Case C-530/20

Request for a preliminary ruling

Date lodged:

20 October 2020

Referring court:

Satversmes tiesa (Constitutional Court, Latvia)

Date of the decision to refer:

6 October 2020

Applicant:

SIA EUROAPTIEKA

Institution which adopted the contested act:

Ministru kabinets (Council of Ministers)

LATVIJAS REPUBLIKAS SATVERSMES TIESA (CONSTITUTIONAL COURT OF THE REPUBLIC OF LATVIA)

[…] [Particulars of the referring court]

DECISION

CONCERNING THE REFERENCE OF QUESTIONS TO THE COURT OF JUSTICE OF THE EUROPEAN UNION FOR A PRELIMINARY RULING

[…] **[case number]**

Riga, 6 October 2020

The Satversmes tiesa (Constitutional Court), […] [composition of the referring court]

having examined in a preparatory hearing the case file in case [...] 'concerning the compatibility of Subparagraph 18.12 of the Ministru kabineta 2011. gada 17. maija noteikumi Nr. 378 "Zāļu reklamēšanas kārtība un kārtība, kādā zāļu ražotājs ir tiesīgs nodot ārstiem bezmaksas zāļu paraugus" (Decree No 378 of the Council of Ministers of 17 May 2011 [on] detailed rules for the advertising of medicinal

products and detailed rules pursuant to which a medicinal product manufacturer may give free samples of medicinal products to medical practitioners) with Articles 100 and 105 of the Latvijas Republikas Satversme (Constitution of the Republic of Latvia) and with the third paragraph of Article 288 of the Treaty on the Functioning of the European Union' […],

states:

I. Relevant factual and legal material in the main proceedings

1 On 8 January 2020, a case was commenced […] before the Satversmes tiesa (Constitutional Court) as a result of the constitutional complaint lodged by SIA EUROAPTIEKA ('the applicant'). […] [procedural issues]

[…] [procedural issues]

2 Subparagraph 18.12 of Decree No 378 of the Council of Ministers of 17 May 2011 [on] detailed rules for the advertising of medicinal products and detailed rules pursuant to which a medicinal product manufacturer may give free samples of medicinal products to medical practitioners ('Decree No 378') provides: 'It shall be prohibited to include in advertising to the general public of a medicinal product any information which encourages the purchase of the medicinal product by justifying the need to purchase that medicinal product on the basis of its price, by announcing a special clearance sale, or by indicating that the medicinal product is sold as a bundle together with other medicinal products (including at a reduced price) or other types of product' ('the contested provision').

3 **The applicant** submits that the contested provision is incompatible with Articles 100 and 105 of the Constitution of the Republic of Latvia ('the Constitution') and with the third paragraph of Article 288 of the Treaty on the Functioning of the European Union.

The applicant is a limited liability company established in Latvia, which carries on a pharmaceutical business and is part of a group of undertakings which is one of the largest networks of pharmacies and medicinal product retail undertakings in Latvia. Although a pharmacy's principal activities are the supply of medicinal products and pharmaceutical care, pharmacies are also authorised, under Article 33 of the Farmācijas likums (Law on pharmacy), to supply other types of product, such as body care products.

In March 2016, the applicant announced a promotion on its website and in its monthly magazine, offering a 15% reduction on the purchase price of any medicinal product where at least three products were purchased. By decision of 1 April 2016, based on the contested provision, the Veselības inspekcijas Zāļu kontroles nodaļa (Medicinal Product Control Section of the Health Inspectorate) banned the applicant from the dissemination of advertising relating to that promotion. Therefore, the contested provision allegedly limits the applicant's right

to freedom of expression, enshrined in Article 100 of the Constitution, and its right to property, granted in Article 105 of the Constitution.

The applicant claims that the prohibition laid down by the contested provision does not relate solely to the advertising of a particular medicinal product but rather to the advertising of medicinal products in general. The applicant contends, first, that the contested provision limits its right to advertise to the general public in order to promote the brand that it owns and build brand awareness. Second, the contested provision prohibits the applicant from informing consumers about the contractual conditions of sale of goods offered to them in pharmacies which come under its brand. The applicant submits, therefore, that the prohibition laid down by the contested provision has restricted the regular customers of its pharmacies. The applicant argues that customers must be treated as property for the purposes of Article 1 of Protocol No 1 to the European Convention for the Protection of Human Rights and Fundamental Freedoms.

[In the applicant's submission,] it can be concluded from the substance and the aim of the Law on pharmacy as a whole that the legislature did not authorise the Council of Ministers to enact measures with terms like those of the contested provision. In that connection, it is necessary to have regard to provisions of EU law, in particular 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 ('Directive 2001/83/EC').

