ECLI:EU:C:2022:1014

Provisional text

JUDGMENT OF THE COURT (Grand Chamber)

22 December 2022 (*)

(Reference for a preliminary ruling – Medicinal products for human use – Directive 2001/83/EC – Article 86(1) – Concept of 'advertising of medicinal products' – Article 87(3) – Rational use of medicinal products – Article 90 – Prohibited advertising methods – Advertising of medicinal products not subject to medical prescription and not reimbursed – Advertising by price – Advertising of promotional offers – Advertising of bundled sales – Prohibition)

In Case C-530/20,

REQUEST for a preliminary ruling under Article 267 TFEU from the Latvijas Republikas Satversmes tiesa (Constitutional Court, Latvia), made by decision of 6 October 2020, received at the Court on 20 October 2020, in the proceedings

'EUROAPTIEKA' SIA

intervening parties:

Ministru kabinets

THE COURT (Grand Chamber),

composed of K. Lenaerts, President, L. Bay Larsen, Vice-President, A. Arabadjiev, C. Lycourgos, E. Regan, P.G. Xuereb, L.S. Rossi (Rapporteur), D. Gratsias and M.L. Arastey Sahún, Presidents of Chambers, J.-C. Bonichot, S. Rodin, F. Biltgen, M. Gavalec, Z. Csehi and O. Spineanu-Matei, Judges,

Advocate General: M. Szpunar,

Registrar: L. Carrasco Marco, Administrator,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– ‘EUROAPTIEKA’ SIA, by M. Pētersons, advokāts,

– the Greek Government, by A. Dimitrakopoulou and V. Karra, acting as Agents,

– the Latvian Government, by J. Davidoviča, K. Pommere, I. Romanovska and V. Soņeca, acting as Agents,

– the Polish Government, by B. Majczyna, acting as Agent,

– the European Commission, by A. Sauka and A. Sipos, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 9 December 2021,

having regard to the order of 2 March 2022 to reopen the oral procedure, and further to the hearing on 22 March 2022,

after considering the observations submitted on behalf of:

– ‘EUROAPTIEKA’ SIA, by M. Pētersons, advokāts,

– the Latvian Government, by I. Romanovska, acting as Agent,

– the European Commission, by A. Sauka and A. Sipos, acting as Agents,

after hearing the additional Opinion of the Advocate General at the sitting on 9 June 2022,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 86(1), Article 87(3) and Article 90 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’).

2 The request has been made in proceedings brought by ‘EUROAPTIEKA’ SIA, a company established in Latvia which carries on a pharmaceutical business in that Member State, concerning the legality of a national provision prohibiting certain forms of advertising of medicinal products.

Legal context

European Union law

3 Recitals 2 and 45 of Directive 2001/83 are worded as follows:

‘(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

…

(45) Advertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered. Advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria which ought to be defined.'

4 Title VIII of that directive, entitled 'Advertising', and Title VIIIa thereof, entitled 'Information and advertising' contain, respectively, Articles 86 to 88 and Articles 88a to 100 of that directive.

5 Article 86 of that directive provides:

'1. For the purposes of this Title, "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; it shall include in particular:

– the advertising of medicinal products to the general public,

…

2. The following are not covered by this Title:

– the labelling and the accompanying package leaflets, which are subject to the provisions of Title V,

– correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product,

– factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims,

– information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.'

6 Article 87 of Directive 2001/83 provides:

'1. 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.

2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.

3. The advertising of a medicinal product:

– shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties,

– shall not be misleading.'

7 Article 88(1) to (3) of that directive provides:

‘1. Member States shall prohibit the advertising to the general public of medicinal products which:

(a) are available on medical prescription only, in accordance with Title VI;

(b) contain substances defined as psychotropic or narcotic by international convention, such as the United Nations Conventions of 1961 and 1971.

2. Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.

