Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

11 June 2020*

(Reference for a preliminary ruling – Protection of public health – Internal market – Medicinal products for human use – Directive 2001/83/EC – Advertising – Article 96 – Distribution of free samples of medicinal products to persons qualified to prescribe them – Pharmacists excluded from the distribution of free samples of medicinal products – Inapplicability to distribution of free samples of non-prescription medicinal products – Consequences for the Member States)

In Case C-786/18,

REQUEST for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Federal Court of Justice, Germany), made by decision of 31 October 2018, received at the Court on 14 December 2018, in the proceedings

ratiopharm GmbH

v

Novartis Consumer Health GmbH,

THE COURT (Third Chamber),

composed of A. Prechal, President of the Chamber, L.S. Rossi, J. Malenovský (Rapporteur), F. Biltgen and N. Wahl, Judges,

Advocate General: G. Pitruzzella,

Registrar: M. Krausenböck, Administrator,

having regard to the written procedure and further to the hearing on 21 November 2019,

after considering the observations submitted on behalf of:

– ratiopharm GmbH, by I.M. Schulte-Franzheim and M. Viefhues, Rechtsänwalte,

– Novartis Consumer Health GmbH, by D. Bruhn, Rechtsanwalt,

– the German Government, by J. Möller and R. Kanitz, acting as Agents,

* Language of the case: German.

– the Greek government, by V. Karra, Z. Chatzipavlou and E. Tsaousi, acting as Agents,

– the Italian Government, by G. Palmieri, acting as Agent, and M. Russo, avvocato dello Stato,

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

– the European Commission, by M. Noll-Ehlers and A. Sipos, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 30 January 2020,

gives the following

Judgment

1 The request for a preliminary ruling concerns the interpretation of Article 96(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').

2 That request was made in the context of a dispute between ratiopharm GmbH and Novartis Consumer Health GmbH ('Novartis'), regarding an application by Novartis that ratiopharm be prohibited from distributing free samples of medicinal products to pharmacists.

Legal context

European Union law

3 Recitals 2 to 4, 14, 45 to 47, 50 and 51 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.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

(4) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations of substances which are foods, animal feeding-stuffs or toilet preparations), and such disparities directly affect the functioning of the internal market.

…

(14) This directive represents an important step towards achievement of the objective of the free movement of medicinal products. Further measures may abolish any remaining barriers to the free movement of proprietary medicinal products will be necessary in the light of experience gained, particularly in the abovementioned Committee for Proprietary Medicinal Products.

…

(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.

(46) Furthermore, distribution of samples free of charge to the general public for promotional ends must be prohibited.

(47) The advertising of medicinal products to persons qualified to prescribe or supply them contributes to the information available to such persons. Nevertheless, this advertising should be subject to strict conditions and effective monitoring, referring in particular to the work carried out within the framework of the Council of Europe.

…

(50) Persons qualified to prescribe medicinal products must be able to carry out these functions objectively without being influenced by direct or indirect financial inducements.

(51) It should be possible within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarise themselves with new products and acquire experience in dealing with them.'

4 Article 1 of that directive states:

'For the purposes of this Directive, the following terms shall bear the following meanings:

…

2. *Medicinal product:*
   (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
   (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

…

19. *Medicinal Prescription*:

Any medicinal prescription issued by a professional person qualified to do so;

…’

5 Under Article 70(1) of that directive:

‘When a marketing authorization is granted, the competent authorities shall specify the classification of the medicinal product into:

a medicinal product subject to medical prescription,

a medicinal product not subject to medical prescription.

To this end, the criteria laid down in Article 71(1) shall apply.’

6 According to Article 71 of Directive 2001/83:

‘1. Medicinal products shall be subject to medical prescription where they:

– are likely to present a danger either directly or indirectly, even when used correctly, if [utilised] without medical supervision, or

– are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or

– contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation, or

– are normally prescribed by a doctor to be administered parenterally.

2. Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors:

– the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions in force, such as the United Nations Conventions of 1961 and 1971 …

…’

7 Under Article 72 of that directive:

‘Medicinal products not subject to prescription shall be those which do not meet the criteria listed in Article 71.’

8 Title VIII of Directive 2001/83, entitled ‘Advertising’, comprises Articles 86 to 88 thereof.

9 Article 86(1) of that directive is worded as follows:

‘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,

– advertising of medicinal products to persons qualified to prescribe or supply them,

– visits by medical sales representatives to persons qualified to prescribe medicinal products,

– the supply of samples,

– the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,

…’

10 Under Article 88 of that directive:

‘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.

…

6. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes.’

11 Title VIIIa of Directive 2001/83, entitled ‘Information and Advertising’, comprises Articles 88a to 100 thereof.

12 Article 89(1) of that directive states:

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

(a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product;

…’

13 Article 90 of that directive provides:

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

…’

14 Article 94(1) to (3) of Directive 2001/83 states:

‘1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

2. Hospitality at sales promotion shall always be reasonable in level and secondary to the main purpose of the meeting and must not be extended to other than health-care professionals.