The provisions of Directive 2001/83/EC refer to advertising which promotes certain medicinal products, within the meaning of Article 1(2) of that directive, and not to any advertising relating to the pharmaceutical sector or medicinal products in general. The applicant contends that Directive 2001/83/EC brings about complete harmonisation in matters relating to the advertising of medicinal products and Member States are not permitted to lay down in their own legislation conditions placing more restrictions on the advertising of medicinal products than those laid down in that directive. By means of the contested provision, the Council of Ministers extended the list of prohibited methods of advertising set out in Article 90 of Directive 2001/83/EC. Accordingly, the contested provision is not compatible with the third paragraph of Article 288 of the Treaty on the Functioning of the European Union.

4 **The institution which adopted the contested act (the Council of Ministers)** submits that the contested provision is compatible with Articles 100 and 105 of the Constitution and with the third paragraph of Article 288 of the Treaty on the Functioning of the European Union.

The Council of Ministers states that the contested provision was inserted into Decree No 378 under Article 5(5) of the Law on pharmacy and in accordance with the criteria in Directive 2001/83/EC.

[In its submission,] the fact that the contested provision lays down stricter conditions for the advertising of medicinal products does not mean that there has been a failure to respect the competence granted to the Council of Ministers. The assessment of whether the conditions laid down in the contested provision are compatible with the competence conferred by the legislature must be conducted directly in the light of the criteria set out in Directive 2001/83/EC and the objective laid down in relation to the supply of medicinal products to the public. The prohibition on advertising medicinal products to the general public is justified by the need to protect public health against the risks of excessive and unreasonable advertising. That is apparent from recital 45 of Directive 2001/83/EC, according to which advertising of non-prescription medicinal products may be permitted by way of exception but only where certain statutory criteria are satisfied. However, that exception to the prohibition on advertising does not include prescription-only medicinal products and therefore that category of medicinal products is subject to an absolute prohibition on advertising. The definition of advertising of medicinal products contained in Directive 2001/83/EC is broad. Pursuant to Article 87(3) of that directive, advertising which encourages the irrational use of a medicinal product is not permitted; that condition does not apply solely to the irrational use of a particular product but of any medicinal product. Therefore, the contested provision was adopted with respect for the competence granted to the Council of Ministers and in accordance with the European Union legislation.

[The Council of Ministers states that,] according to data from the World Health Organization, non-prescription medicinal products are widely used in Latvia. The contested provision was adopted in order to reduce the irrational use of non-prescription medicinal products and, therefore, to protect public health. The Council of Ministers contends that it would be unreasonable and legally unacceptable to promote the use of non-prescription medicinal products on the basis of their price (by means of discounts).

II. Latvian legislation

5 Article 100 of the Constitution provides:

‘Everyone is entitled to freedom of expression, which includes the right to obtain, retain and communicate information freely and to express an opinion. Censorship is prohibited.’

Article 105 of the Constitution provides:

‘Everyone has the right to own property. Goods subject to the right to own property must not be used in a manner contrary to the public interest. The right to property may only be limited by law. Compulsory expropriation in the public interest shall be permitted only in exceptional cases, based on a specific law and in return for fair compensation.’

6 On 10 April 1997, the Saeima (Parliament, Latvia) adopted the Law on pharmacy. That Law entered into force on 8 May 1997. Article 5(5) of the Law on pharmacy provides: ‘The Council of Ministers shall lay down detailed rules for the advertising of medicinal products.’

On 20 December 1999, Parliament adopted the Reklāmas likums (Law on advertising). That Law entered into force on 24 January 2000. Article 7(1) of the Law on advertising provides: ‘Additional conditions in the field of advertising may be laid down in other laws.’ Article 7(2) provides: ‘The Council of Ministers shall determine additional conditions regarding the content, the design and the arrangements for dissemination (including the arrangements for dissemination of advertising on different media) of advertising relating to specific goods, groups of goods or services.’

7 On 17 May 2011, the Council of Ministers adopted, on the basis of Articles 5 and 56 of the Law on pharmacy and Article 7 of the Law on advertising, Decree No 378 of the Council of Ministers [on] detailed rules for the advertising of medicinal products and detailed rules pursuant to which a medicinal product manufacturer may give free samples of medicinal products to medical practitioners. Decree No 378 entered into force on 21 May 2011. Subparagraph 18.12 of Decree No 378 provides: ‘It shall be prohibited to include in advertising to the general public of a medicinal product any information which encourages the purchase of the medicinal product by justifying the need to purchase that medicinal product on the basis of its price, by announcing a special clearance sale, or by indicating that the medicinal product is sold as a bundle together with other medicinal products (including at a reduced price) or other types of product’.

