Reports of Cases

OPINION OF ADVOCATE GENERAL
SHARPSTON
delivered on 30 May 2013 [1]

Case C-109/12

Laboratoires Lyocentre

(Request for a preliminary ruling from the Korkein hallinto-oikeus (Finland))

(Medicinal product — Medical device — CE marking — Product classification — Procedure)

1. A product previously classified by the competent authorities of a Member State as a medical device has been reclassified as a medicinal product. That product remains on the market in some other Member States as a medical device. Against that background, the Court is asked to determine what procedures should apply to such a reclassification and whether a product can be both a medical device and a medicinal product in (i) the market of a single Member State and (ii) the internal market.

Legal background

EU law

Medical Devices Directive

2. Council Directive 93/42/EEC concerning medical devices ('the Medical Devices Directive') [2] applies to medical devices and their accessories which are collectively termed 'devices' for purposes of that directive. [3]

1 — Original language: English.

2 — Council Directive of 14 June 1993 (OJ 1993 L 169, p. 1), as amended. That directive was most recently 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 2007/47'). Member States were required to adopt and publish by 21 December 2008 the measures taken necessary to comply with Directive 2007/47 and those measures had to be applied from 21 March 2010. The decision at issue in this case dates from 14 November 2008 (see point 28 below) and therefore the amendments brought about by Directive 2007/47 as such do not apply. Yet it is also settled case-law that 'during the period prescribed for transposition of a directive, the Member States to which it is addressed must refrain from taking any measures liable seriously to compromise the attainment of the result prescribed by that directive. Such an obligation to refrain owed by all the national authorities must be understood as referring to the adoption of any measure, general or specific, liable to produce such a compromising effect': see Case C-43/10 *Nomarchiaki Aftodioikisi Aitoloakarnanias* [2012] ECR, paragraph 57 and case-law cited. Whilst Directive 2007/47 amended many provisions at issue in this case, it did not amend most of them in a manner that is materially relevant to the questions referred to the Court. Where relevant, I consider Directive 2007/47. The Commission is working on a new directive which is intended to replace the Medical Devices Directive: see http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm. Under Article 73(1) of the Commission's proposal (COM(2012) 542 final), 'a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance …'.

3 — Article 1(1) of the Medical Devices Directive.

3. The third recital in the preamble states that 'national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonised in order to guarantee the free movement of such devices within the internal market'.

4. The sixth recital states that:

'… certain medical devices are intended to administer medicinal products within the meaning of Council Directive 65/65/EEC [4] …; 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 [the Medicinal Products Directive]; … 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 [the Medicinal Products Directive]; … 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 [the Medicinal Products Directive]; … 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 …'

5. The 17th recital states that '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'.

6. Article 1(2)(a) defines a 'medical device' as:[5]

'any instrument, apparatus, appliance, material or other 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,

— 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.'

7. Article 1(3) states:

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

4 — 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 1965-1966, p. 20), as amended. Directive 65/65 was the first directive on the control of medicines and has now been repealed and replaced by the Medicinal Products Directive (see points 16 to 20 below): see Article 128 of the Medicinal Products Directive.

5 — Directive 2007/47 amends solely the introductory paragraph of this definition so as to state: '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'.

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 [the Medicinal Products Directive]. The relevant essential requirements of Annex I to the present Directive shall apply as far as safety and performance related device features are concerned.'

8. According to Article 1(5)(c), the Medical Devices Directive does not apply to 'medicinal products covered by [the Medicinal Products Directive]'. Directive 2007/47 adds a sentence stating that '[i]n deciding whether a product falls under [the Medicinal Products Directive] or this Directive, particular account shall be taken of the principal mode of action of the product'.

9. Article 2 provides:

'Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.'

10. According to Article 3, 'devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned'. Article 5(1) provides that Member States must presume compliance with those requirements 'in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards …'.

11. Article 4(1) provides:

'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.'

12. Article 8 sets out the 'Safeguard clause':

'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.

…'

13. Article 9 provides that devices are to be divided into Classes I, IIa, IIb and III. Article 11 sets out the conformity assessment procedures that apply to each class.

14. Article 17(1) states:

'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.'

15. Article 18 concerns 'Wrongly affixed CE marking' and provides:

'Without prejudice to Article 8:

(a) where a Member State establishes that the CE marking has been affixed unduly, [6] the manufacturer or his authorised representative established within the Community 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.'

Medicinal Products Directive

16. Directive 2001/83/EC on the Community code relating to medicinal products for human use ('the Medicinal Products Directive') [7] defines, in Article 1(2), a 'medicinal product' as:

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

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

6 — Directive 2007/47 amends that provision by adding a second irregular situation to indent (a), namely where a CE marking 'is missing in violation of the Directive'.

