JUDGMENT OF THE COURT (First Chamber)

26 October 2016 (*)

(Reference for a preliminary ruling — Medicinal products for human use — Directive 2001/83/EC — Scope — Article 2(1) — Medicinal products prepared industrially or manufactured by a method involving an industrial process — Point 2 of Article 3 — Officinal formula)

In Case C-276/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Federal Court of Justice, Germany), made by decision of 16 April 2015, received at the Court on 9 June 2015, in the proceedings

Hecht-Pharma GmbH

v

Hohenzollern Apotheke, owned by **Winfried Ertelt,**

THE COURT (First Chamber),

composed of R. Silva de Lapuerta, President of the Chamber, J.-C. Bonichot, A. Arabadjiev, C.G. Fernlund (Rapporteur) and S. Rodin, Judges,

Advocate General: M. Szpunar,

Registrar: V. Tourrès, Administrator,

having regard to the written procedure and further to the hearing on 21 April 2016,

after considering the observations submitted on behalf of:

– Hecht-Pharma GmbH, by J. Sachs and C. Sachs, Rechtsanwälte,

– Hohenzollern Apotheke, owned by Winfried Ertelt, by C. Willhöft, Rechtsanwalt,

– the German Government, by T. Henze, A. Lippstreu and K. Stranz, acting as Agents,

– Ireland, by A. Joyce, C. Toland and L. Williams, acting as Agents,

– the Spanish Government, by A. Rubio González and L. Banciella Rodríguez-Miñón, acting as Agents,

– the Finnish Government, by H. Leppo, acting as Agent,

– the European Commission, by M. Šimerdová, A. Sipos and T.S. Bohr, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 30 June 2016,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of points 1 and 2 of Article 3 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 (OJ 2011 L 174, p. 74) (‘Directive 2001/83’).

2 The request has been made in proceedings between Hecht-Pharma GmbH and the Hohenzollern Apotheke (‘HA’), a pharmacy owned and operated by Mr Winfried Ertelt, concerning the marketing of certain medicinal products.

Legal context

European Union law

3 Directive 2001/83 codified and assembled in a single text the directives on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products for human use, among which was 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).

4 Recital 2 of Directive 2001/83 states that ‘the essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health’.

5 Articles 2 and 3 of that directive come under Title II thereof, entitled ‘Scope’.

6 Article 2(1) of Directive 2001/83 provides:

‘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.’

7 Points 1 and 2 of Article 3 of Directive 2001/83 provide:

‘This Directive shall not apply to:

1. Any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula).

2. Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula).’

8 Under Article 5(1) of that directive:

‘A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.’

9 Article 6(1) of that directive is worded 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 an authorisation has been issued in accordance with Regulation (EC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use ... and Regulation (EC) No 1394/2007.

...’

10 Article 87(1) of Directive 2001/83 states:

‘Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Community law.’

German law

11 Paragraph 3a of the Gesetz über die Werbung auf dem Gebiete des Heilwesens (Heilmittelwerbegesetz) (Law on the advertising of medicines: ‘the HWG’) is worded as follows:

‘Any advertising of medicinal products which require authorisation and which are not authorised or deemed to be authorised under the law on pharmaceutical products is unlawful. The first sentence of the present paragraph applies inter alia where the advertising concerns areas of application or pharmaceutical forms which have not been provided for in the authorisation.’

12 Paragraph 21(2) of the Gesetz über den Verkehr mit Arzneimitteln (Law on the marketing of medicinal products) (‘the AMG’) provides:

‘A marketing authorisation shall not be required for medicinal products which

1. are intended for administration to humans and, on account of the proven frequency with which they are the subject of medical and dental prescriptions, the essential manufacturing steps for such are carried out in a pharmacy as part of the normal pharmacy business producing in the course of one day up to 100 packages ready for dispensation and intended for supply under the existing pharmacy operating licence,

...'

