Reports of Cases

OPINION OF ADVOCATE GENERAL
PITRUZZELLA
delivered on 30 January 2020[1]

Case C-786/18

ratiopharm GmbH
v
Novartis Consumer Health GmbH

(Request for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany))

(Reference for a preliminary ruling — Protection of public health — Internal market — Medicinal products for human use — Advertising — Distribution of free samples of medicinal products to persons qualified to prescribe them — Pharmacists excluded from the distribution of free samples of medicinal products)

1. Does 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[2] prohibit the distribution of free samples of medicinal products to pharmacists? If it does not prohibit it, does the Directive leave it open for the Member States to prohibit it or must that distribution be authorised in all cases? That, in essence, is the issue at play in this reference for a preliminary ruling.

I. Legal context

A. Directive 2001/83

2. Recital 51 of Directive 2001/83 states that '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.'

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

'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,

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

1 Original language: French.

2 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').

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

– the supply of samples,

…’

4. Under Article 88(6) of Directive 2001/83, ‘Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes’.

5. Article 94(1) to (3) of that directive reads as follows:

‘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 events shall always be strictly limited to their main purpose and must not be extended to persons 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.’

6. Article 96 of Directive 2001/83 is worded as follows:

‘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.’

B. German law

7. Paragraph 47(3) and (4) of the Arzneimittelgesetz (Law on medicinal products, 'the AMG'), entitled 'Distribution channels', provides as follows:

'3. Pharmaceutical companies may distribute samples of a finished medicinal product, or allow them to be distributed:

1. to doctors, dentists or veterinarians;

2. to other persons who practise medicine or dentistry in a professional capacity, provided that it is not a prescription-only medicinal product;

3. to training facilities for the health-care professions.Pharmaceutical companies may not distribute samples of a finished medicinal product, or allow them to be distributed, to training facilities for the health-care professions other than for training purposes. The samples must not contain any substance or preparation:

1. within the meaning of Article 2 of the Law on narcotic substances and referred to in Annex II or III of that Law, or

2. which, under the third sentence of Article 48(2), can only be prescribed on a special prescription.

4. Pharmaceutical companies may distribute samples of a finished medicinal product, or allow them to be distributed, to the persons referred to in the first sentence of subparagraph 3 only if requested in writing or electronically, in the smallest pack size and in an amount of no more than two samples a year per finished medicinal product. The samples must be accompanied by a summary of product characteristics where required under Paragraph 11a. The sample is intended in particular to provide the doctor with information about the subject matter of the medicinal product. Evidence of the recipients of the samples and of the nature, scope and date of their distribution must be provided separately for each recipient and submitted to the competent authority on request.'

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

8. Novartis Consumer Health GmbH ('Novartis') manufactures and markets the medicinal product Voltaren Schmerzgel ('Voltaren pain gel') containing the active substance diclofenac. Ratiopharm GmbH, for its part, markets the medicinal product Diclo-ratiopharm-Schmerzgel ('Diclo-ratiopharm pain gel') which contains the same active substance and is supplied only in pharmacies. During 2013, Ratiopharm sales representatives sent 100 g packs of that medicinal product free of charge to German pharmacists, bearing the label 'for demonstration purposes'.

9. According to Novartis, that distribution contravened Paragraph 47(3) of the AMG according to which free samples of medicinal products may not be supplied free of charge to pharmacists. Novartis also took the view that the distribution in question appeared, furthermore, to be a granting of promotional materials, which is prohibited by the German legislation. It therefore brought proceedings before a first instance court seeking an order that Ratiopharm desist from distributing medicinal products free of charge to pharmacists. That court upheld Novartis's application.

