Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

16 July 2015*

(Reference for a preliminary ruling — Medicinal products for human use — Directive 2001/83/EC — Scope — Articles 2(1) and 3, points 1 and 2 — Medicinal products prepared industrially or manufactured by a method involving an industrial process — Exceptions — Medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient — Medicinal products 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 — Directive 2005/29/EC)

In Joined Cases C-544/13 and C-545/13,

REQUESTS for a preliminary ruling under Article 267 TFEU from the Stockholms tingsrätt (Sweden), made by decision of 11 October 2013, received at the Court on 21 October 2013, in the proceedings

Abcur AB

v

Apoteket Farmaci AB (C-544/13),

and

Apoteket AB and Apoteket Farmaci AB (C-545/13),

THE COURT (Third Chamber),

composed of M. Ilešič (Rapporteur), President of the Chamber, A. Ó Caoimh, C. Toader, E. Jarašiūnas and C.G. Fernlund, Judges,

Advocate General: M. Szpunar,

Registrar: I. Illéssy, Administrator,

having regard to the written procedure and further to the hearing on 6 November 2014,

after considering the observations submitted on behalf of:

— Abcur AB, by S. Wilow and G. Åkesson, advokater,

— Apoteket AB and Apoteket Farmaci AB, by E. Johnson, N. Baggio and E. Wernberg, advokater,

— the Portuguese Government, by L. Inez Fernandes and A. P. Antunes, acting as Agents,

* Language of the case: Swedish.

— the United Kingdom Government, by V. Kaye, acting as Agent, and by J. Holmes, Barrister,

— the European Commission, by A. Sipos, M. van Beek.and M. Šimerdová, acting as Agents, and by M. Johansson, advokat,

after hearing the Opinion of the Advocate General at the sitting on 3 March 2015,

gives the following

Judgment

1 These requests for a preliminary ruling concern the interpretation of Articles 2(1) and 3, points 1 and 2, 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 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34; 'Directive 2001/83'), Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (OJ 2005 L 149, p. 22) and Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ 2006 L 376, p. 21).

2 The requests have been made in two disputes between Abcur AB ('Abcur') and Apoteket Farmaci AB ('Farmaci'), in Case C-544/13, on the one hand, and Abcur and Apoteket AB ('Apoteket') and Farmaci, in Case C-545/13, on the other, concerning the manufacture and marketing, in the first case, by Farmaci, between 30 October 2009 and June 2010, of the medicinal product Noradrenalin APL and, in the second case, by Apoteket and Farmaci, between 15 November 2006 and June 2010, of the medicinal product Metadon APL.

Legal context

EU law

Directive 2001/83

3 Directive 2001/83 codified and assembled into 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 were Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ, English Special Edition 1965-1966, p. 20).

4 Recital 2 in the preamble to 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 Recital 35 in the preamble to that directive states that '[i]t is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions ...'.

6 Article 1, point 19, of that directive defines a medicinal prescription as '[a]ny medicinal prescription issued by a professional person qualified to do so'.

7 Articles 2 and 3 of that directive form part of Title II thereof, entitled 'Scope'.

8 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.'

9 Article 3, points 1 and 2, of the directive provides:

'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).'

10 Article 5(1) of Directive 2001/83 provides:

'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 healthcare professional and for use by an individual patient under his direct personal responsibility.'

Directive 2004/27

11 Recital 4 in the preamble to Directive 2004/27 states that 'the primary purpose of any rules concerning the production and distribution of proprietary medicinal products must be to safeguard public health …'.

12 According to recital 7 in the preamble to that directive, '[p]articularly as a result of scientific and technical progress, the definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products for human use …'.

Directive 2005/29

13 According to recital 10 in the preamble to Directive 2005/29:

'… This Directive … applies only in so far as there are no specific [provisions of EU law] regulating specific aspects of unfair commercial practices, such as information requirements and rules on the way the information is presented to the consumer. It provides protection for consumers where there is no specific sectoral legislation at [EU] level and prohibits traders from creating a false impression of the nature of products …'

14 Article 2(d) of that directive defines 'business-to-consumer commercial practices' as meaning 'any act, omission, course of conduct or representation, commercial communication including advertising and marketing, by a trader, directly connected with the promotion, sale or supply of a product to consumers'.