3. Member States shall be entitled to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.’

8 Under Article 89(1) of the directive:

‘Without prejudice to Article 88, all advertising to the general public of a medicinal product shall:

…

(b) include the following minimum information:

– the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance,

…’

9 Article 90 of the same directive reads as follows:

‘The advertising of a medicinal product to the general public shall not contain any material which:

(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;

(b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;

(c) suggests that the health of the subject can be enhanced by taking the medicine;

(d) suggests that the health of the subject could be affected by not taking the medicine; this prohibition shall not apply to the vaccination campaigns referred to in Article 88(4);

(e) is directed exclusively or principally at children;

(f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;

(g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;

(i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;

(j) refers, in improper, alarming or misleading terms, to claims of recovery;

(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.'

Latvian legislation

10 Subparagraph 18.12 of Ministru kabineta 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 the 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), of 17 May 2011 (*Latvijas Vēstnesis*, 2011, No 78) ('Decree No 378') provides:

'It is 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 dispute in the main proceedings and the questions referred for a preliminary ruling

11 EUROAPTIEKA is part of a group which owns a network of pharmacies and companies distributing medicinal products for retail in Latvia. In accordance with Latvian law, pharmacies are permitted to supply healthcare products other than medicinal products.

12 In March 2016, EUROAPTIEKA 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 a decision of 1 April 2016, the Veselības inspekcijas Zāļu kontroles nodaļa (Medicinal Product Control Section of the Health Inspectorate, Latvia) banned EUROAPTIEKA, on the basis of subparagraph 18.12 of Decree No 378, from the dissemination of advertising relating to that promotion.

13 On 8 January 2020, EUROAPTIEKA brought a constitutional appeal before the Latvijas Republikas Satversmes tiesa (Constitutional Court, Latvia), the referring court. In support of that appeal, EUROAPTIEKA submits, in particular, that that provision applies not only to advertising relating to a specific medicinal product, but also to advertising for medicinal products in general. However, the provisions of Directive 2001/83, which Decree No 378 implements, apply not to any advertising relating to the pharmaceutical sector or to medicinal products in general, but only to advertising relating to specific medicinal products. EUROAPTIEKA submits that that directive brought about complete harmonisation in the field of advertising of medicinal products and that it therefore precludes Member States from laying down additional rules in their legislation that restrict that advertising. By laying down subparagraph 18.12 of Decree No 378, the Council of Ministers

extended the list of advertising methods which appear in Article 90 of Directive 2001/83 and thus infringed the third paragraph of Article 288 TFEU.

14 For its part, the Council of Ministers considers that the concept of 'advertising of medicinal products', which appears in Article 86(1) of Directive 2001/83 must be interpreted broadly, and that the prohibition on any advertising that does not satisfy the requirement, laid down in Article 87(3) of that directive, according to which advertising of a medicinal product must promote its rational use, applies not only to a specific medicinal product but also to all medicinal products in general. Subparagraph 18.12 of Decree No 378 was adopted with the aim of reducing irrational use of medicinal products not subject to medical prescription which could result from the advertising of those products by reason of their price. The stricter requirements imposed by that national provision thus rest on the need, as stated in recital 45 of that directive, to safeguard public health against the risks from excessive and ill-considered advertising. That national provision is, therefore, consistent with that directive.

15 The referring court considers that subparagraph 18.12 of Decree No 378 is a law relating to advertising of medicinal products, within the meaning of Directive 2001/83 and that the latter permits rules such as those laid down in that national provision, provided that those rules are consistent with the objectives pursued by that directive. Nevertheless, it has doubts as to the interpretation of Article 86(1), Article 87(3) and Article 90 of that directive.

16 That court emphasises, first of all, that, according to the Court's case-law, the concept of 'advertising of medicinal products', which appears in Article 86(1) of Directive 2001/83, must be interpreted broadly, with the focus on the promotional purpose of the message at issue. It could however result from the wording of the first indent of Article 89(1)(b) of that directive, according to which the advertising of a medicinal product must include the name of the medicinal product, that only advertising of specific, identifiable medicinal products is 'advertising of medicinal products', within the meaning of that directive. If that were the case, the activities referred to in subparagraph 18.12 of Decree No 378 could not fall within that concept, as the latter provision does not relate to information about specific medicinal products, such as the name, but prohibits inclusion in the advertising for medicinal products certain information, such as information which encourages purchase of a medicinal product by justifying the need for that purchase on the basis of its price.