10. Ratiopharm appealed that decision. The appeal court, for its part, held that Paragraph 47(3) of the AMG prohibited the distribution of free samples to pharmacists since it lists exhaustively the persons to whom such samples may be distributed. The appeal court found that Directive 2001/83 does not militate against that interpretation, taking the view that Article 96(1) of that directive does not refer to pharmacists as recipients of the distribution of free samples of medicinal products and mentions

exclusively persons qualified to prescribe medicinal products. Even on the assumption that Article 96(1) of Directive 2001/83 does not govern whether free samples of medicinal products can be distributed to pharmacists, the appeal court found that Article 96(2) authorises the Member States to adopt more restrictive measures in that regard. Lastly, the appeal court did not find that the purported purpose of the free distribution of samples in the present case — that is to say, enabling pharmacists to test the product, check its odour and the consistency and to demonstrate it — suggested any different reading of Paragraph 47(3) of the AMG and Article 96 of Directive 2001/83. Ratiopharm's appeal was therefore dismissed.

11. Ratiopharm then brought an appeal on a point of law before the referring court. That court is of the view that the dispute in the main proceedings raises questions of the interpretation of EU law that are relevant to resolution of that dispute. Indeed, since Paragraph 47(3) of the AMG must be interpreted in conformity with Article 96 of Directive 2001/83, it is necessary to determine whether that article exhaustively governs the distribution of free samples of medicinal products and therefore excludes pharmacists from that distribution. The referring court notes that the wording of that article differs depending on the language version in question and that it can also be argued that Article 96 of Directive 2001/83 regulates only distribution to doctors and stipulates nothing as regards distribution to pharmacists as such. Nor, according to the referring court, is there any reason to treat doctors and pharmacists differently since both categories of professionals have the same need to be informed for free about new medicinal products and to demonstrate their use to patients/customers. Treating doctors and pharmacists differently is therefore not objectively justified and infringes the freedom to choose an occupation and to conduct a business. Recital 51 of Directive 2001/83, for its part, does indeed refer to both pharmacists and doctors. Interpreting Article 96(1) of Directive 2001/83 as prohibiting the distribution of free samples of medicinal products to pharmacists would conflict with Article 94 of that directive according to which the Member States can freely determine discounts in kind.

12. Furthermore, on the assumption that Article 96(1) of Directive 2001/83 does not, in itself, prohibit the distribution of free samples of medicinal products to pharmacists, the referring court asks whether Paragraph 47(3) of the AMG can be regarded as a national rule that further restricts the distribution of samples of certain medicinal products, within the meaning of Article 96(2) of Directive 2001/83, which can therefore be construed as expressly authorising the Member States, where desirable, to prohibit the distribution of free samples of medicinal products to pharmacists. Nevertheless, the wording of Article 96(2) of Directive 2001/83, which refers to 'certain medicinal products' rather than to certain recipients of the products distributed, and recital 51 of that directive could suggest the contrary.

13. Under those circumstances, the Bundesgerichtshof (Federal Court of Justice, Germany) stayed the proceedings and, by a decision received by the Registry of the Court of Justice on 14 December 2018, referred the following questions to the Court 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 Directive 2001/83 and in Paragraph 47(4) of the AMG are met?'

III. Procedure before the Court

14. Novartis, the German, Greek, Italian and Polish governments and the European Commission submitted written observations in this case.

15. At the hearing before the Court on 21 November 2019, Ratiopharm, Novartis and the Commission presented oral argument.

IV. Analysis

A. Preliminary remarks

16. This reference for a preliminary ruling is a further opportunity for the Court to examine the balance to be struck between, on the one hand, the need for pharmaceutical companies to promote the goods they produce and, on the other, the need for health-care professionals, in this case basically doctors and pharmacists, to have objective information about the products they are to prescribe or supply. Such a balance must be struck, furthermore, bearing in mind the compelling requirement to safeguard and protect public health.

17. In that context, it is helpful to remember that the promotion — advertising — carried on by pharmaceutical companies relates to a very particular category of goods, that is to say, medicinal products. A degree of caution is therefore needed when looking at the influence exerted through the advertising of medicinal products. Obviously, that influence may be positive since it allows information to be disseminated and the market expanded, with doctors and pharmacists learning by that means of the arrival of new medicinal products. This increases freedom of choice for consumers and has the effect of stimulating innovation. Nevertheless, precisely because these are not ordinary goods like fruit and vegetables, it is also important to protect those doctors and pharmacists from too marked an economic influence which could undermine the objectivity required of them when discharging their obligations to provide care and advice.