III. European Union legislation

8 The third paragraph of Article 288 of the Treaty on the Functioning of the European Union provides: ‘A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.’

9 […] [With regard to the aims of Directive 2001/83/EC, the referring court cites recitals 2, 29, 40, 42, 43, 45 and 46 thereof].

[…]

Article 1 of Directive 2001/83/EC contains the following definition of ‘medicinal product’: ‘Any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.’

Article 86, in Title VIII (‘Advertising’), of Directive 2001/83/EC includes a definition of advertising of medicinal products: ‘“advertising of medicinal

products" shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'.

Article 87(3) of Directive 2001/83/EC provides that the advertising of a medicinal product must encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties, and that the advertising of a medicinal product may not be misleading.

For its part, Article 90 of Directive 2001/83/EC sets out prohibited methods of advertising […] [citations of that provision, list of material which advertising to the general public may not include]

[…]

IV. Reasons why the Satversmes tiesa (Constitutional Court) has uncertainties regarding the interpretation of EU law

10 […] [procedural issues].

11 Directive 2001/83/EC was transposed into Latvian law by Decree No 378 […]. [reference to the legislative procedure] The Court of Justice has held that the achievement of the objective of Directive 2001/83/EC would be compromised were a Member State to be able to extend the obligations laid down therein and introduce additional restrictions on advertising. Directive 2001/83/EC brought about a complete harmonisation in the field of advertising of medicinal products, since it lists expressly the cases in which Member States are authorised to adopt provisions departing from the rules laid down by that directive *(see judgment of the Court of Justice of the European Union of 8 November 2007,* Gintec, *C-374/05,* […] *EU:C:2007:654, paragraphs 20 and 37*).

Decree No 378 and the contested provision which it contains lay down detailed rules for the advertising of medicinal products. Subparagraph 2.1 of Decree No 378 stipulates that its provisions are to apply to any form of communication, activity or measure which is intended to promote the prescription, supply or use of medicinal products, including advertising of medicinal products to the general public.

In European Union law, Directive 2001/83/EC lays down harmonised rules in relation to the advertising of medicinal products. Article 86(1) of Directive 2001/83/EC defines the advertising of medicinal products as 'any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'. The Court of Justice of the European Union has found that it is apparent from the wording of that provision, in particular from the expression 'any form', that the concept of advertising of medicinal products adopted by the European Union legislature is very broad. The Court has stated that advertising is not mere information, that is to say, it is also clear from the wording of Article 86(1) of Directive 2001/83/EC, in

particular, that the purpose of the message constitutes the fundamental defining characteristic of advertising, and the decisive factor for distinguishing advertising from mere information. If the message is designed to promote the prescription, supply, sale or consumption of medicinal products, it is advertising for the purposes of Directive 2001/83/EC. However, material which is purely informative, without promotional intent, is not covered by the provisions of that directive relating to advertising of medicinal products (*see judgment of the Court of Justice of the European Union of 5 May 2011,* MSD Sharp & Dohme, *C-316/09,* […] *EU:C:2011:275, paragraphs 29, 31 and 32*).

The applicant refers to a judgment of the Court of Justice of the European Union given in a case concerning legislation which set uniform prices in pharmacies and argues, in that regard, that, when establishing a restriction of the kind laid down in the contested provision, it is for the legislature to provide reasons based on scientific research (*see judgment of the Court of Justice of the European Union of 19 October 2016,* Deutsche Parkinson Vereinigung, *C-148/15,* […] *EU:C:2016:776, paragraph 42*). However, that case concerned the free movement of goods and Directive 2001/83/EC was not applicable to it. Accordingly, it is necessary to examine whether the rule contained in the contested provision constitutes a prohibition on advertising for the purposes of Directive 2001/83/EC and whether that directive is applicable […] [to the main proceedings].

Pursuant to Article 89(1)(b), first indent, of Directive 2001/83/EC, the advertising of a medicinal product must include the name of the medicinal product. It can be inferred from this that only the advertising of a particular, identifiable medicinal product constitutes advertising of a medicinal product. An absolute prohibition on advertising exists with regard to prescription-only medicinal products. Accordingly, only the advertising of non-prescription medicinal products is permitted. It follows that the provisions of Title VIII of Directive 2001/83/EC, headed ‘Advertising’, refer to the advertising of specifically identifiable non-prescription medicinal products and those provisions are not intended to govern the advertising of pharmacy services.