17 Next, that court observes that Directive 2001/83 has brought about complete harmonisation in the field of advertising of medicinal products. In that regard, it wonders whether, as the prohibitions laid down in subparagraph 18.12 of Decree No 378 do not correspond to any of the advertising material prohibited by Article 90 of that directive, and assuming that that provision applies, Member States are entitled to provide, in their national legislation, for the prohibition of advertising methods other than that prohibited by that Article 90.

18 In that regard, the referring court observes, lastly, that the Court has held that the compatibility with Directive 2001/83 of criteria other than those expressly laid down in Article 90 thereof can be assessed having regard to the objective pursued by that directive, namely to encourage the rational use of medicinal products, and the need to restrict any excessive and ill-considered advertising which could affect public health. Thus, according to that court, Article 87(3) of that directive, read in the light of its recital 45, could be interpreted as meaning that it permits Member States to prohibit any advertising of medicinal products that is obviously excessive and ill-considered, and capable of affecting public health.

19 In those circumstances the Latvijas Republikas Satversmes tiesa (Constitutional Court) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘(1) Must the activities to which [subparagraph 18.12 of Decree No 378] refers be regarded as advertising of medicinal products within the meaning of Title VIII of Directive 2001/83, entitled “Advertising”?

(2) Must Article 90 of Directive 2001/83 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 that provision?

(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?’

Procedure before the Court

20 On 13 July 2021, the Court decided to assign the present case to the Third Chamber. On the same day, it invited the interested persons referred to in Article 23 of the Statute of the Court of Justice of the European Union to answer certain questions in writing, in application of Article 61(1) of the Rules of Procedure of the Court of Justice. The applicant in the main proceedings, the Greek, Latvian and Polish Governments and the European Commission replied to those questions.

21 Following the partial renewal of the members of the Court and the new composition of the chambers which resulted from that, the Court, by a decision of 13 October 2021, assigned this case to the Fourth Chamber.

22 On 9 December 2021, the Advocate General delivered his opinion and the oral part of the procedure was then closed.

23 Taking the view that the question relating to the implications of the judgments of 1 October 2020, *A (Advertising and sale of medicinal products online)* (C-649/18, EU:C:2020:764) and of 15 July 2021, *DocMorris* (C-190/20, EU:C:2021:609) in order to reply to the questions referred for a preliminary ruling in this case merited the attention of a larger formation of the Court, the Fourth Chamber decided, on 13 January 2022, to refer this case to the Court for reassignment to a larger formation of the Court, pursuant to Article 60(3) of the Rules of Procedure.

24 On 1 February 2022, the Court decided to reassign this case to the Grand Chamber.

25 By its order of 2 March 2022, EUROAPTIEKA, (C-530/20, not published, EU:C:2022:146), the Court, after hearing the Advocate General, ordered the reopening of the oral part of the procedure in the present case, pursuant to Article 83 of the Rules of Procedure.

26 On 9 June 2022, the Advocate General delivered his additional Opinion.

Consideration of the questions referred

The first question

27 It is clear from the order for reference and the case file made available to the Court that the national provision at issue in the main proceedings is interpreted by the judicial and administrative authorities as meaning that it applies both to advertising to the public for a specific medicinal product and to advertising to the public for unspecified medicinal products, that is to say for medicinal products in general or for a set of non-identified medicinal products. In addition, it is clear from the order for reference that the dispute in the main proceedings concerns specifically the legality of that national provision in that it covers advertising within that second category.

28 Accordingly, it should be considered that, by its first question, the referring court asks, in essence, whether Article 86(1) of Directive 2001/83 must be interpreted as meaning that the dissemination of information which encourages the purchase of medicinal products by justifying the need for such a purchase on the basis of the price of those medicinal products, by announcing a special sale or by indicating that those medicinal products are sold together with other medicinal products, including at a reduced price, or with other products, falls within the concept of 'advertising of medicinal products', within the meaning of that provision, even where that information does not refer to a specific medicinal product, but to unspecified medicinal products.

29 In order to reply to that question, it is necessary to determine, as a first step, whether the concept of 'advertising of medicinal products', within the meaning of Article 86(1) of Directive 2001/83, covers only the advertising of a specific medicinal product or whether it also covers the advertising of unspecified medicinal products. As a second step, it will be necessary to assess whether activities such as those referred to in the national provision at issue in the main proceedings may be covered by that concept.