3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2.’

15 Article 96 of that directive provides:

‘1. Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

(a) the number of samples for each medicinal product each year on prescription shall be limited;

(b) any supply of samples shall be in response to a written request, signed and dated, from the prescribing agent;

(c) those supplying samples shall maintain an adequate system of control and accountability;

(d) each sample shall be no larger than the smallest presentation on the market;

(e) each sample shall be marked “free medical sample – not for sale” or shall show some other wording having the same meaning;

(f) each sample shall be accompanied by a copy of the summary of product characteristics;

(g) no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, such as the United Nations Conventions of 1961 and 1971, may be supplied.

2. Member States may also place further restrictions on the distribution of samples of certain medicinal products.’

German law

16 Paragraph 47 of the Arzneimittelgesetz (Law on medicinal products) in the version applicable to the facts of the main proceedings (‘the AMG’), entitled ‘Distribution Channel’, provides, in subparagraphs 3 and 4:

‘(3) Pharmaceutical undertakings may supply, or arrange to have supplied, samples of finished medicinal products to

1. physicians, dentists or veterinarians, or

2. other persons practising medicine or dentistry as a profession, provided no prescription-only medicinal products are involved, or

3. training centres for health professionals.

Pharmaceutical undertakings may supply, or arrange to have supplied, samples of a finished medicinal product to training centres for health professionals only for the purpose of training. Samples may not contain any of the substances or preparations

1. referred to in Paragraph 2 of the Betäubungsmittelgesetz [(Law on narcotic drugs)] or listed as such in Annexes II or III to the Law on narcotic drugs, or

2. which, pursuant to the third sentence of Paragraph 48(2), may only be prescribed by special prescription.

(4) Pharmaceutical undertakings may supply, or arrange to have supplied, to persons referred to in the first sentence of subparagraph 3, only upon written or electronic request, not more than two samples, in the smallest package size, in the course of one year, of a finished medicinal product. Samples shall be accompanied by a summary of product characteristics, in so far as such information is provided for in Paragraph 11a. The purpose of the sample shall be, inter alia, to inform physicians about the medicinal product itself. Separate records shall be kept for each of the recipients of samples, including of the kind and extent of samples supplied and the date of supply thereof, which must be presented to the competent authority upon request.'

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

17 Novartis manufactures and markets the medicinal product Voltaren Schmerzgel which contains the active substance Diclofenac.

18 Ratiopharm markets the medicinal product Diclo-ratiopharm-Schmerzgel, which also contains the active substance Diclofenac, available only in pharmacies. During the year 2013, ratiopharm employees provided German pharmacists with free boxes of that medicinal product for distribution in reduced size packaging, marked 'for demonstration purposes'.

19 Novartis took the view that distributing them in that way was contrary to Paragraph 47(3) of the AMG and was akin to granting promotional gifts which is prohibited by German law.

20 Novartis accordingly brought the matter before the first-instance court to order ratiopharm to stop distributing free samples of medicinal products to pharmacists. That court upheld Novartis' request.

21 The court before which ratiopharm brought its appeal upheld the decision at first instance, on the basis that Paragraph 47(3) of the AMG does not mention pharmacists amongst the persons to whom free samples may be distributed.

22 Ratiopharm lodged an appeal on a point of law against that decision before the Bundesgerichtshof (Federal Court of Justice, Germany).

23 That court is of the view that the dispute in the main proceedings raises questions about the interpretation of EU law, which are critical to resolving the dispute. Since Paragraph 47(3) of the AMG must be interpreted in accordance with Article 96 of Directive 2001/83, it is necessary to determine, first of all, whether that provision is exhaustive in how it governs the distribution of free samples of medicinal products, thereby excluding pharmacists from that distribution.

24 In that regard, while recital 51 of Directive 2001/83 covers both pharmacists and doctors, the wording of Article 96 of that directive is not unambiguous depending on the language version in question and could be interpreted as meaning that it merely regulates the distribution of free samples of medicinal products to doctors without adopting a position on the distribution of those free samples to pharmacists. In any event, since doctors and pharmacists both need, in the same way, to be informed free of charge about new medicinal products and to demonstrate how they are used to their patients or customers, treating those professional categories differently would not be objectively justified and would constitute a breach of the freedom to choose an occupation and of the freedom to conduct a business.

25 Secondly, assuming that Article 96(1) of Directive 2001/83 does not, as such, prohibit the distribution of free samples of medicinal products to pharmacists, the referring court questions whether Article 96(2) of that directive, which allows Member States to further restrict the distribution of samples of certain medicinal products, authorises those Member States to adopt, where appropriate, legislation providing for such a prohibition. In that regard, that court notes, however, that the wording of that provision, in so far as it covers 'certain medicinal products' and not certain recipients of the distribution in question, and of recital 51 of that directive, may suggest an alternative interpretation.