The contested provision does not stipulate that advertising must include information concerning a particular medicinal product, that is to say, the name of the medicinal product; rather, it prohibits the inclusion in advertising for a medicinal product of certain information, in particular, information which encourages the purchase of the medicinal product by justifying the need to purchase that medicinal product on the basis of its price. It can be inferred from this that, in so far as the contested provision refers to products which are not specific medicinal products, Directive 2001/83/EC is not applicable. The advertising at issue in the main proceedings does not refer to the names of medicinal products […]. It is therefore necessary to examine whether the activities governed by the contested provision may fall within in the scope of Directive 2001/83/EC.

The Court of Justice of the European Union has also held that it is for the national court to determine whether the actions concerned constitute advertising or a form of door-to-door information (*see judgment of the Court of Justice of the European Union of 2 April 2009,* […] Frede Damgaard […], *C-421/07,* […] *EU:C:2009:222, paragraph 23*). If the activities to which the rule contained in the contested provision refers must be treated as information activities and not the advertising of medicinal products, Directive 2001/83/EC will not be applicable.

Accordingly, the Satversmes tiesa (Constitutional Court) concludes that, […] [in the main proceedings], the interpretation of Directive 2001/83/EC is decisive for the purposes of the assessment of the contested provision. It must be determined whether the contested provision, which governs information relating to the price of medicinal products included in the advertising of such products and not information relating to medicinal products themselves and their names, comes within the scope of Directive 2001/83/EC. The question also arises of whether Decree No 378 is compatible with the aim pursued by Directive 2001/83/EC of harmonising the provisions relating to the advertising of medicinal products, in the event that the activities to which the contested provision refers should not be regarded, by their very nature, as the advertising of medicinal products in the main proceedings. In the wording of Decree No 378, those activities are referred to as the advertising of medicinal products. Under Article 87(3) of Directive 2001/83/EC, the advertising of a medicinal product is lawful if it encourages the rational use of the medicinal without exaggerating its properties. Accordingly, restrictions on the content of the information provided in the advertising of a medicinal product may be connected to the properties of the medicinal product but not its price.

In the light of the foregoing, reasonable doubts exist concerning whether Decree No 378 conflicts with the aim pursued by Directive 2001/83/EC of harmonising the provisions relating to the advertising of medicinal products and whether that directive was properly transposed into the Member State's national law.

12 It is clear from settled case-law of the Court of Justice of the European Union that prohibitions contained in directives must be expressly transposed into national law (*see judgment of the Court of Justice of 27 April 1988,* Commission *v* France, *252/85,* […] *EU:C:1988:202, paragraph 19*). The prohibition laid down in the contested provision does not reflect any of the prohibited methods of advertising referred to in Article 90 of Directive 2001/83/EC. Accordingly, the question arises of whether a Member State is permitted to extend the list of prohibited methods of advertising included in Article 90 of Directive 2001/83/EC by introducing a new prohibition in national legislation.

For the purposes of transposing a directive, it is necessary, essentially, to interpret the text of the directive concerned (*see judgment of the Court of Justice of the European Union of 7 June 2005,* […] VEMW and Others, *C-17/03,* […] *EU:C:2005:362, paragraph 41*). The Court of Justice has held that the compatibility with Directive 2001/83/EC of criteria other than those expressly laid

down in Article 90 thereof can be assessed by means of interpretation, examining, for example, whether the prohibitions concerned satisfy the objective of Directive 2001/83/EC — the rational use of medicinal products — and the need to restrict any excessive and ill-considered advertising which could affect public health (*see judgment of the Court of Justice of the European Union of 8 November 2007*, Gintec, *C-374/05*, […] *EU:C:2007:654, paragraphs 35 and 55).*

Accordingly, it can be inferred from Article 87(3) of Directive 2001/83/EC that Member States have an obligation to adopt legislation pursuant to which advertising to the general public of medicinal products must encourage the rational use of medicinal products. In other words, the Satversmes tiesa (Constitutional Court) takes the view that legislation of a Member State which is not expressly referred to in Article 90 of Directive 2001/83/EC and which does not refer to methods of advertising prohibited by that article but which encourages the rational use of medicinal products could be compatible with that directive.