Scope of the concept of 'advertising of medicinal products' within the meaning of Article 86(1) of Directive 2001/83

30 Article 86(1) of Directive 2001/83 defines the concept of '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'.

31 Since that provision makes no reference to national laws, that concept must be regarded as an autonomous concept of EU law which must be interpreted in a uniform manner throughout the territory of the European Union taking into consideration not only the wording of that provision, but also the context in which it occurs and the objectives pursued by the rules of which it is part (see, to that effect, judgment of 22 June 2021, *Venezuela* v *Council (Whether a third State is affected)*, C-872/19 P, EU:C:2021:507, paragraph 42 and the case-law cited).

32 As regards, in the first place, the wording of Article 86(1) of Directive 2001/83, it must be observed that that provision systematically refers to 'medicinal products' in the plural. Furthermore, in that provision the concept of 'advertising of medicinal products' is defined very broadly as including 'any form' of door-to-door information, canvassing activity or inducement, including, in particular, 'the advertising of medicinal products to the general public', which is not expressly excluded by Article 86(2) of that directive (see, to that effect, judgment of 5 May 2011, *MSD Sharp & Dohme*, C-316/09, EU:C:2011:275, paragraph 29).

33 Accordingly, it cannot be deduced from the wording of Article 86(1) of Directive 2001/83 that the advertising of unspecified medicinal products does not fall within the concept of 'advertising of medicinal products' within the meaning of that provision.

34 As regards, in the second place, the context of Article 86(1) of Directive 2001/83, it must be observed that, amongst the provisions of Title VIII and Title VIIIa of that directive, some refer to advertising of 'medicinal products', thus suggesting that that advertising may relate to unspecified medicinal products, whereas others refer to advertising of 'a medicinal product'.

35 However, as regards, on the one hand, the provisions of Title VIII of Directive 2001/83, namely those in Articles 86 to 88 of that directive, it should be noted that those provisions lay down general and fundamental rules relating to advertising of medicinal products (see, to that effect, judgment of 5 May 2011, *Novo Nordisk*, C-249/09, EU:C:2011:272, paragraphs 22, 24 and 25). It follows that, as the Advocate General considered, in essence, in point 44 of his opinion of 9 December 2021, those provisions are intended to apply to any activity seeking to promote the prescription, supply, sale or consumption of medicinal products.

36 Thus, even if, unlike Article 88 of that directive, the text of Article 87 thereof refers to advertising of 'a medicinal product', that Article 87 has already been interpreted by the Court as meaning that it contains general principles applicable to all types and parts of advertising for medicinal products (judgment of 5 May 2011, *Novo Nordisk*, C-249/09, EU:C:2011:272, paragraphs 25; see also, to that effect, judgment of 8 November 2007, *Gintec*, C-374/05, EU:C:2007:654, paragraphs 51 and 55).

37 On the other hand, as regards the provisions in Title VIIIa of Directive 2001/83, it is true that Articles 89 and 90 thereof, which lay down specific rules applicable to advertising to the public, refer to 'a medicinal product', in the singular, and that, as the referring court observes, the first indent of Article 89(1)(b) of that directive provides that such advertising must include, as a minimum, the name of the medicinal product.

38 However, Article 89(1) of that directive provides that it applies without prejudice to Article 88 thereof. In addition, as the Polish Government and the Commission have, in essence, submitted, the fact that the specific rules contained in Articles 89 and 90 of that directive concern the advertising of a specific medicinal product is not such as to call into question the very broad definition of the concept of 'advertising of medicinal products' contained in Article 86(1) of Directive 2001/83 nor the general scope of the rules set out in Articles 86 to 88 of that directive. It cannot therefore be deduced from Article 89 of that directive that the concept of 'advertising of medicinal products', within the meaning of Article 86(1) of the same directive, must be understood as covering only advertising carried out with respect to a specific medicinal product.

39 As regards, in the third place, the objectives pursued by Directive 2001/83, it is stated in recital 2 thereof that its essential aim is to safeguard public health.