15 Article 3(1), (3) and (4) of that directive provide:

‘1. This Directive shall apply to unfair business-to-consumer commercial practices, as laid down in Article 5, before, during and after a commercial transaction in relation to a product.

…

3. This Directive is without prejudice to [EU] or national rules relating to the health and safety aspects of products.

4. In the case of conflict between the provisions of this Directive and other Community rules regulating specific aspects of unfair commercial practices, the latter shall prevail and apply to those specific aspects.’

16 Article 5(1) of that directive provides that ‘[u]nfair commercial practices shall be prohibited’.

17 Article 7(1) and (5) of Directive 2005/29 states:

‘1. A commercial practice shall be regarded as misleading if, in its factual context, taking account of all its features and circumstances and the limitations of the communication medium, it omits material information that the average consumer needs, according to the context, to take an informed transactional decision and thereby causes or is likely to cause the average consumer to take a transactional decision that he would not have taken otherwise.

…

5. Information requirements established by [EU] law in relation to commercial communication including advertising or marketing, a non-exhaustive list of which is contained in Annex II, shall be regarded as material.’

Regulation (EC) No 1394/2007

18 Recital 6 in the preamble to Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ 2007 L 324, p. 121) states:

‘This Regulation is a *lex specialis*, which introduces additional provisions to those laid down in Directive 2001/83/EC. The scope of this Regulation should be to regulate advanced therapy medicinal products which are intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process, in accordance with the general scope of the [EU] pharmaceutical legislation laid down in Title II of Directive 2001/83/EC …’

Swedish law

19 Law (1996:1152) on trade in medicinal products etc. (lag (1996:1152) om handel med läkemedel m.m.), in force until 30 June 2009, provided, in the first subparagraph of Paragraph 2 thereof:

‘For the purposes of this Law, “retail trade” shall mean the sale to consumers, a healthcare authority, a hospital or any other healthcare establishment or to any person authorised to prescribe medicinal products. ‘Wholesale trade’ shall mean any other form of sale.’

20 Law (2009:366) on trade in medicinal products (lag (2009:366) om handel med läkemedel), which entered into force on 1 July 2009, replaced Law (1996:1152). The relevant provisions of Chapter 1, Paragraph 4, thereof state as follows:

‘The following terms are used in this Law with the meanings set out below:

“Retail supply”: the sale of medicinal products to consumers, a healthcare authority, a hospital or any other healthcare establishment or to any person authorised to prescribe medicinal products;

…

“Wholesale distribution”: activity including the purchase, possession, export, delivery or any sale of medicinal products which cannot be regarded as retail trade;

“Hospital pharmacy”: the functions or activities which provide supplies of medicinal products to or inside a hospital;

“Care provider”: natural or legal person which provides health care as part of a profession;

“Non-hospital pharmacy”: any establishment authorised to carry out retail supply of medicinal products under the authorisation set out in Chapter 2, Paragraph 1, of this Law.’

21 Law (2008:486) on marketing practices (Marknadsföringslagen (2008:486)) transposed Directives 2005/29 and 2006/114 into Swedish law.

22 Paragraph 3 of that law includes, inter alia, the following definition:

‘“Promotional measures”: advertising and other measures, as part of an economic activity, which are intended to promote the supply of and access to products, including an economic operator’s actions, omissions or any other measure or conduct before, during or after the sale or delivery of products to consumers or economic operators.’

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

23 Abcur is a Swedish company which produces and distributes medicinal products, including Metadon DnE and Noradrenalin Abcur.

24 Before the reorganisation of the regulatory framework for pharmacies in Sweden on 1 July 2009, the sole right to retail medicinal products was held by Apoteket, a Swedish State-owned company. In that context, Apoteket marketed Metadon APL and Noradrenalin APL, prepared by Apotek Produktion och Laboratorier AB (‘Apotek PL’).

25 Until 30 June 2008, Farmaci and Apotek PL were autonomous divisions of Apoteket. On 1 July 2008, Farmaci became a wholly-owned subsidiary of Apoteket. On the same date, Apotek PL became a wholly-owned subsidiary of Apoteket. On 1 July 2010, Apotek PL became an independent company directly owned by the State.

26 Farmaci supplies medicinal products to county councils (landsting), municipalities and private undertakings, and also to public and private healthcare providers. Farmaci also manages around 70 hospital pharmacies.