18. That is why Directive 2001/83 lays down precise rules governing the advertising of medicinal products. The resulting limitation on the freedom of pharmaceutical companies to conduct business is fully justified by what is an essential objective in EU law, namely, as already indicated, that of protecting public health. The provisions of Directive 2001/83 must therefore be read in the light of that objective.

19. I would add that, when it adopted Directive 2001/83, the EU legislature necessarily struck a balance between the development of the internal market in medicinal products and ensuring a high level of protection of public health, as then required by Article 95(3) EC, which was the legal basis of that directive. Nor are we asked here to determine whether or not Article 96 of Directive 2001/83 is valid. That article must be interpreted solely on the basis of its wording which is, as I will demonstrate below, quite clear. Since here we have, I believe, a clearly expressed intention of the EU legislature, it does not seem to me that the Court is dealing with a situation in which there is any room for it to create new law.

20. Let us now analyse the first question referred for a preliminary ruling.

B. The first question referred

21. By its first question, the referring court asks the Court in essence to determine whether Article 96(1) of Directive 2001/83 authorises the distribution of free samples of medicinal products to pharmacists.

22. In accordance with 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.[3]

1. Literal interpretation

23. I note that in the German, French, Italian, English and Spanish[4] language versions, to cite only those, the wording of Article 96(1) of Directive 2001/83 is perfectly clear: sending samples free of charge is exceptional advertising that can be directed only at persons qualified to prescribe medicinal products. It is apparent from that restrictive wording that the only persons who can receive the free samples are persons qualified to prescribe medicinal products, but not persons qualified to supply them. Contrary to the Commission's assertion, I do not believe that the wording of Article 96(1) of Directive 2001/83 is 'open-ended' and that, grammatically, there is nothing to prevent pharmacists from also being regarded as potential recipients of free samples of medicinal products. Nor, in my view, can it be argued that the text of Article 96(1) of Directive 2001/83 does not govern the distribution of free samples of medicinal products to pharmacists, which would then fall outside the scope of application of the directive. To my mind, the literal interpretation that the Commission is proposing lacks any convincing foundation and disregards the obvious natural meaning of the wording of the first sentence of Article 96(1) of Directive 2001/83.

24. Admittedly, recital 51 of Directive 2001/83 provides that '*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'.[5] Besides the fact that this recital refers only to the *possibility* of distributing free samples of medicinal products to pharmacists and doctors, it is in any event clear from the Court's settled case-law that 'the preamble to an EU-law act has no binding legal force and cannot be relied on either as a ground for derogating from the actual provisions of the act in question or for interpreting those provisions in a manner that is clearly contrary to their wording'.[6] The wording of that recital therefore does not alter my reading of Article 96(1) of Directive 2001/83.

25. A purely literal interpretation of Article 96(1) of Directive 2001/83 may however be insufficient because of the language differences that the Greek and Polish governments highlight in their written observations. It appears that in those two versions at least the text of Article 96(1) of Directive 2001/83 refers both to persons qualified to prescribe medicinal products and to persons qualified to supply them. It is clear from consistent case-law of the Court that the wording used in one language version of a provision of EU law cannot serve as the sole basis for the interpretation of that provision or be given priority over the other language versions in that regard. The need for uniform application and, therefore, for uniform interpretation of an EU measure precludes one version of the text being considered in isolation, but requires that the measure be interpreted by reference to the general scheme and purpose of the rules of which it forms part.[7]

3 See, among many, judgment of 18 January 2017, *NEW WAVE CZ* (C-427/15, EU:C:2017:18, paragraph 19 and the case-law cited).

4 The first sentence of Article 96(1) of Directive 2001/83 refers to 'persons qualified to prescribe' in the English version, 'Verschreibung berechtigten Personen' in the German version, to 'persone autorizzate a prescriver[e]' in the Italian version, and to 'personas facultadas para prescribir' in the Spanish version.

