Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

3 October 2013 *

(Reference for a preliminary ruling — Approximation of laws — Medical devices — Directive 93/42/EEC — Medicinal products for human use — Directive 2001/83/EC — Right of the competent national authority to classify as a medicinal product for human use a product marketed in another Member State as a medical device bearing a CE marking — Applicable procedure)

In Case C-109/12,

REQUEST for a preliminary ruling under Article 267 TFEU from the Korkein hallinto-oikeus (Finland), made by decision of 27 February 2012, received at the Court on 29 February 2012, in the proceedings

Laboratoires Lyocentre

v

Lääkealan turvallisuus– ja kehittämiskeskus,

Sosiaali– ja terveysalan lupa– ja valvontavirasto,

THE COURT (Fourth Chamber),

composed of L. Bay Larsen, President of the Chamber, J. Malenovský (Rapporteur), U. Lõhmus, M. Safjan and A. Prechal, Judges,

Advocate General: E. Sharpston,

Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 20 February 2013,

after considering the observations submitted on behalf of:

— Laboratoires Lyocentre, by E. Mikkola, asianajaja,

— the Finnish Government, by J. Heliskoski and J. Leppo, acting as Agents,

— the Czech Government, by S. Šindelková, acting as Agent,

— the Estonian Government, by M. Linntam, acting as Agent,

— the Italian Government, by G. Palmieri, acting as Agent, and W. Ferrante, avvocato dello Stato,

* Language of the case: Finnish.

— the Polish Government, by B. Majczyna, acting as Agent,

— the Government of the United Kingdom of Great Britain and Northern Ireland, by H. Walker, acting as Agent, B. Kennelly and G. Facenna, Barristers,

— the European Commission, by A. Sipos, I. Koskinen and M. Šimerdová, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 30 May 2013,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ 2007 L 247, p. 21, 'Directive 93/42'), and 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 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 (OJ 2006 L 378, p. 1, 'Directive 2001/83').

2 The request has been made in proceedings between Laboratoires Lyocentre, a pharmaceutical company which manufactures a vaginal capsule containing live lactobacilli intended to restore balance to bacterial flora in the vagina, called 'Gynocaps' ('Gynocaps'), and the Lääkealan turvallisuus– ja kehittämiskeskus (the Centre for Safety and Development in the pharmaceutical sectors) and the Sosiaali– ja terveysalan lupa– ja valvontavirasto (Social and Health Authorisation and Supervision Authority), concerning the classification of Gynocaps as a medicinal product.

Legal context

European Union law

Directive 93/42

3 Recital 6 in the preamble to Directive 93/42 states as follows:

'[w]hereas certain medical devices are intended to administer medicinal products within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [(OJ, English Special Edition, Series I Volume 1965-1966 p. 20), as amended by Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets (OJ 1992 L 113, p. 8, 'Directive 65/65')]; whereas, in such cases, the placing on the market of the medical device as a general rule is governed by the present Directive and the placing on the market of the medicinal product is governed by [Directive 65/65]; whereas if, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral unit which is intended exclusively for use in the given combination and which is not reusable, that single-unit product shall be governed by [Directive 65/65]; whereas a distinction must be drawn between the abovementioned devices and medical devices incorporating, inter alia, substances which, if used separately, may be considered to be a medicinal substance within the meaning of [Directive 65/65]; whereas in such cases, if the substances incorporated in the medical devices are liable to act upon the body with action ancillary to that of the device, the placing of the devices on the market is governed by this Directive; …'

4 Recital 17 in the preamble to that directive reads as follows:

'[w]hereas medical devices should, as a general rule, bear the CE mark to indicate their conformity with the provisions of this Directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose'.

5 The medical devices covered by Directive 93/42 are defined in Article 1(2)(a) as follows:

'"medical device" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.'

6 Article 1(3) of that directive provides as follows:

'Where a device is intended to administer a medicinal product within the meaning of Article 1 of [Directive 2001/83], that device shall be governed by the present Directive, without prejudice to the provisions of [Directive 2001/83] with regard to the medicinal product.

If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by [Directive 2001/83]. The relevant essential requirements of Annex I to the present Directive shall apply as far as safety and performance related device features are concerned.'

7 Article 1(4) of Directive 93/42 is worded as follows:

'Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of Article 1 of [Directive 2001/83] and which is liable to act upon the body with action ancillary to that of the device, that device must be assessed and authorised in accordance with this Directive.'