7 — Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 (OJ 2001 L 311, p. 67), as amended. At the relevant time, the version in place was that which was last amended by Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission (OJ 2008 L 81, p. 51). However, that directive did not change any of the provisions at issue in this case – the last relevant amendment was Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 (OJ 2006 L 378, p. 1). For a brief history of the legislation governing medicinal products, see points 4 to 11 of my Opinion in Case C-535/11 *Novartis* [2013] ECR.

17. The present wording of that provision is based on the amendment by Directive 2004/27. [8] Recital 7 in the preamble to the latter states:

'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 … 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 … medical devices …, this Directive should not apply…'

18. Recital 2 in the preamble to the Medicinal Products Directive states that '[t]he essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health'. Recital 14 describes the directive as being 'an important step towards achievement of the objective of the free movement of medicinal products'.

19. Article 2 of the Medicinal Products Directive describes its scope:

'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.

3. Notwithstanding paragraph 1 and Article 3(4), Title IV of this Directive shall apply to medicinal products intended only for export and to intermediate products.'

20. Article 6(1) states:

'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 [9] ...'

Finnish law

21. The Laki terveydenhuollon laitteista ja tarvikkeista ('the Law on medical devices and accessories') and the Lääkelaki ('the Law on medicinal products') implemented, respectively, the Medical Devices Directive and the Medicinal Products Directive.

8 — Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ 2004 L 136, p. 34) ('Directive 2004/27').

9 — 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), as amended.

22. Article 19 of the Law on medical devices and accessories states, in its first paragraph, that in circumstances such as those in which a CE mark is unduly affixed to a medical device, the Lääkelaitos ('the National Agency for Medicines') [10] can either require that the manufacturer takes the necessary measures to ensure that the product is in conformity with the relevant legislation or prohibit the production, sale or other form of economic transfer of the device. According to its third paragraph, the same provisions apply in circumstances where a CE mark was affixed on a product that is not a medical device.

23. Based on Article 6 of the Law on medicinal products, the National Agency for Medicines must decide, where necessary, whether a product should be classified as a medicinal product or another type of product.

Facts, procedure and questions referred

24. Laboratoires Lyocentre manufactures a vaginal capsule used for correcting bacterial imbalances in the vagina. The product's composition consists of a particular bacterium of the lactobacillus genus, together with lactose and magnesium stearate; gelatine is used for the capsule's protective shell.

25. Until 2006, the product was marketed in Finland as a natural medicine under the name Gynophilus. Since 2006, the same product has been marketed there under the name Gynocaps as a medical device with a CE marking. It is sold and marketed in the same manner in, inter alia, Austria, Spain, Italy and France.

26. At the hearing, the representative of Laboratoires Lyocentre said that the product had been classified as a 'Class III medical device'. [11]

27. Whilst the European Medicines Agency ('the EMA') has not taken a position on the classification of this specific product, it appears from the order for reference that it has decided that a gynaecological tampon containing lacto bacteria was to be classified, based on its purpose and effects, as a medicinal product within the meaning of the Medicinal Products Directive. The referring court further mentions that no EU-wide marketing authorisation has been granted for vaginal products such as Gynocaps. [12]

28. On 14 November 2008, the National Agency for Medicines decided that Gynocaps, taking into account its composition and impact mechanism, could no longer be marketed as a medical device within the meaning of the Law on medical devices and accessories. The National Agency for Medicines found that the product contained live lactobacilli and modified, corrected or restored certain physiological functions through a pharmacological and metabolic impact mechanism. A marketing authorisation was thus needed.

29. That decision was taken, after hearing Laboratoires Lyocentre, on the authority's own initiative following another company's notification of its manufacture of a similar product. That product was classified as a medicinal product.

30. The National Agency for Medicines further decided that the safeguard clause procedure in Article 8 of the Medical Devices Directive did not apply if a CE marking had been wrongly affixed to a product.

10 — Since 1 November 2009, the Lääkealan turvallisuus- ja kehittämiskeskus ('the Medicinal Safety and Development Centre') is competent for classifying medicinal products and the Sosiaali-ja terveysalan lupa- ja valvontavirasto ('the Social and Health Authorisation and Supervision Authority') is responsible for medical devices and accessories.

11 — See further points 39 and 40 below.

12 — See also footnote 23 below.

31. Laboratoires Lyocentre appealed against that decision before the Helsingin hallinto-oikeus (Helsinki Administrative Court). After that appeal was filed, the authority contacted the Commission on 11 February 2009.

32. On 17 November 2010, the Helsinki Administrative Court dismissed the appeal. It found that, based on the Court's case-law, the classification of a product as, for example, a foodstuff in one Member State did not preclude the classification by another Member State of the same product as a medicinal product. Gynocaps could thus be classified as a medicinal product in Finland despite the fact that it was sold and marketed as a medical device in other Member States. The need for a marketing authorisation in order to place the product on the Finnish market was not a prohibited restriction on trade between Member States in so far as the product could be classified as a medicinal product.