40 In that regard, the Court has already held that advertising of medicinal products is liable to harm public health (judgment of 5 May 2011, *Novo Nordisk*, C-249/09, EU:C:2011:272, paragraph 32 and the case-law cited) in the light of the serious consequences for health which may arise from improper use or overconsumption of medicinal products available only on prescription (judgment of 5 May 2011, *MSD Sharp & Dohme*, C-316/09, EU:C:2011:275, paragraph 30) and the risks which may also arise from excessive or ill-considered use of medicinal products not subject to medical prescription (see, to that effect, judgment of 1 October 2020, *A (Advertising and sale of medicinal products online)*, C-649/18, EU:C:2020:764, paragraphs 80 and 94).

41 It is necessary also to emphasise the very particular nature of medicinal products, the therapeutic effects of which distinguish them substantially from other goods (see, to that effect, judgment of 18 September 2019, *VIPA*, C-222/18, EU:C:2019:751, paragraph 73 and the case-law

cited). Those therapeutic effects have the consequence that, if medicinal products are consumed unnecessarily or incorrectly, they may cause serious harm to health, without the patient being in a position to realise that when they are administered. Overconsumption or incorrect use of medicinal products entails, furthermore, risks for the financial equilibrium of national social security systems (see, to that effect, judgment of 19 May 2009, *Apothekerkammer des Saarlandes and Others*, C-171/07 and C-172/07, EU:C:2009:316, paragraphs 32 and 33).

42 Accordingly, on the one hand, Article 87(1) and Article 88(1)(a) of Directive 2001/83, respectively, prohibit, without exception, any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with EU law and any advertising to the general public of medicinal products which are available on medical prescription only and, on the other hand, Article 88(3) of that directive permits Member States to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.

43 Likewise, the essential aim of safeguarding public health is met by Article 88(2) of the directive, read in the light of recital 45 thereof, according to which the advertising to the general public of medicinal products not subject to medical prescription is permitted, subject to compliance with the conditions and the restrictions laid down in that same directive (see, to that effect, judgments of 11 December 2003, *Deutscher Apothekerverband*, C-322/01, EU:C:2003:664, paragraph 109, and of 11 June 2020, *ratiopharm*, C-786/18, EU:C:2020:459, paragraph 40), as that advertising could, as stated in recital 45, affect public health were it to be excessive and ill-considered.

44 The essential aim of safeguarding public health would be greatly compromised if Article 86(1) of Directive 2001/83 were to be interpreted as meaning that an activity of door-to-door information, canvassing or inducement seeking to promote the prescription, supply, sale or consumption of medicinal products without making reference to a specific medicinal product did not fall within the concept of ‘advertising of medicinal products’, within the meaning of that provision, and, therefore, avoided the prohibitions, conditions and restrictions laid down by that directive on the subject of advertising.

45 To the extent that advertising for non-specified medicinal products, such as the advertising of an entire class of medicinal products intended to treat the same pathology, may relate equally to medicinal products subject to medical prescription and to medicinal products the cost of which may be reimbursed, to exclude that advertising from the scope of the provisions of Directive 2001/83 on the subject of advertising would result in the prohibitions laid down in Article 88(1)(a) and Article 88(3) of that directive being deprived of their effectiveness to a large extent, by allowing any advertising that does not refer to a specific medicinal product within that class to escape those prohibitions.

46 In addition, as the Advocate General observed, in essence, in points 41, 56 and 60 of his Opinion of 9 December 2021, advertising relating to a set of non-specified medicinal products not subject to medical prescription, such as advertising covering a whole range of medicinal products available for sale in a pharmacy, may, in the same way as advertising in respect of a single specific medicinal product, be excessive and ill-considered and, therefore, harmful to public health, by inducing the irrational use or overconsumption by consumers of the medicinal products concerned.

47 It therefore follows from a literal, contextual and teleological interpretation of Article 86(1) of Directive 2001/83 that the concept of ‘advertising of medicinal products’, covers any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of unspecified medicinal products.

48 The judgments of 1 October 2020, *A (Advertising and sale of medicinal products online)* (C-649/18, EU:C:2020:764), and of 15 July 2021, *DocMorris* (C-190/20, EU:C:2021:609), do not provide a reason for a different interpretation of Article 86(1) of Directive 2001/83.