13 Paragraph 55 of the AMG is worded as follows:

'(1) The pharmacopoeia is a collection of recognised pharmaceutical rules published by the Federal Institute for Medicinal Products and Medical Devices in agreement with the Paul Ehrlich Institute and the Federal Agency for Consumer Protection and Food Safety regarding the quality, testing, storage, dispensing and designation of medicinal products and the substances used in their manufacture. The pharmacopoeia also contains requirements regarding the composition of containers and outer packaging.

...

(8) Only substances and containers and outer packaging, in so far as they come into contact with the medicinal products, and only pharmaceutical forms which are in compliance with recognised pharmaceutical rules, may be used in the manufacture of medicinal products. The first sentence shall apply to medicinal products which are manufactured exclusively for export with the proviso that the regulations in force in the country of destination may be taken into consideration.

...'

14 The Verordnung über den Betrieb von Apotheken (Apothekenbetriebsordnung) (Regulation on the operation of pharmacies) ('the ApBetrO'), provides in Paragraph 1a(9):

'A medicinal product prepared on the basis of a general prescription is a medicinal product manufactured in advance as part of the normal operation of the pharmacy in a quantity of up to 100 packages per day or an equivalent quantity.'

15 In accordance with Paragraph 6 of the ApBetrO:

'(1) Medicinal products produced in a pharmacy must be of the required quality in line with pharmaceutical science. They must be manufactured and checked in accordance with recognised pharmaceutical rules, and, if the pharmacopoeia contains rules, those products must be manufactured and checked in accordance with those rules. As part of the check, it is possible to apply methods and use apparatus other than those set out in the German pharmacopoeia on condition that these achieve the same results as the methods and apparatus set out therein. In so far as is necessary, the checks must be repeated at appropriate intervals.

(2) In the manufacture of medicinal products, it is necessary to take appropriate precautions to avoid harmful reciprocal influences and interactions between the medicinal product and its raw materials and the packaging and labelling materials.

(3) The medicinal product may also be checked outside the pharmacy by the pharmacist who is responsible for the checking process:

1. in premises which have obtained a licence under Paragraph 13 of the AMG,

2. in premises in a Member State of the European Union or of the European Economic Area which have, in accordance with national law, been authorised under Article 40 of Directive 2001/83 ..., last amended by [Directive 2011/62], in the version then in force, ...;

3. in premises which have been authorised under Paragraph 1(2), read in conjunction with Paragraph 2, of the Law on pharmacies; or

4. by an expert within the meaning of Paragraph 65(4) [of the AMG].

The person on the premises who is responsible for carrying out the check or the person referred to in point 4 must certify — specifying the batch, the date and the conclusions of the analysis — that the medicinal product has been checked in accordance with recognised pharmaceutical rules and is of the required quality (control certificate). The conclusions of the control certificate must be the basis for validation in the pharmacy. In the pharmacy, the identity of the medicinal product must, as a minimum requirement, be checked; the information on the checks carried out should be recorded.

...'

16 Paragraph 8 of the ApBetrO reads as follows:

'Medicinal products prepared on the basis of a general prescription

(1) A medicinal product prepared on the basis of a general prescription must be manufactured in accordance with manufacturing instructions which are written down in advance and which must be signed by a pharmacist from the pharmacy. The manufacturing instructions must in particular provide information concerning:

1. the basic ingredients contained in the product, the materials of the primary packaging and the apparatus used;

2. the technical and organisational measures designed to avoid cross contamination and reactions, including preparation of the work area;

3. the description of the various stages of the manufacturing process, including theoretical values and, in so far as is possible, the checks carried out during the manufacturing process;

4. the labelling, stating inter alia the date of manufacture, the expiry date or the additional checks and, in so far as necessary, the storage conditions and safety precautions; and

5. the marketing authorisation, within the meaning of Paragraph 4(17) [of the AMG].