8 Article 1(5)(c) of Directive 93/42 provides that the directive is not to apply to medicinal products covered by Directive 2001/83. For the purpose of deciding whether a product falls under that directive or Directive 93/42, particular account is to be taken of the principal mode of action of the product.

9 Article 4(1) of Directive 93/42 imposes the following obligation on Member States:

'Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 17 which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11.'

10 Article 8 of that directive, entitled ‘Safeguard clause’, permits the Member States to adopt the following measures:

‘1. Where a Member State ascertains that the devices referred to in Article 4(1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

(a) failure to meet the essential requirements referred to in Article 3;

(b) incorrect application of the standards referred to in Article 5, in so far as it is claimed that the standards have been applied;

(c) shortcomings in the standards themselves.

…

3. Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.’

11 Article 17(1) of Directive 93/42 provides:

‘Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.’

12 Article 18 of that directive, entitled ‘Wrongly affixed CE marking’, is worded as follows:

‘Without prejudice to Article 8:

(a) where a Member State establishes that the CE marking has been affixed unduly or is missing in violation of the Directive, the manufacturer or his authorised representative shall be obliged to end the infringement under conditions imposed by the Member State;

(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8.

Those provisions shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.’

Directive 2001/83

13 According to Recital 3 in the preamble to Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83 (OJ 2004 L 136, p. 34):

‘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.’

14 Recital 7 in the preamble to that directive states as follows:

‘Particularly as a result of scientific and technical progress, the definitions and scope of [Directive 2001/83] 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.’

15 Under Article 1(2) of Directive 2001/83, ‘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.’

16 Article 2(1) and (2) of that directive 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.’

17 Article 6(1) of Directive 2001/83 states as follows:

‘No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or unless an authorisation has been granted in accordance with [Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1)], read in conjunction with [Regulation No 1901/2006].

When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in

accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1).'

Finnish law

The Law on medical devices

18 Under the first subparagraph of Article 3(1) of the Law on medical devices (Laki terveydenhuollon laitteista ja tarvikkeista), in the version applicable to the main proceedings:

'"medical device" means any instrument, apparatus, appliance, material or other device or article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process, or

— control of conception.

The function of the medical device as referred to in the second subparagraph of Article 3(1) may be assisted by pharmacological, immunological or metabolic means, provided that the principal action sought is not achieved by those means.'

19 Article 19 of that law sets out the restrictions on the manufacture and sale of medical devices. The first paragraph of that article provides that if a medical device infringes the law or any provision or requirement laid down by law, or if a CE marking has wrongly been provided to it, the Lääkelaitos (National Agency for Medicines), which was, at the material time, the competent public body prior to its tasks being entrusted, from 1 November 2009, to the Lääkealan turvallisuus– ja kehittämiskeskus and the Sosiaali– ja terveysalan lupa– ja valvontavirasto, may:

— require the manufacturer to take the necessary measures to ensure that the device complies with the law or any provision or requirement laid down by law, or

— prohibit the manufacture, sale or other form of transfer of the medical device in the course of economic activity.

Under the third paragraph of Article 19 of that law, the provisions set out above also apply where the CE marking for medical devices has been affixed to products that are not medical devices.

The law on medicinal products

20 Under the first paragraph of Article 3 of the Law on medicinal products (Lääkelaki), in the version applicable to the main proceedings, 'medicinal product' means any substance, whether administered by internal or external means, which is intended to cure, alleviate or prevent disease or its symptoms in human beings or in animals.

21 According to the second paragraph of Article 3 of the Law on medicinal products, any substance or combination of substances, for internal or external use, which may be administered to human beings or to animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to establishing the cause of disease or state of health are also to be regarded as medicinal products.

22 The third paragraph of Article 3 of the Law on medicinal products provides that, in cases of doubt, where, having regard to all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of another preparation covered by other legislation or by Union measures, the provisions applicable to medicinal products are to be applied first and foremost to the preparation.

23 According to Article 6 of the Law on medicinal products, the Lääkelaitos must, where necessary, specify whether a substance or preparation is to be regarded as a medicinal product, a traditional herbal preparation or a homeopathic preparation.

24 Under Article 20a of the Law on medicinal products, the sale to the public of a pharmaceutical preparation or any other form of release for consumption presupposes that the Lääkelaitos has given its consent to the preparation or has registered it in accordance with that law, or that a competent institution established in the Union has authorised the marketing of the product.