27 The medicinal product Noradrenalin Abcur, authorised since 3 July 2009, is a pharmaceutical preparation for infusion, mainly used to treat acute low blood pressure in emergency and intensive care units. Before that date, there was no noradrenaline medicinal product which held a marketing authorisation (MA) for sale in Sweden, the needs in that Member State being met by using Noradrenalin APL, produced by Apotek PL.

28 Metadon DnE, authorised since 10 August 2007, is used to treat opiate addiction. Before that date, there was no medicinal product in Sweden with an MA containing methadone and needs in that Member State were met by using Metadon APL, prepared by Apotek PL. Metadon DnE and Metadon APL contain the same active substance and are used in the same way. However, they differ in terms of their sugar and alcohol content, and taste.

29 Abcur brought legal proceedings against Apoteket and Farmaci claiming that they had advertised Noradrenalin APL (Case C-544/13) and Metadon APL (Case C-545/13). Abcur claimed that the national court should order the promotion of those two medicinal products to be ceased and also sought the payment of damages. It is not in dispute that Farmaci has supplied patients with Noradrenalin APL and that Apoteket and Farmaci have supplied patients with Metadon APL.

30 It is against that background that the Stockholms tingsrätt (District Court, Stockholm), decided to stay the proceedings in those cases and to refer, in Case C-544/13, the following questions to the Court for a preliminary ruling:

‘(1) Can a prescription-only medicinal product for human use which is used only in emergency health care, for which no marketing authorisation has been granted by the competent authority in a Member State or pursuant to Regulation … No 2309/93, and which is prepared by an operator such as that involved in the [main proceedings] and ordered by healthcare institutions on the conditions material to the [main proceedings], be covered by any of the exceptions in Article 3, points 1 or 2, of Directive 2001/83 …, in particular in a situation where there is another authorised medicinal product with the same active substance, same dosage and same pharmaceutical form?

(2) If a prescription-only medicinal product for human use such as that referred to in Question 1 is covered by Articles 3, points 1 or 2, or 5(1) of Directive 2001/83, may legislation on advertising measures for medicinal products be regarded as non-harmonised or are the kind of measures which are purported in this case to constitute advertising governed by Directive 2006/114 …?

(3) If Directive 2006/114 … is applicable in accordance with Question 2, under what basic conditions do the measures … (use of a product name, product number and AnatomicTherapeuticChemical code for the medicinal product, application of a fixed price for the medicinal product, supply of information on the medicinal product in the National Substance Register for Medicinal Products (NPL), attachment of an NPL identifier to the medicinal product, dissemination of an information sheet on the medicinal product, supply of the medicinal product via an electronic ordering service for health services and the supply of information on the medicinal product via a publication issued by a national professional organisation) [on which the Stockholms tingsrätt is asked to rule] constitute advertising within the meaning of Directive 2006/114?’

31 In Case C-545/13, the referring court referred the following questions to the Court for a preliminary ruling:

‘1. Can a prescription-only medicinal product for human use which is prepared and supplied in the circumstances at issue in the [main proceedings], for which no [MA] has been granted by the competent authority in a Member State or pursuant to Regulation … No 2309/93, be regarded as

constituting a medicinal product within the meaning of either Article 3, points 1 or 2, of Directive 2001/83 …, in particular where there is another authorised medicinal product with the same active substance, the same dosage and the same form?

2. If a prescription medicinal product for human use which is prepared and supplied in the circumstances at issue in the [main proceedings] is covered by Directive 2001/83, can Directive 2005/29 … be applicable in parallel with Directive 2001/83 in respect of the purported advertising measures?

3. If a prescription medicinal product for human use which is prepared and supplied in the circumstances at issue in the [main proceedings] is covered by Articles 3, points 1 or 2, or 5(1) of Directive 2001/83, may legislation on advertising measures for medicinal products be regarded as non-harmonised or are the kind of measures which are purported in this case to constitute advertising governed by Directive 2006/114 … and/or Directive 2005/29 …?