49 The case that gave rise to the judgment of 1 October 2020, *A (Advertising and sale of medicinal products online)* (C-649/18, EU:C:2020:764), concerned the activity of a pharmacy established in a Member State, which consisted in carrying out a wide-ranging and multifaceted advertising campaign, directed at consumers in another Member State, for its online services for sales of medicinal products. The Court held, in essence, that the advertising and sale of medicinal products online did not fall within the scope of application of Directive 2001/83 relating to the advertising of medicinal products, but within the scope of Directive 2000/31/CE of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ 2000 L 178, p.1) (see, to that effect, judgment of 1 October 2020, *A (Advertising and sale of medicinal products online)*, C-649/18, EU:C:2020:764, paragraphs 50 and 59).

50 As regards the case that gave rise to the judgment of 15 July 2021, *DocMorris* (C-190/20, EU:C:2021:609), that case concerned the advertising campaign in the form of a prize draw that enabled participants to win everyday items other than medicinal products, participation in that prize draw being subject to making an order for a medicinal product subject to a medical prescription. It is in that particular context that the Court held, in paragraphs 21 and 22 of that judgment that that advertising campaign sought to influence not the customer's choice of a given medicinal product but the choice, taken at a later stage, of the pharmacy from which that customer would purchase that medicinal product, with the result that that advertising campaign did not fall within the scope of application of Title VIII of Directive 2001/83.

51 However, notwithstanding what is stated in paragraph 50 of the judgment of 1 October 2020, *A (Advertising and sale of medicinal products online)*, C-649/18, EU:C:2020:764, and in paragraph 20 of the judgment of 15 July 2021, *DocMorris* (C-190/20, EU:C:2021:609), the scope of application of provisions of Directive 2001/83 on the advertising of medicinal products is not limited to advertising of a specific medicinal product only.

The classification of activities such as those referred to in the provision of national law at issue in the main proceedings as 'advertising of medicinal products', within the meaning of Article 86(1) of Directive 2001/83

52 It is clear from the wording of Article 86(1) of Directive 2001/83 that the purpose of the message constitutes the fundamental defining characteristic of 'advertising of medicinal products', within the meaning of that provision, 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. By contrast, material which is purely informative, without promotional intent, is not covered by the provisions of that directive relating to advertising of medicinal products (judgment of 5 May 2011, *MSD Sharp & Dohme*, C-316/09, EU:C:2011:275, paragraphs 31 and 32).

53 In the present case, it is clear from the order for reference that the activities to which the national provision at issue in the main proceedings applies do not relate merely to dissemination to the public solely of information about medicinal products, such as the objective information as to their price, but are activities which encourage the purchase of medicinal products by justifying the need for such a purchase on the basis of the price, by announcing a special sale, or by offering a sale

that is bundled together with the sale of other medicinal products, as the case may be at a reduced price, or with the sale of other products sold by the pharmacy concerned.

54 Subject to verification by the referring court, such activities appear to have a promotional purpose and, consequently, fall within the concept of 'advertising of medicinal products', within the meaning of Article 86(1) of Directive 2001/83.

55 Having regard to all the foregoing considerations, the answer to the first question is that Article 86(1) of Directive 2001/83 must be interpreted as meaning that the dissemination of information which encourages the purchase of medicinal products, by justifying the need for such a purchase on the basis of the price of those medicinal products, by announcing a special sale or by indicating that those medicinal products are sold together with other medicinal products, including at a reduced price, or with other products, falls within the concept of 'advertising of medicinal products', within the meaning of that provision, even where that information does not refer to a specific medicinal product, but to unspecified medicinal products.

The second and third questions

56 By its second and third questions, which should be examined together, the referring court asks, in essence, first, whether Article 87(3) and Article 90 of Directive 2001/83 must be interpreted as precluding a national provision that imposes restrictions not provided for in that Article 90, by prohibiting the inclusion, in advertising to the public of medicinal products, information that encourages the purchase of medicinal products by justifying the need for that purchase on the basis of the price of those medicinal products, by announcing a special sale, or by offering a sale of those medicinal products bundled together with other medicinal products, including at a reduced price, or of other products. It also asks, second, whether such a national provision may be regarded as promoting the rational use of medicinal products, within the meaning of Article 87(3) of that directive.