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

25 'Gynocaps' is a vaginal capsule containing live lactobacilli intended to restore balance to the vagina's normal protective bacterial flora. The product is intended for women of all ages and may be used during pregnancy or breastfeeding.

26 Until 2008, Gynocaps was marketed in Finland as a 'medical device or accessory', bearing a CE marking. The capsule is currently also marketed as a 'medical device or accessory' bearing a CE marking in a number of other Member States, including the Kingdom of Spain, the French Republic, the Italian Republic and the Republic of Austria.

27 The European Medicines Agency (EMA) has not specifically adopted a position on the classification of vaginal preparations which, like Gynocaps, contain live lactobacilli. It has, however, taken the view that on the basis of its intended use and effects, a gynaecological tampon containing live lactobacilli satisfied the conditions for classification as a 'medicinal product for human use', within the meaning of Directive 2001/83.

28 The Lääkelaitos was informed of the marketing, as a medicinal product, of a vaginal preparation similar to Gynocaps, containing live lactobacilli.

29 In the light of that information, the Lääkelaitos took the view that, taking into account its composition and its mode of action, Gynocaps was not a medical device, but a preparation that may be used as a medicinal product. According to the Lääkelaitos, the principal effect of a vaginal capsule containing live lactobacilli, such as Gynocaps, is achieved, taking account of its intended use, through metabolic and pharmacological action. The preparation affects certain physiological functions, correcting or restoring them. The sale and advertising of such a product therefore required marketing authorisation as a medicinal product.

30 By decision adopted on 14 November 2008, after hearing Laboratoires Lyocentre, the French company that manufactures Gynocaps, the Lääkelaitos, therefore decided, on its own initiative to classify Gynocaps as a medicinal product within the meaning of Directive 2001/83. In consequence, a marketing authorisation was thereafter required.

31 On 11 February 2009, the decision of the Lääkelaitos was notified to the Commission. The Lääkelaitos interpreted Directive 93/42 as meaning that where a CE marking has been wrongly affixed, the safeguard clause procedure provided for in Article 8 of that directive was not applicable because the issue was not strictly one of non-compliance.

32 Laboratoires Lyocentre challenged the decision of the Lääkelaitos before the Helsingin hallinto-oikeus (Helsinki Administrative Court), which dismissed the action holding, inter alia, that according to the case-law of the Court of Justice, the fact that a product is classified, for example, as a foodstuff in one Member State does not preclude that same product from being classified in another Member State as a medicinal product. According to the Helsingin hallinto-oikeus, the Lääkelaitos was entitled to classify Gynocaps in Finland as a medicinal product, even though that preparation is marketed as a medical device in a number of other Member States of the Union.

33 Laboratoires Lyocentre appealed against that judgment to the Korkein hallinto-oikeus (Supreme Administrative Court). In that appeal, it claimed, in particular, in essence, that the action performed by Gynocaps is limited to inducing the effects created by the introduction of live lactobacilli into the human body. Therefore, given that that mode of action does not proceed from an immediate pharmacological or other effect on the human body, Laboratoires Lyocentre argued that Gynocaps should not be classified as a medicinal product.

34 In those circumstances the Korkein hallinto-oikeus decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

‘(1) Does a definition given in one Member State in accordance with Directive 93/42, by which a product is regarded as a medical device or accessory in accordance with that directive and is provided with a CE marking, preclude the competent national authority of another Member State from defining the product concerned, on the basis of its pharmacological, immunological or metabolic effects, as a medicinal product in accordance with Article 1(2)(b) of Directive [2001/83]?

(2) If the answer to the previous question is in the negative, can that competent national authority define the product as a medicinal product observing only the procedures under Directive [2001/83] or is it necessary, prior to initiating procedures under that directive to define the product as a medicinal product, to follow the safeguard procedure in Article 8 of Directive [93/42] or to comply with the provisions of Article 18 concerning an unduly affixed CE marking?

(3) Does Directive [2001/83], Directive [93/42] or other European Union legislation (including legislation concerning the protection of human life and health and consumer protection) preclude products containing the same substance and having the same modes of action from being marketed in the same Member State both as medicinal products in accordance with Directive [2001/83], requiring a marketing authorisation, and as medical devices or accessories in accordance with Directive [93/42]?’

Consideration of the questions referred

The first question

35 By its first question, the referring court asks, in essence, whether the classification of a product, in one Member State, as a medical device bearing a CE marking, in accordance with Directive 93/42, precludes the competent authorities of another Member State from classifying the same product, on the basis of its pharmacological, immunological or metabolic action, as a medicinal product within the meaning of Article 1(2)(b) of Directive 2001/83.