26 In those circumstances, the Bundesgerichtshof (Federal Court of Justice) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is Article 96(1) of [Directive 2001/83] to be interpreted as meaning that pharmaceutical companies may also distribute free finished medicinal products to pharmacists, if their packaging is labelled "for demonstration purposes", the medicinal products are used by the pharmacist to test the product, there is no risk of further distribution (of the unopened product) to end users and the further conditions for distribution set out in Article 96(1)(a) to (d) and (f) to (g) of that directive are met?

(2) If the answer to Question 1 is in the affirmative: Does Article 96(2) of [Directive 2001/83] permit a national provision such as Paragraph 47(3) of [the AMG], if that provision is interpreted as meaning that pharmaceutical companies may not distribute free finished medicinal products to pharmacists, if their packaging is labelled "for demonstration purposes", the medicinal products are used by the pharmacist to test the product, there is no risk of further distribution (of the unopened product) to end users and the further conditions for distribution set out in Article 96(1)(a) to (d) and (f) to (g) of that directive and in Paragraph 47(4) of the AMG are met?'

Consideration of the questions referred

The first question

27 By its first question, the referring court essentially seeks to ascertain whether Article 96(1) of Directive 2001/83 must be interpreted as authorising, under certain conditions, pharmaceutical companies to distribute free samples of medicinal products also to pharmacists.

28 In accordance with the Court's settled case-law, for the purpose of interpreting a provision of EU law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part (judgment of 18 January 2017, *NEW WAVE CZ*, C-427/15, EU:C:2017:18, paragraph 19 and the case-law cited).

29 As regards the wording of Article 96(1) of Directive 2001/83, it should be pointed out at the outset that, in almost all linguistic versions, that provision restricts the right to receive free samples of medicinal products to 'persons qualified to prescribe'. On the other hand, the terms of that provision do not, in themselves, make it possible to ascertain whether that restriction extends to all medicinal products defined in Article 1(2) of that directive or only to those that are subject to medical prescription within the meaning of Article 1(19) of that same directive.

30 In those circumstances, and in so far as, in particular, according to settled case-law, the wording used in one of the language versions of a provision of EU law cannot serve as the sole basis for the interpretation of that provision or be given precedence over the other language versions (judgment of 12 September 2019, *A and Others*, C-347/17, EU:C:2019:720, paragraph 38, and the case-law cited), Article 96(1) of Directive 2001/83 must be interpreted uniformly, having regard also to the other criteria referred to in paragraph 28 of the present judgment.

31 As regards the objectives pursued by the Directive 2001/83, which concerns, as can be seen from its title, 'medicinal products for human use', it follows from recital 2 thereof that the safeguarding of public health is the essential aim of that directive (judgment of 5 May 2011, *Novo Nordisk*, C-249/09, EU:C:2011:272, paragraph 37 and cited case-law).

32 That being the case, it should be noted, first, that the purpose of Directive 2001/83 relates also, as set out in particular in recitals 4 and 14 thereof, to the free movement of medicinal products in the internal market through the elimination of barriers to trade in medicinal products within the European Union.

33 On the other hand, the Court has already ruled that that directive has brought about complete harmonisation in the field of advertising of medicinal products and explicitly lists the cases in which Member States are authorised to adopt provisions deviating from the rules laid down in that directive (judgment of 8 November 2007, *Gintec*, C-374/05, EU:C:2007:654, paragraph 39).

34 Regarding the context of which Article 96(1) of Directive 2001/83 forms part, it is important in particular to highlight that Article 70(1) of that directive provides that, when they grant a marketing authorisation of a medicinal product, the competent authorities must specify whether that medicinal product falls under the category of medicinal products subject to medical prescription or under the category of medicinal products not subject to medical prescription.

35 Regarding medicinal products subject to medical prescription, the criteria which they meet, as set out in Article 71(1) of Directive 2001/83, reflect the idea that, in view of the dangers of their use or the uncertainty around their effects, those medicinal products cannot be used without medical supervision.

36 In contrast, and as stated in Article 72 of that directive, medicinal products not subject to prescription are those which do not meet the criteria set out in Article 71(1) of that directive, since their use does not present, in principle, risks similar to those posed by prescription-only medicinal products.

37 Such a distinction between prescription-only medicinal products and medicinal products not subject to prescription implies that prescription-only medicinal products must necessarily, as Directive 2001/83 iteratively states in its recitals and its provisions, and in particular in Article 1(19), be prescribed by people deemed 'qualified to prescribe', namely doctors trained to manage the risks inherent in a given patient using them.

