Reports of Cases

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

Abcur AB
v
Apoteket Farmaci AB
and
Apoteket AB

(Request for a preliminary ruling from the Stockholms tingsrätt)

(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)

Summary — Judgment of the Court (Third Chamber), 16 July 2015

1. *Questions referred for a preliminary ruling — Jurisdiction of the Court — Identification of the relevant elements of EU law — Reformulation of the questions*

   (Art. 267 TFEU)

2. *EU law — Interpretation — Principles — Independent and uniform interpretation*

3. *Approximation of laws — Medicinal products for human use — Directive 2001/83 — Scope — Exceptions — Medicinal products industrially or manufactured by a method involving an industrial process — Concept*

   (European Parliament and Council Directive 726/2004; European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Art. 2(1) and 3 points 1 and 2)

4. *Approximation of laws — 'Medicinal products' for human use — Directive 2001/83 — Scope — Exceptions — Conditions — Cumulative nature*

   (European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Art. 3 points 1 and 2)

5. *Approximation of laws — Medicinal products for human use — Directive 2001/83 — Scope — Exceptions — Medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient — Requirement that the medicinal product be prepared in accordance with a medical prescription — Scope*

   (European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Art. 3, point 1))

6. *Approximation of laws — Medicinal products for human use — Directive 2001/83 — Scope — Exceptions — 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 — Requirement that the medicinal product be supplied directly — Scope*

   (European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Art. 3, point 2)

7. *Consumer protection — Unfair business-to-consumer commercial practices — Directive 2005/29 — Scope — Advertising practices concerning medicinal products for human use — Included — Condition — Application of the provisions of Directive 2001/83 as a lex specialis for the specific aspects of unfair commercial practices*

   (European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Title VIII; European Parliament and Council Directive 2005/29)

1. See the text of the decision.

(see paras 33, 34)

2. See the text of the decision.

(see para. 45)

3. Medicinal products for human use 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 No 726/2004 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 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27, 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 that regard, 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. 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. 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.

(see paras 50, 51, 71, operative part 1)

4. See the text of the decision.

(see paras 58, 59, 66)

5. With regard to the concept of 'medical prescription' as defined in Article 1, point 19, of Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27, 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 in order to benefit from the exception from Directive 2001/83 laid down in that provision, 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. 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 that patient must be identified before the medicinal product is produced and it must be produced specifically for that patient.

Nevertheless, 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.

(see paras 60, 61, 64)

6. In order to benefit from the exception provided for in Article 3, point 2, of Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27, the medicinal product must be prepared in a pharmacy and supplied directly to the patients served by the pharmacy 'in question'. Thus, that exception cannot apply as regards medicinal products which are not supplied directly by the pharmacy which prepared them to the patients supplied by that same pharmacy.

(see paras 67, 70)

7. As regards medicinal products for human use, falling within the scope of Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27, advertising practices relating to those medicinal products can also fall within the scope of Directive 2005/29 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450, Directives 97/7, 98/27 and 2002/65, provided that the conditions for application of that directive are satisfied.

In that regard, Directive 2001/83, containing specific rules on the advertising of medicinal products, 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. 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.

(see paras 80-82, operative part 2)