4. If Directive 2006/114 … is applicable in accordance with Question 3, under what basic conditions do the measures under consideration before the Stockholms tingsrätt (use or attachment of a product name, product number and ATC code for the medicinal product, application of a fixed price for the medicinal product, supply of information on the medicinal product in the National Substance Register for Medicinal Products (NPL), attachment of an NPL identifier to the medicinal product, dissemination of an information sheet on the medicinal product and information thereon via an electronic healthcare ordering service and via an undertakings' own homepage, supply of information on the medicinal product via a publication issued by a national trade organisation, supply of information on the medicinal product in the Apoteket's Central Product Register [(ACA database)] and the associated register (JACA), supply of information on the medicinal product in another national information database for medicinal products (SIL), supply of information via the Apoteket Terminal System (ATS) or similar dispensing system, provision of information on an undertakings own or a competing supplier's medicinal product in correspondence with doctors' surgeries and patient organisations, marketing of the medicinal product, measures relating to pharmaceutical checks on the medicinal product and competing medicinal products, failure to notify documented and relevant differences between products, failure to notify the contents of an undertaking's own medicinal product and the assessment of the medicinal product by the Läkemedelsverket (Swedish Medical Products Agency), failure to inform the health care service of the Läkemedelsverket's scientific advisory board's assessment of competing products, to maintain a fixed price level for the medicinal product, to set a validity period of three months for a prescription, to dispense the medicinal product from a pharmacy instead of a competing medicinal product despite the fact that the patient has a prescription for that competing product, and to hinder and prevent market transfers of standardised preparations to the competing medicinal product, including local pharmacies refusing delivery of the competing medicinal product, and application of a fixed price as part of the scheme under which medicines are eligible for subsidies without a prior decision from the national authority) constitute advertising within the meaning of Directive 2006/114?'

32 By order of the President of the Court of 12 December 2013, Cases C-544/13 and C-545/13 were joined for the purposes of the written and oral procedure and the judgment.

Considerations of the questions referred

The first question in Cases C-544/13 and C-545/13

33 As a preliminary point, it should be noted that, in the context of the procedure established by Article 267 TFEU providing for cooperation between national courts and the Court of Justice, it is for the latter to provide the national court with an answer which will be of use to it and enable it to determine the case before it. To that end, the Court may have to reformulate the questions referred to it. Moreover, the Court has a duty to interpret all provisions of EU law which national courts require in order to decide the actions pending before them, even if those provisions are not expressly indicated in the questions referred to the Court of Justice by those courts (judgments in *eco cosmetics and Raiffeisenbank St. Georgen*, C-119/13 and C-120/13, EU:C:2014:2144, paragraph 32, and *Subdelegación del Gobierno en Guipuzkoa — Extranjeria*, C-38/14, EU:C:2015:260, paragraph 25).

34 To that end, the Court may extract from all the information provided by the national court, in particular from the grounds of the decision to make the reference, the legislation and the principles of EU law that require interpretation in view of the subject-matter of the dispute in the main proceedings (see, to that effect, judgments in *eco cosmetics and Raiffeisenbank St. Georgen*, C-119/13 and C-120/13, EU:C:2014:2144, paragraph 33, and *Aykul*, C-260/13, EU:C:2015:257, paragraph 43 and the case-law cited).

35 In that regard, it must be noted that although the first question in Cases C-544/13 and C-545/13 only expressly relates to the interpretation of Article 3, points 1 and 2, of Directive 2001/83, which provides for exceptions to the scope of that directive, it is apparent from the orders for reference that, having regard to a disagreement between the parties to the main proceedings as to whether Noradrenalin APL and Metadon APL were prepared industrially or manufactured by a method involving an industrial process, the Stockholms tingsrätt also queries the interpretation to be given to Article 2(1) of that directive, which defines its scope.

36 Accordingly, the view must be taken that, by its first question in Cases C-544/13 and C-545/13 the referring court asks, in essence, whether a prescription-only medicinal product for human use, such as those at issue in the main proceedings, for which no MA has been granted by the competent authority in a Member State or pursuant to 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) can be covered by any of the exceptions in Articles 2(1) or 3, points 1 or 2, of Directive 2001/83, in particular, which regard to that provision, in a situation where there is another medicinal product with the same active substance, same dosage and same pharmaceutical form.

37 First of all, it is appropriate to note that Articles 2(1) and 3, points 1 and 2, of Directive 2001/83 form part of Title II thereof, which defines the scope of that directive.