5 Emphasis added.

6 See, in particular, judgments of 19 June 2014, *Karen Millen Fashions* (C-345/13, EU:C:2014:2013, paragraph 31 and the case-law cited), and of 13 March 2019, *Srf konsulterna* (C-647/17, EU:C:2019:195, paragraph 32 and the case-law cited).

7 See judgment of 8 June 2017, *Sharda Europe* (C-293/16, EU:C:2017:430, paragraph 21 and the case-law cited).

26. At this stage of the analysis, the meaning I am giving to Article 96(1) of Directive 2001/83 is therefore not called into question either by recital 51 of that directive, which has no legal force, or by the mere existence of differences between the language versions of that article which are not, as such, decisive.

27. Before moving onto the next stage of the analysis, it is worth noting that those differences in the wording of the first sentence of Article 96(1) of Directive 2001/83 do not appear to be capable of changing the effect of that article. Indeed, the Greek and Polish governments correctly acknowledge that, in the light of the wording of the first two conditions laid down in Article 96(1) of Directive 2001/83,[8] which expressly refer to the 'prescribing agent' of medicinal products, the first sentence of that provision had to be understood as referring only to persons qualified to prescribe medicinal products.

28. It is therefore apparent from the scheme of Article 96 of Directive 2001/83 that the EU legislature conceived of the distribution of free samples of medicinal products as being aimed only at persons qualified to prescribe them.

2. Contextual and systematic interpretation

29. That literal interpretation is borne out by analysis of the context of Article 96(1) of Directive 2001/83 and of its immediate setting in particular.

30. Article 96 of Directive 2001/83 is in Title VIIIa of that directive, which governs information and advertising in relation to medicinal products. Advertising of medicinal products, defined in the preceding title,[9] covers 'any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products',[10] including, therefore, where that advertising is aimed at pharmacists and doctors[11] and where it takes the form of supplying samples.[12] Title VIIIa[13] comprises provisions setting out the legal regime governing advertising according to the form it takes and its recipients: the public[14] and then persons qualified to prescribe or supply medicinal products.[15] For most of those provisions, the legislature has indicated specifically whether they relate to advertising to the public or advertising to health-care professionals.

31. Article 94 of Directive 2001/83, which forms the immediate setting for Article 96(1) of that directive[16] likewise governs the promotion of medicinal products to persons qualified to prescribe or supply them. According to that article '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.'[17] Article 94 then prohibits persons qualified to prescribe or supply medicinal products from soliciting or accepting the inducements described above.

8 That is to say, Article 96(1)(a) and (b) of Directive 2001/83.

9 That is to say, Title VIII, entitled 'Advertising'.

10 Article 86(1) of Directive 2001/83.

11 See the second indent of Article 86(1) of Directive 2001/83.

12 See the fourth indent of Article 86(1) of Directive 2001/83.

13 On the structure of that title, see judgment of 5 May 2011, *Novo Nordisk* (C-249/09, EU:C:2011:272, paragraph 22), and point 30 of Advocate General Jääskinen's Opinion in that case (C-249/09, EU:C:2010:616).

14 See Article 89, in conjunction with Article 88 in the preceding title, and Article 90, of Directive 2001/83.

15 See Articles 91, 92 and 94 of Directive 2001/83.

16 Article 95 of Directive 2001/83, for its part, addresses the specific case of hospitality offered at events for purely professional and scientific purposes.

17 Article 94(1) of Directive 2001/83.

32. As I noted previously, according to Article 86(1) of Directive 2001/83, the 'supply of samples'[18] is one of the possible forms of advertising. It is a different form from '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'.[19] Whilst Article 94 of that directive establishes the principle that advertising in that latter form is prohibited, Article 96 must be read as an exception to that principle, given that Article 96 concerns a particular form of the supply of samples, namely the distribution of free samples of medicinal products, that is capable, because the samples are free, of amounting to an offer of 'benefits in kind'.[20] Resituated in the context and scheme that it forms together with Article 94, the complete meaning of the restrictive wording of Article 96(1) of Directive 2001/83 becomes apparent given that it enshrines a derogation from the principle of the general prohibition in Article 94. Furthermore, understood as an exception to that principle, Article 96 of that directive must be interpreted restrictively.