33. Laboratoires Lyocentre appealed against that decision before the Korkein hallinto-oikeus (Supreme Administrative Court), which seeks a preliminary ruling on the following questions:

'1. Does a definition given in one Member State in accordance with the [Medical Devices Directive], by which a product is regarded as a [medical] device or accessory in accordance with the [Medical] Devices 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 the Medicinal Products Directive …?

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 the Medicinal Products Directive … or is it necessary, prior to initiating procedures under the Medicinal Products Directive to define the product as a medicinal product, to follow the safeguard clause procedure in Article 8 of the [Medical] Devices Directive or to comply with the provisions of Article 18 concerning an unduly affixed CE marking?

3. Does the Medicinal Products Directive …, the [Medical Devices Directive] or other European Union legislation (including the protection of human health and life and consumer protection) preclude products containing the same substance and having the same modes of action from being on the market in the same Member State both as medicinal products in accordance with the Medicinal Products Directive …, requiring a marketing authorisation, and as medical devices or accessories in accordance with the [Medical Devices Directive]?'

34. Written observations have been submitted by Laboratoires Lyocentre, the Estonian, Italian, Polish, Finnish and UK Governments and by the Commission. A hearing was requested and granted. At that hearing, held on 20 February 2013, Laboratoires Lyocentre, the Finnish, Czech and UK Governments and the Commission presented oral argument.

Assessment

Preliminary remarks

35. By its first and third questions, the national court in essence asks whether the definitions of a 'medical device' and a 'medicinal product' in, respectively, the Medical Devices Directive and the Medicinal Products Directive are mutually exclusive. The first question concerns the classification by different Member States of the same product as either a medical device or a medicinal product, whereas the third question focuses on the classification by a single Member State of products, containing the same substance and having the same modes of action, as both a medical device and a medicinal product. I shall therefore, in what follows, consider the first and third questions together.

36. Neither question concerns the actual classification of the product at issue in the proceedings before the Supreme Administrative Court. I therefore take no position on the merits of the National Agency for Medicines' decision that Gynocaps, whilst previously on the market as a medical device, is in fact a medicinal product.

The first and third questions

37. The Medical Devices Directive and the Medicinal Products Directive apply to different types of product.

38. A *medical device* is defined by reference to its (i) physical presentation (it can be 'any instrument, apparatus, appliance, material or other article'); (ii) use ('for human beings'); (iii) purpose (the four categories of functions listed in Article 1(2)(a) of the Medical Devices Directive); and (iv) means of achieving its principal intended action or mode of action (which cannot be achieved 'in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in its function by such means'). [13]

39. If a product is a medical device covered by the Medical Devices Directive, no market authorisation is needed. Rather, whether the competent authority or a notified body (that is to say, a body designated by a Member State to perform tasks described in Article 11 of the directive and possibly other specific tasks [14]) needs to intervene and, if so, the extent of that intervention, depends on the type of device. Medical devices are divided into four product classes based on the vulnerability of the human body, taking account of the potential risks associated with their technical design and manufacture. For example, for 'Class I devices' – corresponding to a low level of vulnerability – the manufacturer alone is responsible for carrying out the conformity assessment procedures and making all relevant documentation available during a certain period to the national authorities for inspection. [15] By contrast, 'Class III devices' are the most critical devices and cannot be placed on the market without an explicit prior authorisation issued by a notified body with regard to conformity. [16]

40. The Medical Devices Directive requires Member States to take all necessary steps to ensure that devices are placed on the market or put into service only if they comply with the requirements set out in that directive, in particular the essential requirements set out in Annex I to that directive. [17] Compliance with those essential requirements is presumed where devices are in conformity with

13 — Article 1(2)(a) of the Medical Devices Directive.

14 — Article 16(1) of the Medical Devices Directive.

15 — See 15th recital in the preamble to and Article 11(5) of the Medical Devices Directive. See also Annex VII to that directive.

16 — See 15th recital in the preamble to, and Articles 9 and 11(1) of, the Medical Devices Directive.

17 — See Articles 2 and 3 of the Medical Devices Directive.

national standards adopted pursuant to harmonised standards.[18] Devices that are considered to meet those requirements must bear the CE marking when placed on the market.[19] That mark indicates that medical devices are in conformity with the Medical Devices Directive and enables them to move freely within the internal market and be put into service in accordance with their intended purpose.[20] Whilst products bearing a CE mark are presumed to comply with the Medical Devices Directive and must therefore be allowed to circulate freely, that presumption is rebuttable in certain circumstances.[21] In order to affix that mark to a Class III device, the manufacturer must follow either the full quality assurance system (Annex II) or an EC type-examination procedure (Annex III) coupled with (i) the EC verification procedure (Annex IV) or (ii) the production quality assurance procedure (Annex V).