(2) The manufacture must be documented in accordance with the manufacturing regulations at the time of manufacture by the person who is responsible (manufacturing protocol); the protocol must make it possible to retrace all of the main steps in the manufacturing process. The manufacturing protocol must set out the manufacturing regulations and must, in particular, state the following:

1. the date of manufacture and the designation of the batches;

2. the basic substances used, their weight or their dimensions and the designation of the batches or the control numbers;

3. the results of the checks carried out during the manufacturing process;

4. the manufacturing specifications;

5. the total quantity manufactured and, in so far as appropriate, the number of derived pharmaceutical forms;

6. the expiry date or the additional control date; and

7. the signature of the person who manufactured the medicinal product.

The manufacturing protocol must be completed by a pharmacist's certification that the manufactured medicinal product complies with the manufacturing conditions (validation).

(3) The checking of medicinal products manufactured in accordance with a general prescription must be subject to control instructions, which must be signed by a pharmacist from the pharmacy. The control instructions must, as a minimum requirement, include information concerning the taking of samples, the control methods and procedures, including in respect of theoretical values or authorised limit values.

(4) The checking must be carried out in accordance with instructions on the control procedures referred to in (3) above and be documented by the person who has carried out the check (control protocol). The control protocol must refer to the instructions on the control procedures and must, in particular, indicate the following:

1. the date of the check;

2. the results of the check and their validation by the responsible pharmacist who has carried out or supervised the check.'

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

17 Hecht-Pharma manufactures in Germany, on an industrial scale, incense capsules which are sold as food supplements.

18 HA is a pharmacy established in Germany. In compliance with that Member State's legislation on medicinal products, HA sells products which are substitutable for those produced by Hecht-Pharma, without, however, having a marketing authorisation for that purpose. HA uses a variety of marketing methods to promote its products commercially.

19 Hecht-Pharma brought an action against HA seeking an injunction requiring it to refrain from advertising those products. That action was dismissed by the court of first instance, and that decision was upheld on appeal. Hecht-Pharma thereupon brought an appeal on a point of law before the referring court.

20 The referring court takes the view that the outcome of the case depends on whether the product manufactured by HA must be subject to a marketing authorisation. If that is the case, Hecht-Pharma would then be entitled to obtain an injunction to stop the advertising under the national legislation

concerning unfair competition. If that is not the case, the application for an injunction would be unfounded.

21 In its action, Hecht-Pharma maintains that the prohibition of advertising set out in Paragraph 3a of the HWG must be interpreted as meaning that it requires the advertising prohibition laid down in Article 87 of Directive 2001/83 to be extended to all medicinal products that do not have a marketing authorisation.

22 The referring court, however, considers that Article 87 of Directive 2001/83 does not prohibit the advertising of every medicinal product that does not have a marketing authorisation. That directive, in its view, prohibits advertising only in respect of medicinal products which do not have a marketing authorisation in cases where one is required. The requirement to have a marketing authorisation and the prohibition of advertising concern only medicinal products which come within the scope of Directive 2001/83, as defined in Article 2(1) of that directive, and which are not exempted under its Article 3.

23 According to the referring court, the scope of the exemption from the authorisation requirement laid down in point 1 of Paragraph 21(2) of the AMG is wider than that in point 1 of Article 3 of Directive 2001/83. That national provision does not require the pharmacist to prepare the medicinal product 'in accordance with a medical prescription for an individual patient'. It suffices that the manufacture is carried out on the basis of a 'general' medical prescription which has a documented frequency. It is apparent from point 1 of Paragraph 21(2) of the AMG that the medicinal product is prepared in accordance with a prediction based on statistical assumptions without an actual prescription for an individual patient. Academic opinion is divided on the question as to whether that provision is compatible with Article 3 of Directive 2001/83.

24 The referring court takes the view that the exclusion from the scope of Directive 2001/83 laid down in point 1 of Article 3 of that directive, which concerns medicinal products prepared in a pharmacy in accordance with 'a medical prescription for an individual patient', does not apply to a medicinal product which is prescribed by a doctor or dentist at a documented frequency. The referring court is unsure whether the protection of public health calls for a strict interpretation of point 1 of Article 3 of Directive 2001/83. Although medicinal products which are manufactured in a pharmacy do not in principle present any risk to safety, the manufacture of a quantity which may reach 100 packages per day presents a greater potential risk than does the preparation of a single medicinal product intended to respond to the specific needs of an individual patient.