36 As regards, first, the term 'medicinal product', Article 1(2)(a) and (b) of Directive 2001/83 provides two definitions. A product is a medicinal product if it comes within one or other of those two definitions (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 49).

37 According to the second definition of that term, set out in Article 1(2)(b) of Directive 2001/83, medicinal product means '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.'

38 As regards, secondly, the term 'medical device', as set out in Article 1(2)(a) of Directive 93/42, this refers, inter alia, to any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap, which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

39 So far as concerns the respective scope of those two terms, it is apparent from Article 1(5)(c) of Directive 93/42 that that directive does not apply to medicinal products covered by Directive 2001/83.

40 Furthermore, in cases of doubt, Article 2(2) of Directive 2001/83 requires the application of Directive 2001/83, by providing that, 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 Union legislation, it is the provisions of Directive 2001/83 on medicinal products that are to apply.

41 Consequently, a product that falls within the definition of a 'medicinal product' within the meaning of Directive 2001/83 must be regarded as a medicinal product and may not be classified as a medical device within the meaning of Directive 93/42.

42 Whether a product falls within the definition of a medicinal product by virtue of its function for the purposes of Directive 2001/83 must be determined by the national authorities on a case-by-case basis, acting under the supervision of the courts, 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 (C-140/07 *Hecht-Pharma* [2009] ECR I-41, paragraph 39, and C-27/08 *BIOS Naturprodukte* [2009] ECR I-3785, paragraph 18).

43 In the context of that case-by-case examination, the pharmacological, immunological or metabolic properties of a product constitute 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 (*BIOS Naturprodukte*, paragraph 20).

44 As regards more particularly the distinction between medicinal products and medical devices, Article 1(5)(c) of Directive 93/42 specifically requires the competent authorities to take particular account of the principal mode of action of the product. It thus follows from Article 1(2)(a) of that directive that only a product which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means may be classified as a medical device.

45 None the less, as Union law currently stands, until harmonisation of the measures necessary to ensure the protection of health is more complete, it will be difficult to avoid the existence of differences in the classification of products as between Member States in the context of Directive 2001/83 (see, to that effect, inter alia, Case C-201/96 *LTM* [1997] ECR I-6147, paragraph 24, and *Hecht-Pharma*, paragraph 28).

46 As the Advocate General has stated in point 63 of her Opinion, asymmetries in scientific information, new scientific developments and differing assessments of risks to human health and the desired level of protection can explain why different decisions are taken by the competent authorities of two Member States as regards the classification of a product.

47 In addition, the fact that a product is classified as a medical device in accordance with Directive 93/42 in one Member State does not prevent it being classified, in another Member State, as a medicinal product in accordance with Directive 2001/83 if it displays the characteristics of such a product (see, by analogy, Case C-150/00 *Commission* v *Austria* [2004] ECR I-3887, paragraph 60, and *HLH Warenvertrieb and Orthica*, paragraph 56).

48 In the light of all the foregoing considerations, the answer to the first question is that the classification of a product in one Member State as a medical device bearing a CE marking, in accordance with Directive 93/42, does not preclude the competent authorities of another Member State from classifying the same product, on the basis of its pharmacological, immunological or metabolic action, as a medicinal product within the meaning of Article 1(2)(b) of Directive 2001/83.

The second question

49 By its second question, the referring court asks, in essence, whether in order to classify as a medicinal product in accordance with Directive 2001/83 a product already classified in another Member State as a medical device bearing a CE marking in accordance with Directive 93/42, the competent authorities of a Member State must, before applying the classification procedure under Directive 2001/83, apply the procedure under Article 8 of Directive 93/42 or the procedure under Article 18 of Directive 93/42.

50 It must be pointed out, at the outset, that the second paragraph of Article 18 of Directive 93/42 expressly states that, without prejudice to the application of Article 8 of that directive, the provisions of Article 18 are applicable where the CE marking has been affixed in accordance with the procedures in the directive, but inappropriately, on products that are not covered by the directive.

51 It is therefore necessary to determine whether, in circumstances such as those in the main proceedings, the CE marking affixed to a product already classified in one Member State as a medical device, which the competent authorities of another Member State are minded to classify as a medicinal product, must be regarded as having been affixed inappropriately, within the meaning of the second paragraph of Article 18 of Directive 93/42.