41. A *medicinal product* is defined by reference to its (i) physical presentation (it can be 'any substance or combination of substances') and (ii) its properties (the so-called 'medicinal products by virtue of their presentation' because they are presented as having 'properties for treating or preventing disease in human beings' – Article 1(2)(a) of the Medical Products Directive) or its function and mode of action (the so-called 'medicinal products by virtue of their function',[22] whose function is 'restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action' or 'making a medical diagnosis'; in order to achieve those functions, they 'may be used in or administered to human beings' – Article 1(2)(b) of the Medicinal Products Directive).

42. If a product is a medicinal product covered by the Medicinal Products Directive,[23] it cannot be placed on the market of a Member State without a marketing authorisation issued by the competent authority of that Member State[24] following an application filed to that effect.[25]

43. Based on these definitions, contact lenses (for example) are likely to be classified as medical devices and antibiotics in capsule form may be classified as medicinal products.

44. By contrast, as the facts of this case show, that clarity of classification does not appear to apply to Gynocaps. Can one Member State classify that product as a medicinal product whilst another classifies it as a medical device?

45. In my opinion, the Medical Devices Directive and the Medicinal Products Directive do not exclude that possibility.

46. Both directives recognise that their respective scopes of application can overlap and provide rules in order to ensure that in principle, at any given time, a single directive governs a product and to exclude any doubt in that regard. Those rules guarantee that no product satisfying the definition of a medicinal product is put on the market without a marketing authorisation.

18 — Article 5(1) of the Medical Devices Directive. See also point 89 of my Opinion in Case C-6/05 *Medipac-Kazantzidis* [2007] ECR I-4557.

19 — Article 17(1) of the Medical Devices Directive.

20 — 17th recital in the preamble to the Medical Devices Directive.

21 — See, for example, Case C-288/08 *Nordiska Dental* [2009] ECR I-11031, paragraph 23, and *Medipac-Kazantzidis*, cited in footnote 18 above, paragraph 44.

22 — See, for example, Case C-319/05 *Commission* v *Germany* [2007] ECR I-9811, paragraph 41 and case-law cited.

23 — But not if it is a medicinal product covered by 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), as amended most recently by Regulation (EU) No 1027/2012 of 25 October 2012 (OJ 2012 L 316, p. 38). Such medicinal products, which are defined in the Annex to Regulation No 726/2004, are subject to a centralised EU procedure and the authorisation issued under that procedure is valid throughout the EU. The national court has asked this Court to consider its questions only under the Medicinal Products Directive. I shall therefore not address this regulation.

24 — Article 6(1) of the Medicinal Products Directive.

25 — Article 8(1) of the Medicinal Products Directive.

47. If it is clear that a product satisfies the elements of the definition of a medical device and is *not* a medicinal product, evidently the Medical Devices Directive applies. However, that directive does not apply to medicinal products covered by the Medicinal Products Directive. [26]

48. Conversely it might not always be clear that a product is a medicinal product covered by the Medicinal Products Directive. The directives themselves attempt to address those uncertainties by setting out rules resolving possible conflicting positions on the proper classification.

49. For example, the Medical Devices Directive foresees that medical devices may be used to administer medicinal products. [27] In that event, the first subparagraph of Article 1(3) states that the Medical Devices Directive is to apply without prejudice to (what is now) the Medicinal Products Directive. The Medical Devices Directive applies to a device even if it incorporates, as an integral part, a substance which may be considered to be a medicinal product if used separately and which is liable to act upon the body with action ancillary to that of the device. [28] Yet, insofar as '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', the second subparagraph of Article 1(3) provides that the Medicinal Products Directive shall govern that product.

50. Article 2(2) of the Medicinal Products Directive sets out a more general rule according to which that directive applies to a product that, based on all its characteristics, may fall within the definition of both a 'medicinal product' and a product covered by other EU legislation (including the Medical Devices Directive). That rule corresponds to the principle developed by the Court according to which a product satisfying the elements of the definition of a medicinal product is covered only by EU law governing medicinal products, despite the fact that the same product may fall within the scope of other, less stringent, EU law. [29]

51. At first sight, Article 2(2) thus appears to exclude the possibility that different Member States may characterise the same product as both a medicinal product and medical device because, if in doubt, the Medicinal Products Directive applies.

52. However, there is no situation of doubt when two Member States each are clear in reaching their differing conclusions as to whether the product is a medical device or a medicinal product.

53. Indeed, it follows from the definitions of both types of product that Member States may, for example, classify the same product as satisfying the description of the physical presentation of both a medical device and a medicinal product. If a product contains properties for treating or preventing diseases, one Member State might find on the basis of available scientific evidence that that characteristic corresponds with the purpose described in the first indent of Article 1(2)(a) of the Medical Devices Directive ('diagnosis, prevention, monitoring, treatment or alleviation of disease') whilst another might use that element to classify the product as a medicinal product within the meaning of Article 1(2)(a) of the Medicinal Products Directive. Thus, if the first Member State takes the view, based on the available scientific evidence, that the principal intended action is not achieved in or on the human body by pharmacological, immunological or metabolic means, it may, despite the classification by the second Member State, classify the product as a medical device.