25 Furthermore, the referring court doubts whether the exemption from the requirement for a marketing authorisation laid down by national legislation is in accordance with point 2 of Article 3 of Directive 2001/83, in so far as that exemption does not require that the medicinal product, on the basis of a general prescription, be prepared in accordance with an officinal formula.

26 The referring court takes the view that it is not clear from the wording of point 1 of Article 3 of Directive 2001/83 that the application of that provision depends on the existence of a medical prescription issued to an individual patient before the manufacture of the medicinal product even begins. Considerations of safety and profitability do not require this. In particular, it would be reasonable for hospital pharmacies, which have extensive experience, to manufacture the quantity of medicinal products required on the basis of a general prescription in order to ensure that the medicinal product in question is available for patients without delay.

27 It was in those circumstances that the Bundesgerichtshof (Federal Court of Justice, Germany) decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Do points 1 and 2 of Article 3 of Directive 2001/83 preclude a national provision such as point 1 of Paragraph 21(2) of the AMG, according to which no marketing authorisation is required for medicinal products that are intended for administration to humans and, on account of the proven

frequency with which they are the subject of medical and dental prescriptions, the essential manufacturing steps for such products are carried out in a pharmacy as part of the normal pharmacy business producing up to 100 packages per day ready for dispensation and intended for supply under the existing pharmacy operating licence?

(2) If the first question is answered in the affirmative: does this conclusion also apply where a national provision such as point 1 of Paragraph 21(2) of the AMG is interpreted to mean that no marketing authorisation is required for medicinal products that are intended for administration to humans and, on account of the proven frequency with which they are the subject of medical and dental prescriptions, the essential manufacturing steps for such products are carried out in a pharmacy as part of the normal pharmacy business producing up to 100 packages per day ready for dispensation and intended for supply under the existing pharmacy operating licence, provided that the medicinal product is either supplied to an individual patient in accordance with a medical prescription, not necessarily submitted before the preparation of the medicinal product, or is prepared in the pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to patients?'

Consideration of the questions referred

28 It is apparent from the explanations provided by the referring court that the outcome of the case in the main proceedings depends on the scope of the prohibition of advertising laid down in Article 87 of Directive 2001/83 with regard to medicinal products for human use which do not have a marketing authorisation. The referring court notes in this regard that both the requirement to have a marketing authorisation and the prohibition of advertising concern only medicinal products for human use which come within the scope of Directive 2001/83, as defined in Article 2(1) of that directive, and not those which come under one of the exceptions laid down in Article 3 thereof.

29 It should be recalled, in this regard, that Article 2(1) of Directive 2001/83 makes a positive determination of the scope of that directive, by providing that it is to 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, while Article 3, points 1 and 2, of that directive provides for certain exceptions to its scope. It follows that, in order to come within the scope of Directive 2001/83, the product in question, first, must satisfy the conditions laid down in Article 2(1) of that directive and, secondly, must not come within one of the exceptions expressly provided for in Article 3 thereof (judgment of 16 July 2015, *Abcur*, C-544/13 and C-545/13, EU:C:2015:481, paragraphs 38 and 39).

30 Although the questions referred for a preliminary ruling relate exclusively to the interpretation of Article 3 of Directive 2001/83, it is appropriate to consider that, by those questions, the referring court is asking, in essence, whether a medicinal product for human use, such as that at issue in the main proceedings, may come within the scope of Directive 2001/83. In order to provide a useful answer to that question, it is necessary to determine, first, whether such a medicinal product may come within the scope of Directive 2001/83 pursuant to Article 2(1) thereof and, if that is the case, to examine, secondly, whether that medicinal product comes within the exceptions laid down in Article 3 of that directive.