38 On the other hand, where they are not legally authorised to prescribe medicinal products, pharmacists fall not within the category of 'persons qualified to prescribe' for the purposes of Directive 2001/83, but within the category of 'persons qualified to supply' medicinal products within the meaning of that directive.

39 The distinction thereby made between prescription-only medicinal products and medicinal products not subject to prescription is also relevant in the context of the provisions of Titles VIII and VIIIa of Directive 2001/83 regarding, in particular, advertising activities (see, to that effect, judgment of 11 December 2003, *Deutscher Apothekerverband*, C-322/01, EU:C:2003:664, paragraph 109).

40 In that regard, it follows from Article 88(1) and (2) and Articles 89 and 90 of Directive 2001/83, which appear under Title VIIIa of that directive, read in the light of recital 45 thereof, that advertising of medicinal products not subject to medical prescription to the general public is not prohibited but allowed, subject to the conditions and the restrictions provided for by that directive.

41 It thus follows from the scheme of Directive 2001/83 that the relevant provisions of Titles VIII and VIIIa, including Article 96(1) of that directive, cannot be viewed as covering all medicinal products, regardless of the category to which they belong.

42 Article 96(1) sets the strict conditions governing the delivery of free samples. Taken as a whole, those conditions reflect the potentially dangerous nature of the medicinal products covered by that provision, which nature is not common to all medicinal products.

43 That potential danger is in particular inherent in the use of prescription-only medicinal products, as was noted in paragraph 35 of the present judgment. Consequently, the distribution of those medicinal products in the form of free samples must comply with the conditions laid down in Article 96(1) of Directive 2001/83, conditions which make it possible, inter alia, to carry out a subsequent review of both the nature of the samples supplied and the recipients thereof.

44 In the light of such an objective, and in order to avoid any risk of breaching the rules on the supply of prescription-only medicinal products, that provision must therefore be interpreted in such a manner that only persons qualified to prescribe those medicinal products, within the meaning of Directive 2001/83, may be supplied with free samples of those medicinal products, as a result of which pharmacists are excluded from that right.

45 Furthermore, that interpretation of Article 96(1) of Directive 2001/83 is borne out by the fact the only category of persons expressly referred to in paragraphs (a) and (b) of that provision are 'prescribers'.

46 Finally, regarding Article 96(2) of that directive, Member States may place 'further' restrictions on the distribution of samples of certain medicinal products. It flows from the use of the term 'further' that that provision must be read in conjunction with Article 96(1) of that directive and covers the same matters as that paragraph. Consequently, it can refer only to prescription-only medicinal products.

47 The interpretation of Article 96 of Directive 2001/83 in the preceding paragraphs of the present judgment does not, however, mean, as is apparent from a number of recitals in the preamble to that directive, that pharmacists are totally barred from receiving free samples under that directive.

48 While recital 46 of Directive 2001/83 specifies that the distribution of free samples to the general public for promotional purposes is prohibited, it does not provide for such a prohibition regarding healthcare professionals, in particular, persons qualified to supply medicinal products. Thus, as regards the promotion of medicinal products, it cannot therefore be presumed that there is a prohibition on the distribution of free samples to pharmacists.

49 Moreover, it follows explicitly from recital 51 of that directive that free samples of medicinal products may be supplied, in compliance with certain restrictive conditions, in particular to persons qualified to supply medicinal products. That possibility is justified in the eyes of the EU legislature since the supply of such samples allows those persons to become familiar with new medicinal products and to gain experience in using them.

50 In addition, with respect to the promotion of medicinal products in particular to persons qualified to supply them, Article 94(1) of that directive, read in the light of recitals 46 and 51 thereof may cover, amongst other forms of advertising, even if not mentioned explicitly, the supply of such samples, provided that those persons do not reap any more than a marginal benefit therefrom.

51 It follows that Directive 2001/83 does allow for the possibility of providing free samples to pharmacists under national law, subject to restrictive conditions, in accordance with the objectives pursued by that directive.

52 That being so, and in any event, that possibility cannot in any way affect the requirements flowing from Article 96(1) of that directive and, therefore, does not include the possibility of distributing to pharmacists free samples of medicinal products falling under that provision, namely those that are prescription-only.

53 In the light of the foregoing considerations, the answer to the question referred is that Article 96(1) of Directive 2001/83 must be interpreted as precluding pharmaceutical companies from distributing free samples of medicinal products to pharmacists. However, that provision does not preclude distributing free samples of non-prescription medicinal products to pharmacists.

The second question

54 In view of the reply given to the first question, there is no need to answer the second question.

Costs

55 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:

Article 96(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/EC of the European Parliament and of the Council of 31 March 2004, must be interpreted as precluding pharmaceutical companies from distributing free samples of medicinal products to pharmacists. However, that provision does not preclude distributing free samples of non-prescription medicinal products to pharmacists.

[Signatures]