38 It follows from the wording of those provisions 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.

39 It follows therefrom that, in order to fall within the scope of Directive 2001/83, the product in question, firstly, must satisfy the conditions laid down in Article 2(1) of that directive and, secondly, must not fall within one of the exceptions expressly provided for in Article 3 of that directive (see, to that effect, judgment in *Octapharma France*, C-512/12, EU:C:2014:149, paragraph 38).

40 That restriction of the scope of Directive 2001/83 is clear, furthermore, from recital 6 in the preamble to Regulation No 1394/2007, which recalls that the regulation of medicinal products which are prepared industrially or manufactured by a method involving an industrial process is 'in accordance with the general scope of the [EU] pharmaceutical legislation laid down in Title II of Directive 2001/83' (see also, to that effect, judgments in *Hecht-Pharma*, C-140/07, EU:C:2009:5, paragraphs 21 and 22, and *Octapharma France*, C-512/12, EU:C:2014:149, paragraphs 29 and 30).

41 Firstly, with regard to the applicability of Article 2(1) of Directive 2001/83, it must be noted that, in accordance with the wording of that provision, the scope of that directive is restricted 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.

42 Although it is established that the products at issue are medicinal products for human use, within the meaning of Directive 2001/83, and that they are intended to be placed on the market in the Member States, the referring court notes, with regard to the preparation of the medicinal products at issue, firstly, that Noradrenalin APL was prepared by the unit of Apotek PL responsible for the preparation of magistral formulae. The referring court adds that, according to Abcur, Noradrenalin APL is a standardised product, prepared and marketed to be stocked and sold wholesale.

43 Secondly, that court states, in essence, that Metadon APL was prepared for pharmacies by Apotek PL on a number of large-scale or serial production sites. The referring court adds that, according to Abcur, it is apparent from their own sales statistics that the defendants in the main proceedings achieved sales of Metadon APL for 2009 of around 130 000 boxes.

44 It is appropriate to note that Directive 2001/83 does not define the concepts of 'prepared industrially' and 'manufactured by a method involving an industrial process'. The same is true of Council Directive 89/341/EEC of 3 May 1989 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1989 L 142, p. 11), which inserted the notion of medicinal products 'prepared industrially' in Article 2 of Directive 65/65, and of Directive 2004/27, which amended Article 2 of Directive 2001/83 to include in its scope medicinal products 'manufactured by a method involving an industrial process'.

45 According to the Court's settled case-law, the need for a uniform application of EU law and the principle of equality require the terms of a provision of EU law which makes no express reference to the law of the Member States for the purpose of determining its meaning and scope normally to be given an independent and uniform interpretation throughout the European Union; that interpretation must take into account not only its wording but also its context and the objectives pursued by the rules of which it is part (see, to that effect, judgments in *Ekro*, 327/82, EU:C:1984:11, paragraph 11, and *A*, C-523/07, EU:C:2009:225, paragraph 34 and the case-law cited).

46 As has been pointed out in paragraph 41 of the present judgment, it is apparent from the terms of Article 2(1) of Directive 2001/83 that that directive applies not only to medicinal products prepared industrially, but also, since the amendment of that provision by Article 2 of Directive 2004/27, to medicinal products manufactured by a method involving an industrial process, which were originally not covered by that provision.

47 With regard to the objectives pursued by the rules on medicinal products for human use, both recital 2 in the preamble to Directive 2001/83 and recital 4 in the preamble to Directive 2004/27 recall that the primary purpose of any rules concerning the production and distribution of proprietary medicinal products must be to safeguard public health (see also judgments in *Antroposana and Others*, C-84/06, EU:C:2007:535, paragraph 36, and *Commission* v *Poland*, C-185/10, EU:C:2012:181, paragraph 27).

48 It is also appropriate to note that, in accordance with recital 7 in the preamble to Directive 2004/27, which amended the scope of Directive 2001/83, particularly as a result of scientific and technical progress, it was necessary to clarify the definitions and scope of Directive 2001/83 'in order to achieve high standards for the quality, safety and efficacy of medicinal products for human use'.

49 Furthermore, recital 35 in the preamble to Directive 2001/83 refers to the necessity of exercising control over the entire chain of distribution of medicinal products, from their manufacture or import into the EU through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions.

50 Having regard to the objective of protection of public health pursued by the EU rules on medicinal products for human use and thus recalled, 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. Such a 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.