31 With regard to the question whether Article 2(1) of Directive 2001/83 must be interpreted as meaning that a medicinal product for human use, such as that at issue in the main proceedings, can be regarded as having been prepared industrially or manufactured by a method involving an industrial process within the meaning of that provision and consequently comes within the scope of that directive, the Court has already held that, having regard to the objective of protection of public health pursued by the EU rules on medicinal products for human use, the terms 'prepared industrially' and 'manufactured by a method

involving an industrial process' cannot be interpreted narrowly. Those terms must therefore include, at the very least, any preparation or manufacture involving an industrial process (judgment of 16 July 2015, *Abcur*, C-544/13 and C-545/13, EU:C:2015:481, paragraph 50).

32 An industrial process differs from an artisanal process in the means of production used and, consequently, in the quantities produced. The Court has thus held that an industrial process is characterised in general by a succession of operations, which may, in particular, be mechanical or chemical, in order to obtain a significant quantity of a standardised product (judgment of 16 July 2015, *Abcur*, C-544/13 and C-545/13, EU:C:2015:481, paragraph 50).

33 The Court has thus held, in paragraph 51 of the judgment of 16 July 2015, *Abcur* (C-544/13 and C-545/13, EU:C:2015:481), that the standardised production of significant quantities of a medicinal product to be stocked and sold wholesale and the large-scale or serial production of magistral formulae in batches are characteristic of industrial preparation or manufacture by a method involving an industrial process.

34 In the present case, it is apparent from the documents before the Court that the medicinal product at issue in the main proceedings is produced, not industrially by an entity operating on a large scale, but in small quantities by artisanal methods by an officinal pharmacy, estimated by HA at 213 packages in 2015. It should be noted that German law limits the maximum authorised production of officinal formulae to 100 packages per day. As the Advocate General stated in point 23 of his Opinion, that limit precludes the view being taken that the production of officinal formulae under the regulatory conditions existing in Germany reaches a sufficient scale to be considered significant and to come within the concept of 'industrial process' within the meaning of Article 2(1) of Directive 2001/83.

35 It follows that a medicinal product for human use, such as that at issue in the main proceedings, does not appear to be prepared on an industrial basis or manufactured according to a method involving an industrial process within the meaning of that provision and, consequently, does not appear to come within the scope of that directive. However, it is for the national court to determine whether that is the case.

36 If the factual findings of the referring court might lead it to take the view that the medicinal product at issue is prepared industrially or manufactured according to a method involving an industrial process, that court will then have to determine whether that medicinal product comes within the exceptions laid down in Article 3 of Directive 2001/83. In that regard, it should be noted that, pursuant to point 1 of that article, that directive does not apply to any 'medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula)'. However, it is apparent from the documents submitted to the Court that the medicinal product at issue in the main proceedings is not prepared according to such a prescription. Consequently, that medicinal product does not come within the exception set out in point 1 of Article 3 of Directive 2001/83.

37 Pursuant to point 2 of Article 3 of Directive 2001/83, that directive does not apply to any 'medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula)'. It is clear from the wording of that provision that the implementation of the exception for which it provides is subject to the fulfilment of a set of conditions concerning the medicinal products in question. Those products must be prepared 'in a pharmacy', 'in accordance with the prescriptions of a pharmacopoeia' and 'intended to be supplied directly to the patients served by the pharmacy in question'. Those conditions are also cumulative, with the result that the exception provided for in that provision cannot be applied if one of them is not satisfied (judgment of 16 July 2015, *Abcur*, C-544/13 and C-545/13, EU:C:2015:481, paragraph 66).

38 The referring court has doubts as to whether point 1 of Paragraph 21(2) of the AMG is compatible with point 2 of Article 3 of Directive 2001/83, in so far as, while that national provision expressly requires that a medicinal product be prepared in a pharmacy, it does not, however, require that that preparation be carried out 'in accordance with the prescriptions of a pharmacopoeia'.