57 It should be noted at the outset that, according to the indications provided to the Court by the Latvian Government and which it is for the referring court to verify, the national provision at issue in the main proceedings governs only advertising to the general public of medicinal products placed on the market and authorised and which are neither subject to medical prescription nor reimbursed. In its reply to the questions posed by the Court and inviting a written response, the Latvian Government stated that advertising of unauthorised medicinal products, subject to medical prescription or which may be reimbursed is prohibited in Latvia, in accordance with Article 87(1) and Article 88(1)(a) and Article 88(3) of Directive 2001/83.

58 Having made that clarification, in order to reply to the questions referred it is necessary to determine, as a first step, whether Article 87(3) of Directive 2001/83 permits Member States, in order to promote the rational use of medicinal products, to prohibit the inclusion of methods other than those referred to in Article 90 of that directive of advertising to the general public of medicinal products that are neither subject to medical prescription nor reimbursed and next, as a second step, whether prohibitions such as those provided for in the provision of national law at issue in the main proceedings in fact refer to methods that do not promote rational use.

Whether Member States have the power to prohibit the inclusion of methods other than those referred to in Article 90 of Directive 2001/83 in advertising to the general public of medicinal products not subject to medical prescription and not reimbursed

59 As has been stated in paragraphs 40 to 43 of this judgment, since advertising of medicinal products is liable to harm public health, including when it refers to medicinal products not subject to medical prescription, that advertising is the subject of prohibitions, conditions and restrictions laid down in Directive 2001/83.

60 Furthermore, that directive has brought about complete harmonisation in the field of advertising of medicinal products. Consequently, where the option of laying down different rules is not given to Member States expressly, the only conditions which they can place on advertising for medicinal products are those laid down by that directive (see, to that effect, judgment of 8 November 2007, *Gintec*, C-374/05, EU:C:2007:654, paragraphs 20 and 25).

61 As regards advertising to the general public of medicinal products which are neither subject to medical prescription nor reimbursed, such as that referred to in the national provision at issue in the main proceedings, amongst the conditions and restrictions framing the authorisation in principle to which that advertising is subject under Article 88(2) of Directive 2001/83, are those provided for in Articles 87, 89 and 90 of that directive.

62 As regards, more specifically, the relationship between the requirement that that advertising promotes the rational use of medicinal products, provided for in Article 87(3) of Directive 2001/83, and the restrictions referred to in Article 90 of the directive in the form of a list of banned advertising methods, it follows from the Court's case-law that the fact that that directive, in particular Article 90, does not contain any specific rules concerning certain advertising material does not preclude that, with the aim – referred to in recital 45 of that directive – of preventing any excessive and ill-considered advertising of medicinal products which could affect public health, Member States may prohibit, on the basis of Article 87(3) of the directive, that material to the extent that it encourages the irrational use of medicinal products (see, to that effect, judgment of 8 November 2007, *Gintec*, C-374/05, EU:C:2007:654, paragraphs 51, 55 and 59).

63 Thus, even if it follows from Article 88(2) of Directive 2001/83 that advertising of medicinal products not subject to medical prescription is permitted, in order to prevent risks to public health in accordance with the essential aim of safeguarding public health set out in recitals 2 and 45 of that directive, Member States must prohibit the inclusion, in advertising to the public of medicinal products which are neither subject to medical prescription nor reimbursed, of material which is of such a nature as to promote the irrational use of such medicinal products.

64 It follows from the foregoing considerations that Article 87(3) of Directive 2001/83, having regard to recital 45 thereof, must be interpreted as meaning that it is for Member States to prohibit the inclusion of material other than that referred to in Article 90 of that directive in advertising to the general public of medicinal products that are neither subject to medical prescription nor reimbursed, where that material is such of such a nature as to encourage the irrational use of those medicinal products.

Prohibitions such as those at issue in the main proceedings

65 As regards the questions whether prohibitions such as those at issue in the main proceedings cover such material, it must be observed that, as regards medicinal products which are neither subject to medical prescription nor reimbursed, it is frequently the case that, as the Advocate General observes in point 30 of his additional Opinion of 9 June 2022, that the end consumer himself or herself evaluates, without the assistance of a doctor, the usefulness or need to purchase such medicinal products. However, that consumer does not necessarily have the specific and objective knowledge enabling him or her to evaluate their therapeutic value. Advertising may

therefore exercise a particularly strong influence on the evaluation and choice made by that consumer, both as regards the quality of the medicinal product and the amount to purchase.