51 In those circumstances, the view must be taken 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.

52 In the present case, without prejudice to findings of fact which it is for the referring court to make, products such as those at issue in the main proceedings, provided that they satisfy the conditions referred to in Article 2(1) of Directive 2001/83, by virtue of that provision fall within the scope of that directive.

53 Secondly, the referring court asks whether medicinal products such as those at issue in the main proceedings are capable of being covered by any of the exceptions in Article 3, points 1 or 2, of Directive 2001/83, in particular where there are other authorised medicinal products with the same active substance, same dosage and same pharmaceutical form which have obtained an MA.

54 In order to interpret those provisions, it must be taken into account that, generally, provisions which are in the nature of exceptions to a principle must, according to settled case-law, be interpreted strictly (see in particular, to that effect, *Erotic Center*, C-3/09, EU:C:2010:149, paragraph 15, and *Commission* v *Poland*, C-185/10, EU:C:2012:181, paragraph 31 and the case-law cited).

55 As a preliminary point, it must be noted that the fact raised by the referring court, which refers to Article 5(1) of Directive 2001/83, pursuant to which there are other medicinal products with the same active substance, same dosage and same pharmaceutical form which have obtained an MA, is irrelevant for the purpose of the application of the exceptions set out in Article 3, points 1 and 2, of Directive 2001/83, which requires only that the conditions expressly provided for in that article be met.

56 Moreover, by virtue of Article 5(1) of Directive 2001/83, a Member State may, to fulfil special needs, exclude from the provisions of that directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under his direct personal responsibility. In that regard, the court has held that it is apparent from the conditions as a whole set out in that provision, read in the light of the fundamental objectives of that directive, and in particular the objective of seeking to safeguard public health, that the exception provided for in that provision can only concern situations in which the doctor considers that the state of health of his individual patients requires that a medicinal product be administered for which there is no authorised equivalent on the national market or which is unavailable on that market (see, to that effect, judgment in *Commission* v *Poland*, C-185/10, EU:C:2012:181, paragraphs 29 and 36).

57 It follows therefrom, as the Advocate General noted in point 55 of his Opinion, that where medicinal products having the same active substances, the same dosage and the same form as those which the doctor providing treatment considers that he must prescribe to treat his patients are already authorised and available on the national market, there cannot in fact be a question of 'special needs', within the meaning of Article 5(1) of Directive 2001/83, necessitating a derogation from the requirement for an MA (see, to that effect, judgments in *Commission* v *Poland*, C-185/10, EU:C:2012:181, paragraph 37, and *Novartis Pharma*, C-535/11, EU:C:2013:226, paragraph 46).

58 With regard to Article 3, point 1, of Directive 2001/83, it is apparent from the wording of that provision that the implementation of the exception for which it provides is subject to a set of conditions being met concerning the preparation of the medicinal product in question 'in a pharmacy', 'in accordance with a medical prescription' which must be 'for an individual patient'.

59 Those conditions are cumulative, so that the exception provided for in Article 3, point 1, of Directive 2001/83 cannot apply if one of them is not satisfied.

60 The concept of 'medical prescription' is defined in Article 1, point 19, of Directive 2001/83 as being 'any medicinal prescription issued by a professional person qualified to do so'. Since it is clear from the very wording of Article 3, point 1, of Directive 2001/83 that the medicinal product in question must be prepared 'in accordance with a medical prescription', the view must be taken that it must of necessity be prepared on the basis of a prior prescription issued by a professional person qualified to do so.

61 In addition, the medical prescription must, in accordance with that provision, be 'for an individual patient'. It follows therefrom that that prescription must be for a particular named patient and, as the Advocate General noted in point 47 of his Opinion, that patient must be identified before the medicinal product is produced and it must be produced specifically for that patient.

62 According to the referring court, Noradrenalin APL was prepared by Apotek PL on the basis of the needs known in advance, to be used in emergency departments and, in any event, on the basis of orders placed before a specified patient had been identified.

63 With regard to Metadon APL, the referring court states that when that medicinal product is used in a healthcare establishment, it is not medically prescribed for a specified patient. It notes, however, that that medicinal product is also delivered to non-hospital pharmacies, on the basis of a system which the defendants in the main proceedings call 'subscription', to which each of those pharmacies subscribes. Thus, even if an 'initial medical prescription' was drawn up for each specific patient, the production and delivery of Metadon APL are, in the view of that court, carried out on the basis of the relatively immediate needs of those pharmacies known in advance.