54. In the present case, the National Agency for Medicines appears to have decided that Gynocaps ought to be reclassified as a medicinal product within the meaning of Article 1(2)(b) of the Medicinal Products Directive, since it is a 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

26 — Article 1(5)(c) of the Medical Devices Directive.

27 — See the sixth recital in the preamble to and Article 1(3) of the Medical Devices Directive.

28 — Article 1(4) of the Medical Devices Directive.

29 — Case C-319/05 *Commission* v *Germany*, cited in footnote 22 above, paragraph 63 and case-law cited.

functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis'.[30] Those are products whose 'pharmacological properties … have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions'.[31] As several parties have pointed out in their written observations, it is often the principal function of a product or substance and mode of action that determines which directive applies.[32] Article 1(5)(c) of the Medical Devices Directive, as amended by Directive 2007/47, now states a similar rule.[33]

55. In my opinion, as long as there is no complete harmonisation with respect to these types of product, it is possible for one Member State to conclude with confidence that a given product is a medical device whereas another takes the position that the same product is a medicinal product.

56. The Court has said that, in classifying a product as a medicinal product by virtue of its function, 'national authorities … 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'.[34] The risk to health is a separate factor that needs to be considered in that assessment.[35] Although Directive 2004/27 has amended the definition of a medicinal product, the Court has confirmed that these factors remain relevant to establishing whether a product satisfies the definition of a medicinal product by function.[36]

57. In *Kreussler*, the Court thus found that a product containing a substance that has a physiological effect cannot automatically be classified as a medicinal product by virtue of its function. Rather, the authorities were required to make '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'.[37] They had also to take into account 'all the characteristics of the product, including, inter alia, its composition, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail' and whether the product was 'capable of appreciably restoring, correcting or modifying physiological functions in human beings'.[38]

58. Indeed, at the present stage of harmonisation, manufacturers are required to apply for a marketing authorisation in each Member State where they intend to put a medicinal product on the market.[39] They likewise need to comply with national procedures for placing medical devices on the market of a Member State.

30 — Article 1(2)(b) of the Medicinal Products Directive.

31 — See, for example, Case C-140/07 *Hecht-Pharma* [2009] ECR I-41, paragraph 25 and case-law cited.

32 — See also, in that regard, the European Commission's Guidelines relating to the application of … Council Directive 90/385/EEC on active implantable medical devices [and] … the Council Directive 93/42/EEC on medical devices, MEDDEV 2.1/3 rev 3, p. 9. On the interpretive relevance of this type of document, see Case C-308/11 *Chemische Fabrik Kreussler* [2012] ECR, paragraphs 23 to 27.

33 — See point 8 above.

34 — Case C-319/05 *Commission* v *Germany*, cited in footnote 22 above, paragraph 55 and case-law cited (regarding the Medical Products Directive). See also Case C-387/99 *Commission* v *Germany* [2004] ECR I-3751, paragraph 57 and case-law cited (regarding Directive 65/65).

35 — See, for example, Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 *HLH Warenvertrieb and Orthica* [2005] ECR I-5141, paragraphs 53 and 54 and case-law cited.

36 — See *Hecht-Pharma*, cited in footnote 31 above, paragraph 37.

37 — Cited in footnote 32 above, paragraph 33 and case-law cited.

38 — Cited in footnote 32 above, paragraphs 34 and 35 and case-law cited.

39 — This is without prejudice to the provisions in Chapter 4 of Title III of the Medicinal Products Directive regarding 'Mutual recognition procedure and decentralised procedure'. It does not appear that those procedures have been used in connection with Gynocaps.

59. By necessary implication, each Member State remains competent to authorise marketing of a medicinal product and to apply national procedures governing the placing on the market of medical devices without being bound by the classification made by the competent authority of another Member State.

60. In that regard, the Court has already recognised, in respect of Directive 65/65 and later the Medicinal Products Directive, that it is difficult to avoid the existence of differences in the classification of products as between Member States because harmonisation in this field is incomplete.[40] As a result, the Court has accepted that one Member State may consider it established that a product is a medicinal product by function whereas another Member State may decide that the product should be classified differently.[41] In my opinion, it makes no difference in that regard whether the alternative classification of the product is as a foodstuff, a cosmetic, a medical device or any other type of product. In each case, the principle remains that each Member State is competent to examine, based on all relevant information available, a product's function, mode of action and other pertinent features.

61. Each Member State must of course apply the same definitions that are set out, respectively, in the Medicinal Products Directive and Medical Devices Directive. The competent authorities of different Member States will probably often reach the same conclusion on the classification of a particular product: they will have available the same or similar information, that evidence will be clear as to the elements of each definition and they will assess that information in a similar manner.

