘by presentation’).

11 As substance-based medical devices are also intended, in accordance with the first indent of Article 1(2)(a) of Directive 93/42, to alleviate, prevent or treat diseases, there is no difference between medical devices and medicinal products as regards their intended therapeutic purpose. Information provided to that effect in the use instructions is not on its own a suitable criterion for distinguishing between the two in this respect. There is thus doubt as to whether a product placed on the market by the manufacturer as a Class I medical device within the meaning of Article 11(5) of Directive 93/42 is then capable of being regarded as a medicinal product within the meaning of Article 1(2)(a) of Directive 2001/83 if it is by presentation intended to treat or alleviate diseases, but does not claim any specific medicinal effect.

12 While mere classification as a medical device on the part of the manufacturer does not make presentation as a medicinal product impossible on the basis of the overall impression produced by the packaging, the manufacturer’s information must be taken into account as part of the presentation of the product. It may be ‘persuasive evidence’ for the interpretation (see judgment of 21 March 1991, *Delattre*, C-369/88, EU:C:1991:137, paragraph 41). A CE mark affixed to the packaging of the product may also be significant in this respect. It cannot in principle be assumed that a reasonable average consumer will consider a preparation expressly offered as a medical device to be a medicinal product. Special additional circumstances are required for this.

13 The reference to an intended therapeutic purpose should not be sufficient in any event to substantiate such evidence where the product is not promoted as having specific medicinal actions. A medical device may also be presented to treat irritation of the nasal mucosa caused by viral rhinitis. By providing such information, the manufacturer is not creating the impression of a medicinal product, but is instead indicating the intended purpose of a medical device, as required by law (see also, in relation to the indication of the intended purpose of a

cosmetic product, judgment of 17 December 2020, *A.M. (Étiquetage des produits cosmétiques)*, C-667/19, EU:C:2020:1039).

14 Nor should the reference to 'interactions' and 'adverse effects' lead to the conclusion that the product is being presented in a specifically medicinal manner. Although it is true that such information bears some similarity to the compulsory information that must appear on the package leaflet of a medicinal product (see Article 59(1)(c)(iii) and Article 59(1)(e) of Directive 2001/83), the information required for labelling medical devices in accordance with point 13.3 of Annex I to Directive 93/42 also includes special operating instructions (j) and warnings and/or information on any precautions to be taken (k).

15 Finally, the fact that the product is distributed through pharmacies should not constitute a special circumstance in support of the applicant presenting it as a medicinal product rather than a medical device. This is because pharmacy-exclusive distribution is not reserved for medicinal products under German law, but is instead also provided for in respect of certain medical devices.

The fourth question referred

16 Under Article 2(2) of Directive 2001/83, 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 EU legislation the provisions of this Directive shall apply.

17 The primacy thus accorded to the regime governing medicinal products applies to 'medicinal products' and also refers, by its wording, to medicinal products by presentation, within the meaning of Article 1(2)(a) of Directive 2001/83. Only a medicinal product by function, within the meaning of Article 1(2)(b) of Directive 2001/83, may have 'characteristics' that must be taken into account in accordance with Article 2(2) of Directive 2001/83. The pharmacological, immunological or metabolic properties of a product constitute the factor on the basis of which it must be ascertained whether it may be used with a view to restoring, correcting or modifying physiological functions (judgment of 3 October 2013, *Laboratoires Lyocentre*, C-109/12, EU:C:2013:626, paragraph 43). By contrast, the concept of a medicinal product by presentation is conceived in broad terms, referring, in particular, only to claimed 'characteristics' of the product that are not actually present (judgment of 15 January 2009, *Hecht-Pharma*, C-140/07, EU:C:2009:5, paragraph 25). It would therefore also be conceivable to limit the rule of priority to medicinal products by function within the meaning of Article 1(2)(b) of Directive 2001/83.

18 This could also be supported by the fact that, in cases where a pharmacological action of the substance has not been established, there should be no reason to accord primacy to the law on medicinal products. Although it is true that the consumer must be protected from products which do not have the effectiveness they would be expected to have on the basis of their presentation, as long as the

product falls under the definition of another product, such as a medical device within the meaning of Article 1(2)(a) of Directive 93/42, that protection may also result from the laws that apply to that product (see judgment of 3 October 2013, *Laboratoires Lyocentre*, C-109/12, EU:C:2013:626, paragraph 53). Those rules are likely to be more relevant than those of the law on medicinal products, in light of the actual characteristics of the product. The application of the law on medicinal products could therefore prove to be a disproportionate restriction on the free movement of goods.