64 Nevertheless, as the Advocate General noted in point 46 of his Opinion, the view must be taken that in order to benefit from the exception provided for in Article 3, point 1, of Directive 2001/83, a medicinal product must of necessity be prepared after the prescription for a specified patient has been issued. Accordingly, that exception cannot apply to a 'subscription' supply system to which a non-hospital pharmacy subscribes on the basis of an estimate of its short-term needs for a medicinal product which is not prepared specifically for a previously identified patient.

65 Thus, since one of the conditions for application of Article 3, point 1, of Directive 2001/83 is not satisfied, that provision cannot apply as regards medicinal products such as those at issue in the main proceedings if they are not prepared in accordance with a medical prescription issued before their preparation, which must be specifically for a previous identified patient, which it is for the referring court to ascertain.

66 With regard to Article 3, point 2, of Directive 2001/83, the view must be taken, as has been noted in paragraph 58 of this judgment concerning the exception provided for in Article 3, point 1, of that directive, that the implementation of the exception for which it provides is also subject to the fulfilment of a set of conditions concerning the medicinal products in question. They 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 so that the exception provided for in that provision cannot be applied if one of them is not satisfied.

67 In that regard, as the Advocate General noted in point 52 of his Opinion, it is clear from the very wording of Article 3, point 2, of Directive 2001/83 that the medicinal product must be prepared 'in a pharmacy' and supplied 'directly' to the patients served by the pharmacy 'in question'. Thus, in order to benefit from the exception provided for in that provision, that medicinal product must be supplied directly by the pharmacy which prepared it to the patients supplied by that same pharmacy.

68 The referring court notes, in that regard, that Noradrenalin APL is administered only by emergency healthcare establishments and that the patients cannot obtain that medicinal product for their personal use.

69 With regard to Metadon APL, that court states that that product is prepared by Apotek PL, which does not, however, supply it directly to the patient concerned, that supply being carried out by a healthcare establishment or by a non-hospital pharmacy.

70 Thus, since one of the conditions for application of Article 3, point 2, of Directive 2001/83 is not satisfied, that provision cannot apply as regards medicinal products such as those at issue in the main proceedings unless they are intended for delivery directly to patients supplied by the pharmacy which prepared them, which it is for the referring court to ascertain.

71 Having regard to the foregoing considerations, the answer to the first question referred in Cases C-544/13 and C-545/13 is that medicinal products for human use, such as those at issue in the main proceedings, prescription-only and for which no MA has been granted by the competent authorities in a Member State or pursuant to Regulation No 726/2004 fall within the scope of Directive 2001/83, by virtue of Article 2(1) thereof, if they have been prepared industrially or manufactured by a method involving an industrial process. Those medicinal products are covered by the exception referred to in Article 3, point 1, of that directive only if they have been prepared in accordance with a medical prescription issued before their preparation, which must be specifically for a previously identified patient. Those medicinal products are covered by the exception referred to in Article 3, point 2, of Directive 2001/83 only if they are delivered directly to patients supplied by the pharmacy which prepared them. It is for the referring court to ascertain whether the conditions for application of those provisions are satisfied in the main proceedings.

The second question in Case C-545/13

72 By its second question in Case C-545/13, the referring court asks, in essence, whether, if medicinal products for human use, such as those at issue in the main proceedings, fall within the scope of Directive 2001/83, advertising practices relating to those medicinal products, such as those alleged in the main proceedings, can also fall within the scope of Directive 2005/29.

73 It is clear from Article 3(1) of Directive 2005/29 that that directive applies to unfair business-to-consumer commercial practices, as laid down in Article 5, before, during and after a commercial transaction in relation to a product. Article 2(d) of that directive defines such practices as 'any act, omission, course of conduct or representation, commercial communication including advertising and marketing, by a trader, directly connected with the promotion, sale or supply of a product to consumers'.

74 As the Court has already held, Directive 2005/29 is characterised by a particularly wide scope *ratione materiae* which extends to any commercial practice directly connected with the promotion, sale or supply of a product to consumers (judgment in *Mediaprint Zeitungs- und Zeitschriftenverlag*, C-540/08, EU:C:2010:660, paragraph 21).