62. However, although the legislature has tried to define two types of product in a way that is, as far as possible, mutually exclusive, it has not managed to exclude the possibility that, in certain circumstances, different Member States might classify a product differently (because, for example, they do not have the same information, or the available evidence is assessed differently). Within the area of overlap therefore, and in the absence of greater harmonisation, the directives do not preclude Member States from reaching different decisions.

63. In particular, asymmetries in (scientific) information, new (scientific) developments,[42] and differing assessments of risks to human health and the desired level of protection[43] can explain such decisions.[44]

64. Member States must assess evidence, including scientific information, in support of each of the elements of the definitions of both medical devices and medicinal products. For example, the competent authority must determine the principal mode of action of the product in deciding whether a product is a medical device and, in that regard, might need to consider available and relevant scientific data. In so doing, the authority's standard of review involves a certain degree of appreciation. The scientific evidence might not be unanimous and the available information might be contradictory. In the current state of harmonisation, authorities of different Member States remain entitled to conclude differently on, for example, the principal mode of action of a product.

40 — See, for example, Case C-387/99 *Commission* v *Germany*, cited in footnote 34 above, paragraph 52 and case-law cited (regarding Directive 65/65) and Case C-319/05 *Commission* v *Germany*, cited in footnote 22 above, paragraphs 36 and 37 and case-law cited (regarding the Medicinal Products Directive).

41 — See, for example, *Hecht-Pharma*, cited in footnote 31 above, paragraph 28 and case-law cited, and Case C-387/99 *Commission* v *Germany*, cited in footnote 34 above, paragraph 53 and case-law cited.

42 — For example, on the need to consider new information relevant to the evaluation of the quality, safety or efficacy of the medicinal product at issue, see Article 21(4) of the Medicinal Products Directive.

43 — That margin of appreciation is apparent, for example, from Article 26 of the Medicinal Products Directive, which provides that a marketing authorisation shall be refused if, inter alia, 'the risk-benefit analysis is not considered to be favourable'. See Article 26(1)(a) of that directive.

44 — Efforts are being made towards ensuring coherence in Member States' classification of products and eliminating information asymmetries. For example, as pointed out by several parties, there is within the European Commission a 'Borderline and Classification medical devices' expert group', which consists of industry representatives and competent authorities in the Member States. That group has produced a 'Manual on borderline and classification in the Community Regulatory Framework for medical devices'. Provisions on transparency in both directives also form part of those efforts.

65. Moreover, despite the efforts made at promoting the exchange of information, we cannot presume that the authorities of every Member State have at their disposal an identical set of data and other information on the basis of which they determine the classification of a product.

66. What would be the implications of reaching the opposite conclusion, namely that the authorities of all Member States had to adopt the same position on the classification of a particular product as either a medical device or a medicinal product? That would imply that, in essence, the authority which first classified a particular product in the light of the information available to it became *de facto* the centralised body whose decision must be followed by authorities of other Member States; those other authorities could not thereafter classify the product differently. Neither directive foresees that possibility.

67. It is admittedly true that classifying the same product differently in different Member States may result in legal uncertainty and create some impediment to the smooth functioning of the single market. In my opinion, those consequences are the corollary of incomplete harmonisation.

68. Against that background, I conclude that the answer to the first question must be negative.

69. Do the same considerations also lead to the conclusion that, with regard to the third question, a single Member State can classify products containing the same substance and having the same modes of action as both a medical device and a medicinal product?

70. No.

71. It appears to me that, by its third question, the national court asks whether both directives preclude the Finnish authorities from classifying Gynocaps as a medical device whilst classifying another similar product as a medicinal product.[45] It is not clear from the order for reference whether the national court considers the two products to be identical or merely similar and, if similar, to what extent.

72. If two products are identical in all respects relevant to their classification as either a medical device or a medicinal product, they cannot be put on the market of a single Member State as, respectively, a medical device and medicinal product and thus be governed by different rules, namely the Medical Devices Directive and the Medicinal Products Directive. Only one of those directives can apply to both identical products. In the event of doubt, it is the Medicinal Products Directive that must apply.

73. However, if there is no such perfect identity and products share only the same substance and modes of action, I consider that the directives do not exclude the possibility that (based on a separate and individual assessment, for each product, of the other factors that need to be considered in assessing what directive applies) one product might be put on the market as a medical device and the other as a medicinal product. Put differently, identity of substance and mode of action will not on their own automatically lead to the same classification of two products.

74. I therefore take the view that the mere fact that two products contain the same substance and have the same modes of action is insufficient to conclude that they must be classified and put on the market in the same manner, that is to say, as being both either medicinal products under the Medicinal Products Directive or medical devices under the Medical Devices Directive.

45 — See point 29 above.