It is apparent from the contested provision that it is prohibited to include in advertising to the general public of a medicinal product information which encourages the purchase of the medicinal product by justifying the need to purchase that medicinal product on the basis of its price. The Court of Justice examined the issue of pricing of medicinal products in a case concerning the free movement of goods, in which it was necessary to determine whether residents of a Member State could receive prescription-only medicinal products by mail order, under conditions which differed from those applicable to the purchase of such products in a pharmacy in their own Member State. The Court of Justice held that price competition could be capable of benefiting the patient in so far as it would allow, where relevant, for medicinal products to be offered at more attractive prices than those currently imposed by the Member State concerned. The effective protection of health and life of humans demands, inter alia, that medicinal products be sold at reasonable prices (*see judgment of the Court of Justice of the European Union of 19 October 2016*, […] Deutsche Parkinson Vereinigung, *C-148/15*, […] *EU:C:2016:776, paragraph 43*). Therefore, advertising relating to the price of medicinal products is not always at odds with the aim pursued by Directive 2001/83/EC of encouraging the rational use of medicinal products.

In addition, the Satversmes tiesa (Constitutional Court) must establish, as regards the contested provision, whether the rational use of medicinal products is encouraged by the fact that the legislation relating to the advertising to the general public of medicinal products prohibits information concerning the application to medicinal products of a discount which encourages the purchase of a medicinal product as part of a bundle together with other medicinal products. The prohibition on advertising medicinal products to the general public is justified by the need to protect public health against the risks of ‘excessive and unreasonable advertising’. That is apparent from recital 45 of Directive 2001/83/EC, according to which advertising of non-prescription medicinal products may be permitted by way of exception but only where certain statutory criteria are satisfied.

Accordingly, it follows that Article 87(3) of Directive 2001/83/EC grants Member States the right to restrict methods of advertising medicinal products which are regarded as clearly excessive or ill-considered and which could affect public health. Furthermore, the condition in question is not intended to restrict the advertising of medicinal products as far as a specific product is concerned but rather the irrational use of medicinal products in general.

Therefore, in order to assess whether the contested provision is compatible with higher-ranking legal rules, the Satversmes tiesa (Constitutional Court) must determine whether the contested provision, which is intended to prohibit excessive or ill-considered advertising of medicinal products, is compatible with the aim pursued by Directive 2001/83/EC.

13 Having regard to the foregoing considerations, divergent conclusions can be drawn, namely:

1) The activities to which the contested provision refers do not constitute advertising within the meaning of Directive 2001/83/EC but rather an indication of information, as a result of which that directive is not applicable to the main proceedings.

2) Directive 2001/83/EC brought about a complete harmonisation, which means that Member States are required to comply with the restrictions on the advertising of medicinal products laid down in Article 90 of the directive and are not permitted to extend the list of prohibited methods of advertising in their national legislation and lay down additional criteria.

3) Although Article 90 of Directive 2001/83/EC does not include a prohibition like that laid down by the contested provision, Member States are entitled to adopt legislation aimed at preventing excessive or ill-considered advertising which is contrary to the aim of Directive 2001/83/EC and does not encourage the rational use of medicinal products.

The Satversmes tiesa (Constitutional Court) takes the view that the contested provision constitutes a rule which governs the advertising of medicinal products. In its view, Directive 2001/83/EC could permit a rule like that contained in the contested provision, given that it is compatible with the aims of the directive.

Accordingly, […] [in the main proceedings,] it is necessary to determine whether Directive 2001/83/EC precludes the prohibition laid down in the contested provision as far as concerns the information which may be included in advertising to the public of medicinal products. Although the Court of Justice of the European Union has interpreted Directive 2001/83/EC, doubts remain as to whether Directive 2001/83/EC actually prohibits Member States from imposing, in their national legislation, restrictions on the advertising of medicinal products to the general public which differ from those provided for in Article 90 of the directive, which includes the list of prohibited methods of advertising.

Therefore, the outcome of the dispute depends on the interpretation of European Union law. Consequently, the facts of the […] [main proceedings] justify the submission of a request for a preliminary ruling to the Court of Justice.

In the light of the foregoing considerations and in accordance with […] Article 267 of the Treaty on the Functioning of the European Union […], the Satversmes tiesa (Constitutional Court)

decides:

1. **To refer the following questions to the Court of Justice of the European Union [for a preliminary ruling]:**

   1.1. Must the activities to which the contested provision refers be regarded as advertising of medicinal products within the meaning of Title VIII of Directive 2001/83/EC ('Advertising')?

   1.2. Must Article 90 of Directive 2001/83/EC be interpreted as precluding legislation of a Member State which extends the list of prohibited methods of advertising and imposes stricter restrictions than those expressly provided for in Article 90 of that directive?

   1.3. Must the legislation at issue in the main proceedings be considered to restrict advertising of medicinal products in order to encourage the rational use of such products, within the meaning of Article 87(3) of Directive 2001/83/EC?

2. **To stay the proceedings pending a ruling from the Court of Justice of the European Union.**

[…] **[procedural issue]**

This decision is not open to appeal.

[…] [signatures] […]