39 However, according to the explanations provided by the referring court and the observations of the German Government, Paragraph 21(2), point 1, of the AMG must be read in conjunction with Paragraph 6(1) of the ApBetrO, which specifies that those medicinal products 'must be of the required quality in line with pharmaceutical science. They must be manufactured and checked in accordance with recognised pharmaceutical rules, and, if the pharmacopoeia contains rules, those products must be manufactured and checked in compliance with those rules'.

40 In the light of the foregoing, point 2 of Article 3 of Directive 2001/83 must be interpreted as not precluding provisions, such as those laid down in Paragraph 21(2), point 1, of the AMG, read in conjunction with Paragraph 6(1) of the ApBetrO, in so far as they require, in essence, pharmacists to comply with the pharmacopoeia during the manufacture of officinal formulae. It is, however, for the referring court to ascertain whether, on the facts of the case before it, the medicinal product at issue in the main proceedings has been prepared in accordance with the prescriptions of a pharmacopoeia.

41 Having regard to the foregoing considerations, the answer to the questions referred is that Article 2(1) of Directive 2001/83 must be interpreted as meaning that a medicinal product for human use, such as that at issue in the main proceedings, which, under national legislation, does not require a marketing authorisation by reason of the proven frequency with which it is the subject of medical and dental prescriptions, the essential manufacturing steps for such products are carried out in a pharmacy as part of the normal pharmacy business producing in the course of one day up to 100 packages ready for dispensation and intended for supply under the existing pharmacy operating licence, cannot be regarded as having been prepared industrially or manufactured by a method involving an industrial process, within the meaning of that provision, and consequently does not come within the scope of that directive, subject to the findings of fact which it is for the referring court to make.

42 However, should those findings lead the referring court to take the view that the medicinal product at issue in the main proceedings has been prepared industrially or manufactured by a method involving an industrial process, the answer to the referring court's questions must also be that point 2 of Article 3 of Directive 2001/83 must be interpreted as meaning that it does not preclude provisions such as those laid down in Paragraph 21(2), point 1, of the AMG, read in conjunction with Paragraph 6(1) of the ApBetrO, in so far as those provisions, in essence, require pharmacists to comply with the pharmacopoeia when manufacturing officinal formulae. It is, however, for the referring court to determine whether, on the facts of the case before it, the medicinal product at issue in the main proceedings has been prepared in accordance with the prescriptions of a pharmacopoeia.

Costs

43 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (First Chamber) hereby rules:

Article 2(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, must be

interpreted as meaning that a medicinal product for human use, such as that at issue in the main proceedings, which, under national legislation, does not require a marketing authorisation by reason of the proven frequency with which it is the subject of medical and dental prescriptions, the essential manufacturing steps for such products are carried out in a pharmacy as part of the normal pharmacy business producing in the course of one day up to 100 packages ready for dispensation and intended for supply under the existing pharmacy operating licence, cannot be regarded as having been prepared industrially or manufactured by a method involving an industrial process, within the meaning of that provision, and consequently does not come within the scope of that directive, subject to the findings of fact which it is for the referring court to make.

However, should those findings lead the referring court to take the view that the medicinal product at issue in the main proceedings has been prepared industrially or manufactured by a method involving an industrial process, the answer must also be that point 2 of Article 3 of Directive 2001/83, as amended by Directive 2011/62, must be interpreted as meaning that it does not preclude provisions such as those laid down in Paragraph 21(2), point 1, of the Law on the marketing of medicinal products, read in conjunction with Paragraph 6(1) of the Regulation on the operation of pharmacies, in so far as those provisions, in essence, require pharmacists to comply with the pharmacopoeia when manufacturing officinal formulae. It is, however, for the referring court to determine whether, on the facts of the case before it, the medicinal product at issue in the main proceedings has been prepared in accordance with the prescriptions of a pharmacopoeia.

[Signatures]

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*Language of the case: German.