The second question

75. By its second question, the referring court asks how to reclassify a medical device as a medicinal product. Is it sufficient to apply only the procedures set out in the Medicinal Products Directive or do those set out in Articles 8 and/or 18 of the Medical Devices Directive also apply?

76. I begin by considering the application of Articles 8 and/or 18 of the Medical Devices Directive. I then ask, should Article 18 apply, whether it is possible to comply with both the requirements set out in that provision and the requirements of the Medicinal Products Directive.

Application of Article 8 and/or 18 of the Medical Devices Directive

77. In my view, Article 18 of the Medical Devices Directive applies and, in the circumstances at issue, Article 8 can apply only by virtue of Article 18.

78. The title of the English language version of Article 18 suggests that it applies if a CE mark has been 'wrongly' affixed. However, the text of Article 18, first paragraph, (a), refers to an 'unduly' affixed mark. The texts of other language versions do not necessarily use two different words in that regard.

79. As I read the introductory phrase of Article 18 ('[w]ithout prejudice to Article 8'), the procedure described there coexists with that set out in Article 8. Whilst the two procedures apply in separate circumstances, it is not impossible that both provisions might apply to a particular set of circumstances.

80. Apart from its introductory phrase, Article 18 consists of two paragraphs, the first comprising two indents, (a) and (b). The first circumstance to which the Article 18 procedure applies is 'where a Member State established that the CE marking has been affixed unduly' (Article 18, first paragraph, (a)). The second circumstance is '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' (Article 18, second paragraph). The first circumstance concerns a CE mark that was affixed not in accordance with the procedures set out in the Medical Devices Directive. By contrast, the second circumstance involves a CE mark that is affixed to a product other than a medical device covered by the Medical Devices Directive. In that case, 'those provisions', that is, Article 18, first paragraph, (a) and (b), 'shall also apply'.

81. The second paragraph of Article 18 thus applies to products that are no longer, or should never have been, covered by that directive.

82. Article 18 neither prescribes a detailed procedure nor defines a particular context in which the finding that a CE marking was wrongly affixed is to be made. In my opinion, it therefore does not preclude an authority from making that finding following a procedure initiated of its own motion.

83. Article 18, first paragraph, (a), states that, based on that finding, the manufacturer or his authorised representative 'shall be obliged' to put an end to that situation under conditions imposed by the Member State. In the first instance, it is therefore the manufacturer's responsibility to terminate the infringement of the directive resulting from the wrongly affixed CE mark. If the manufacturer does not do so and thus the infringement continues, the obligation shifts to the Member State to take all appropriate measures to restrict or prohibit the placing on the market of the product or to ensure that it is withdrawn from the market. Article 18, first paragraph, (b), prescribes that that must be done in accordance with the procedure set out in Article 8 of the Medical Devices Directive. Only in that situation do the procedural provisions enumerated in the second sentence of Article 8(1) to

Article 8(4) apply by virtue of Article 18 and must the Member State, inter alia, immediately inform the Commission of the measures taken pursuant to Article 18, first paragraph, (b), of the Medical Devices Directive. According to Article 8(2), following that notification and consultations with the parties, the Commission may find that the measures are justified or unjustified.

84. In circumstances such as those at issue, the safeguard clause in Article 8 therefore cannot apply independently. That clause applies to products *properly classified* under the Medical Devices Directive but which 'may compromise the health and/or safety of patients, users or, where applicable, other persons'[46] and, in particular, it applies in cases of non-compliance listed at indents (a) to (c) of Article 8(1). To sum up, if – as would appear to be the case here – a medical device does *not* pose a risk to the health and/or safety of patients, users or, where applicable, other persons, Article 8 does not apply.

Compliance with Article 18 of the Medical Devices Directive and the Medicinal Products Directive

85. If a product that bears a CE marking as a medical device is in fact a medicinal product, its manufacturer must take the necessary steps both to end non-compliance with the Medical Devices Directive *and*, if he wishes to continue marketing the product, to comply with the Medicinal Products Directive. Whilst both directives apply to separate types of product and therefore do not apply together to a single product, in circumstances such as those of the present case, the question of how to comply with both directives does arise.

86. If Article 18 applies, is it possible to comply immediately with both the requirements of that provision and those set out in the Medicinal Products Directive?

87. Yes, provided the product is withdrawn from the market and only introduced again following the grant of a marketing authorisation.

88. The extent of the implementation obligation under Article 18 depends on the circumstances at issue, including the types of condition imposed by the relevant Member State.

89. Whilst Article 18 does not prescribe a period within which non-compliance must end, the relationship between its two subparagraphs and the use of the word 'continues' appears to be based on the understanding that a Member State can intervene under indent (b) solely if, *after some time*, it finds that non-compliance continues because the manufacturer has not taken the necessary measures to comply. Only in that situation must the Commission be notified in order to take a final decision on the Member State's measures.