66 In that context, as the Advocate General observed in points 87 and 88 of his Opinion of 9 December 2021, advertising methods such as those referred to in the national provision at issue in the main proceedings are of such a nature as to encourage consumers to purchase medicinal products which are neither subject to medical prescription nor reimbursed according to an economic criterion connected with the price of those medicinal products. Those methods are, therefore, likely to lead consumers to purchase and consume those medicinal products without those consumers carrying out an objective evaluation based on the therapeutic properties of those products and on specific medical needs.

67 Advertising that distracts the consumer from an objective evaluation of the need to take such medicine encourages the irrational and excessive use of that medicinal product (see, to that effect, judgment of 8 November 2007, *Gintec*, C-374/05, EU:C:2007:654, paragraphs 56).

68 Such irrational and excessive use of medicinal products may also arise as a result of advertising material that, like that referred to in the national provision at issue in the main proceedings, by referring to promotional offers or bundled sales of medicinal products and other products, treats medicinal products in the same way as other consumer goods, which are in general the subject of discounts and price reductions where a certain level of expenditure is exceeded.

69 In those circumstances, it must be held that, in that they prevent the use of advertising material that encourages the irrational and excessive use of medicinal products that are neither subject to medical prescription nor reimbursed, prohibitions such as those laid down in the provision at issue in the main proceedings meet the essential aim of safeguarding public health.

70 In that regard, it should be noted that those prohibitions do not cover the dissemination of merely informative statements, which lack any promotional intent, about those medicinal products but rather they cover the dissemination of content that seeks to encourage the purchase of those medicinal products, whether by reference to their price, to a special sale or a sale bundled with other medicinal products, including at a reduced price, or with the sale of other products.

71 It is true that the Court has held that the effective protection of health and life of humans demands, inter alia, that medicinal products be sold at reasonable prices and that, therefore, price competition could be capable of benefiting the patient in so far as it would allow, where relevant, for prescription-only medicinal products to be offered at more attractive prices (see, to that effect, judgment of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraph 43 and the case-law cited).

72 Nevertheless, it is clear from the case file available to the Court that the national provision at issue in the main proceedings merely prohibits advertising of promotional offers or bundled sales and advertising on the basis of price, without prejudice to the possibility, recognised under Latvian law, for undertakings that trade in medicinal products to grant discounts and price reductions when selling medicinal products and other health products.

73 Having regard to all the foregoing considerations, the answer to the second and third questions is that Article 87(3) and Article 90 of Directive 2001/83 must be interpreted as not precluding a national provision that prohibits the inclusion, in advertising to the general public of medicinal products that are neither subject to medical prescription nor reimbursed, information which encourages the purchase of medicinal products by justifying the need for that purchase on the

basis of the price of those medicinal products, by announcing a special sale, or by indicating that those medicinal products are sold together with other medicinal products, including at a reduced price, or with other types of products.

Costs

74 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 (Grand Chamber) hereby rules:

1. **Article 86(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 2004/27/EU of the European Parliament and of the Council of 31 March 2004,**

must be interpreted as meaning that the dissemination of information that encourages the purchase of medicinal products by justifying the need for that purchase on the basis of the price of those medicinal products, by announcing a special sale or by indicating that those medicinal products are sold together with other medicinal products, including at a reduced price, or with other products, falls within the concept of 'advertising of medicinal products', within the meaning of that provision, even where that information does not refer to a specific medicinal product, but to unspecified medicinal products.

2. **Article 87(3) and Article 90 of Directive 2001/83, as amended by Directive 2004/27,**

must be interpreted as not precluding a national provision that prohibits the inclusion, in advertising to the general public of medicinal products that are neither subject to medical prescription nor reimbursed, of information which encourages the purchase of medicinal products by justifying the need for that purchase on the basis of the price of those medicinal products, by announcing a special sale, or by indicating that those medicinal products are sold together with other medicinal products, including at a reduced price, or with other types of products.

[Signatures]

---

* Language the case: Latvian.