75 According to Article 3(3) of that directive, it is to apply 'without prejudice to [EU] or national rules relating to health and safety aspects'.

76 Directive 2001/83 forms part of the EU provisions relating to health, recital 2 in the preamble to that directive recalling that safeguarding public health must be the essential aim of any rules governing the production, distribution and use of medicinal products.

77 It follows that Directive 2005/29 applies without prejudice to the provisions of Directive 2001/83 relating to advertising for the medicinal products which fall within the scope of the latter directive.

78 As the Advocate General noted in point 61 of his Opinion, the complementary nature of Directives 2005/29 and 2001/83 is apparent, moreover, from a combined reading of Article 7 of and Annex II to Directive 2005/29. In accordance with Article 7(1) thereof, a commercial practice is to be regarded as misleading if, in its factual context, taking account of all its features and circumstances and the limitations of the communication medium, it omits material information that the average consumer needs, according to the context, to take an informed transactional decision and thereby causes or is likely to cause the average consumer to take a transactional decision that he would not have taken otherwise. Information requirements established by EU law in relation to commercial communication including advertising or marketing, a non-exhaustive list of which is contained in Annex II, are, in accordance with Article 7(5) of Directive 2005/29, to be regarded as material. That annex makes express reference, in that context, to Articles 86 to 100 of Directive 2001/83.

79 Finally, it must be pointed out that Article 3(4) of Directive 2005/29 provides that, in the case of conflict between the provisions of that directive and other EU rules regulating specific aspects of unfair commercial practices, the latter are to prevail and apply to those specific aspects. That directive accordingly applies only in so far as there are no specific EU law provisions regulating specific aspects of unfair commercial practices, such as information requirements and rules on the way the information is presented to the consumer.

80 Since Directive 2001/83 contains specific rules on the advertising of medicinal products, it constitutes a special rule as compared with the general rules concerning protection of consumers against unfair commercial practices by undertakings towards them, such as those provided for in Directive 2005/29 (see, by analogy, judgment in *Gintec*, C-374/05, EU:C:2007:654, paragraph 31).

81 It follows therefrom that, in the event of conflict between the provisions of Directive 2005/29 and those of Directive 2001/83, in particular the provisions in Title VIII of the latter concerning advertising, those provisions of Directive 2001/83 take precedence and apply to those specific aspects of unfair commercial practices.

82 Having regard to the foregoing considerations, the answer to the second question referred in Case C-545/13 is that even where medicinal products for human use, such as those at issue in the main proceedings, fall within the scope of Directive 2001/83, advertising practices relating to those medicinal products, such as those alleged in the main proceedings, can also fall within the scope of Directive 2005/29 provided that the conditions for application of that directive are satisfied.

83 Having regard to the answers given to the first question referred in Cases C-544/13 and C-545/13 and the second question referred in Case C-545/13, there is no need to answer the other questions referred. Those questions are referred in the event that the exceptions provided for in Article 3, points 1 and 2, of Directive 2001/83 applied.

Costs

84 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 (Third Chamber) hereby rules:

1. **Medicinal products for human use, such as those at issue in the main proceedings, issued in accordance with a medical prescription and for which no marketing authorisation has been granted by the competent authorities in a Member State or pursuant to 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 fall within the scope 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 2004/27/EC of the European Parliament and of the Council of 31 March 2004, by virtue of Article 2(1) thereof, if they have been prepared industrially or manufactured by a method involving an industrial process. Those medicinal products are covered by the exception referred to in Article 3, point 1, of that directive, as amended, only if they have been prepared in accordance with a medical prescription issued before their preparation, which must be specifically for a previously identified patient. Those medicinal products are covered by the exception referred to in Article 3, point 2, of Directive 2001/83, as amended by Directive 2004/27, only if they are delivered directly to patients supplied by the pharmacy which prepared them. It is for the referring court to ascertain whether the conditions for application of those provisions are satisfied in the main proceedings.**

2. **Even where medicinal products for human use, such as those at issue in the main proceedings, fall within the scope of Directive 2001/83, as amended by Directive 2004/27, advertising practices relating to those medicinal products, such as those alleged in the main proceedings, can also fall within the scope of Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council, provided that the conditions for application of that directive are satisfied.**

[Signatures]