90. Article 18 does not differentiate between products depending on whether or not they should be classified differently under other EU legislation. It therefore takes no account of the time needed to comply with other EU legislation that may apply to the product to which the CE mark was wrongly affixed: the implementation obligation is triggered solely by non-compliance with the Medical Devices Directive.

91. In the circumstances at issue, the product has been held not to be a medical device. Since the CE mark that it bears has therefore been unduly affixed to it, the product must be removed from the market.

46 — See also, for example, *Nordiska Dental*, cited in footnote 21 above, paragraph 24.

92. If the product is in fact a medicinal product, in principle it cannot be put on the market 'unless a marketing authorisation has been issued by the competent authorities'.[47] Some time will be needed for preparing the application for obtaining a marketing authorisation and completing that procedure and then preparing the product, and in particular its packaging, in order to put it on the market (again).[48] In that regard, Article 17(1) of the Medicinal Products Directive requires that the procedure be completed within a maximum of 210 days after the submission of a valid application.

93. The Medical Devices Directive thus foresees a certain time for ending non-compliance, including for *removing a product from the market*, whereas the Medicinal Products Directive appears to anticipate some time will be needed for *putting the product on the market*.

94. The first rule is permissive, offering the manufacturer a reasonable and proportionate framework[49] within which to take the necessary measures of compliance, whereas the second is prescriptive and seeks to safeguard public health.

95. In my opinion, despite the fact that in other circumstances the manufacturer might have available a reasonable period to end non-compliance, where a product which has previously been classified as a medical device ought in fact to be classified as a medicinal product only immediate removal from the market can achieve compliance with both sets of rules.

96. If such a product is immediately removed from the market following a decision of the competent authority pursuant to Article 18 of the Medical Devices Directive, then there is no need for further Member State action under Article 18, first paragraph, (b), or for Commission intervention under Article 8, of the same directive. At the same time, immediate removal from the market also ensures compliance with the Medicinal Products Directive: if the product is a medicinal product, it cannot be on the market without a marketing authorisation.[50]

97. Allowing a medical device reclassified as a medicinal product to remain on the market for a so-called grace period, during which the manufacturer applies for and obtains a marketing authorisation, would be contrary to the fundamental interest that underpins the marketing authorisation requirement, namely the protection of public health. Nor does it appear to be feasible for the competent national authority, in a single decision, to find that a CE mark was inappropriately affixed and to grant a marketing authorisation (enabling the product at issue to remain on the market but without a CE mark affixed to it). In that regard, a decision that a product is properly to be classified as a medicinal product rather than a medical device is separate from that determining that the medicinal product satisfies the conditions for a marketing authorisation.

98. Against that background, I consider that a product that is reclassified as a medicinal product cannot remain or be placed on the market until a marketing authorisation has been obtained and the other conditions set out in the Medicinal Products Directive have been met.

47 — Article 6(1) of the Medicinal Products Directive. There is nothing in the order for reference suggesting that the national court also wishes the Court to consider the manufacturing authorisation (see Title IV on 'Manufacture and importation' in the Medicinal Products Directive).

48 — For example, Article 54 of the Medicinal Products Directive lists the particulars that should appear on the outer packaging or, where relevant, the immediate packaging of medicinal products.

49 — When asked at the hearing whether the freedom of Member States to implement Article 18 was constrained by other aspects of EU law including EU general principles of law, the Commission stated, more than once, that, in its view, the actual procedure for withdrawing a wrongly affixed CE mark was governed solely by national law. I strongly disagree: the procedure must be consistent with relevant rules of EU law, including EU general principles of law such as the principle of proportionality.

50 — Very few exceptions to that principle exist. For example, Article 126a(1) of the Medicinal Products Directive, provides that '[i]n the absence of a marketing authorisation or of a pending application for a medicinal product authorised in another Member State … a Member State may for justified public health reasons authorise the placing on the market of the said medicinal product'. The mere fact of reclassifying a product as a medicinal product does not appear to me likely to be a 'public health reason' within the meaning of that provision.

Conclusion

99. In the light of the foregoing considerations, I am of the opinion that the Court should answer the questions referred by the Korkein hallinto-oikeus to the following effect:

— Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended, does not preclude a Member State from classifying a product, 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/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, even where another Member State considers that product to be a medical device within the meaning of Directive 93/42.

— Article 18 of Directive 93/42 applies to a product to which a CE marking was affixed despite the fact that the product is not covered by that directive. By contrast, Article 8 of the same directive can apply only by virtue of Article 18. In addition, the relevant procedures in Directive 2001/83 must be satisfied in order to put on the market a product that is properly classified as a medicinal product rather than as a medical device.

— Where there are two similar products containing the same substance and having the same modes of action European Union law does not preclude a Member State from classifying one as a medicinal product and the other as a medical device. By contrast, a single Member State cannot, in the case of two identical products, classify one as a medicinal product and the other as a medical device.