52 In this connection, it is apparent from the answer to the first question referred that the fact that a product is classified in one Member State as a medical device does not preclude the competent authorities of another Member State from deciding to classify an identical product as a medicinal product.

53 Where the competent authorities of a Member State, acting, where appropriate, under the supervision of the courts, decide to classify as a medicinal product a product already classified in another Member State as a medical device, they must regard the CE marking, affixed to the product in question

following its classification as a medical device in that other Member State, as having been affixed inappropriately. It will be apparent from the decision of those authorities that the marking in question would appear to have been affixed to a product that is not covered by Directive 93/42.

54 It follows that, in a situation such as that in the main proceedings, the procedural provisions laid down in Article 18 of Directive 93/42 and, where appropriate, even those laid down in Article 8 of that directive, must be applied.

55 In the light of the foregoing considerations, the answer to the second question is that, in order to classify as a medicinal product in accordance with Directive 2001/83 a product already classified in another Member State as a medical device bearing a CE marking in accordance with Directive 93/42, the competent authorities of a Member State must, before applying the classification procedure under Directive 2001/83, apply the procedure under Article 18 of Directive 93/42 and, where appropriate, the procedure under Article 8 of Directive 93/42.

The third question

56 It is clear from the order for reference that the decision of the Lääkelaitos to declassify Gynocaps as a medical device in order to reclassify it as a medicinal product was, to all appearances, based on the fact that, in Finland, another product which, while not strictly identical to Gynocaps, none the less has in common with it an identical substance and the same mode of action, was already being marketed as a medicinal product. Laboratoires Lyocentre disputes, however, that that fact is capable of justifying such a decision.

57 In the light of the specific context of the dispute in the main proceedings, the referring court seeks to ascertain, in essence, whether, within the same Member State, a product which, while not identical to another product classified as a medicinal product, none the less has in common with it an identical substance and the same mode of action, may be marketed as a medical device in accordance with Directive 93/42.

58 To the extent that another product has several of the significant characteristics set out in Article 1(2)(b) of Directive 2001/83, namely, where it has one of the same substances and the same mode of action as the product classified as a medicinal product, the former should, in principle, also be classified and marketed as a medicinal product. That being the case, it is for the referring court to verify, on a case-by-case basis, as referred to in paragraph 42 above, that another characteristic that is specific to that product and relevant for the purposes of Article 1(2)(a) of Directive 93/42 does not preclude the product from being classified as a medicinal product and marketed as such.

59 It should, moreover, be recalled that Article 2(2) of Directive 2001/83 states that, in cases of doubt, where, taking into account all of its characteristics, a product may fall within the definition of a ‘medicinal product’ and within the definition of a product covered by other Union legislation, it must be classified as a medicinal product.

60 In the light of the foregoing considerations, the answer to the third question is that, within the same Member State, a product, which, while not identical to another product classified as a medicinal product, none the less has in common with it an identical substance and the same mode of action, cannot, in principle, be marketed as a medical device in accordance with Directive 93/42, unless as a result of another characteristic that is specific to that product and relevant for the purposes of Article 1(2)(a) of Directive 93/42, it must be classified and marketed as a medical device, which is a matter for the referring court to verify.

Costs

61 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 (Fourth Chamber) hereby rules:

1. **The classification of a product in one Member State as a medical device bearing a CE marking, in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, does not preclude the competent authorities of another Member State from classifying the same product, on the basis of its pharmacological, immunological or metabolic action, as a medicinal product within the meaning of Article 1(2)(b) 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 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006.**

2. **In order to classify as a medicinal product in accordance with Directive 2001/83, as amended by Regulation No 1901/2006, a product already classified in another Member State as a medical device bearing a CE marking, in accordance with Directive 93/42, as amended by Directive 2007/47, the competent authorities of a Member State must, before applying the classification procedure under Directive 2001/83, as amended by Regulation No 1901/2006, apply the procedure under Article 18 of Directive 93/42, as amended by Directive 2007/47, and, where appropriate, the procedure under Article 8 of Directive 93/42.**

3. **Within the same Member State, a product which, while not identical to another product classified as a medicinal product, none the less has in common with it an identical substance and the same mode of action, cannot, in principle, be marketed as a medical device in accordance with Directive 93/42, as amended by Directive 2007/47, unless, as a result of another characteristic that is specific to that product and relevant for the purposes of Article 1(2)(a) of Directive 93/42, it must be classified and marketed as a medical device, which is a matter for the referring court to verify.**

[Signatures]