33. In that context, as I see it, the fact that Article 96(1) of Directive 2001/83 refers only to persons qualified to prescribe medicinal products is neither due to chance nor the result of oversight or imprecision by the EU legislature, that article being the last relevant provision of the title governing a question relating to advertising. After addressing advertising aimed at the public and then advertising aimed at both persons qualified to prescribe medicinal products and those qualified to supply them, in Article 96 the directive regulates a specific issue within the general advertising regime — namely that of the distribution of free samples of medicinal products — which therefore relates only to persons qualified to prescribe medicinal products.

34. At this stage of the analysis, an interpretation of Article 96(1) of Directive 2001/83 according to which the free distribution of samples of medicinal products, on the conditions it defines, is reserved only to persons qualified to prescribe medicinal products is confirmed both by what follows the first sentence of Article 96(1) of that directive[21] and by its surrounding context comprising the preceding provisions.

35. It remains to check, if ever such a check were necessary, that such an interpretation does not conflict with the objective pursued by Directive 2001/83.

3. Teleological interpretation

36. The Court has already held that 'advertising of medicinal products is liable to harm public health, the safeguarding of which is the essential aim of Directive 2001/83'.[22] Recital 2 of the directive reiterates that essential aim. Admittedly, that 'aim must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the [Union]'[23] and Directive 2001/83 'represents an important step towards achievement of the objective of the free movement of medicinal products.'[24] Nevertheless, that trade in medicinal products and their free movement are organised in conformity with the essential — even primordial — objective of protecting public health, and the EU legislature, when it adopted Directive 2001/83, itself struck a balance between the development of the internal market and protecting public health. In any event, I find it difficult to see how prohibiting the distribution of free samples of medicinal products to pharmacists in any way threatens the development of the pharmaceutical industry.

18 See the fourth indent of that paragraph.

19 The fifth indent of Article 86(1) of Directive 2001/83.

20 It is impossible to rule out that the intrinsic value of the sample distributed free of charge may not necessarily be 'minimal', given the wide variety of medicinal products at equally varied prices.

21 See point 27 of this Opinion.

22 Judgment of 5 May 2011, *Novo Nordisk* (C-249/09, EU:C:2011:272, paragraph 32 and the case-law cited). See also paragraph 37 of that judgment.

23 Recital 3 of Directive 2001/83.

24 Recital 14 of Directive 2001/83.

37. Accordingly, not only the EU legislature but also the Court of Justice have confirmed that advertising for medicinal products must be regulated if it is not to threaten public health.[25] That explains the attention that the legislature gave to the matter in Directive 2001/83 and, in particular, why advertising is subject to strict conditions and monitoring.[26] The Court has held to that effect, in relation to Article 94(1) of Directive 2001/83, that 'that prohibition, which concerns primarily the pharmaceutical industry when promoting the medicinal products which it markets, seeks to prevent promotional practices which may induce health-care professionals to act in accordance with their economic interests when prescribing or supplying medicinal products. The provision thus seeks to promote medical and pharmacological practices which comply with rules of professional conduct.'[27]

38. Doctors and pharmacists do indeed have the same need to be informed, which Directive 2001/83 recognises, but that information may reach them through different channels. The legislature was therefore legitimately entitled to conclude that the economic interest in supplying medicinal products may be more immediate than the interest in prescribing them and that in the case of pharmacists there is a greater risk of products reaching consumers, since consumers know that pharmacists have access to the medicinal products. The distribution of free samples of medicinal products to the general public for promotional ends is prohibited.[28] Excluding pharmacies from that distribution would, at the same time, remove any risk of that prohibition relating to the public being circumvented.

39. It is apparent from the foregoing that an interpretation of Article 96(1) of Directive 2001/83 according to which free samples of medicinal products can only be distributed to persons qualified to prescribe medicinal products appears to be in line with the essential aim of safeguarding public health.

40. Admittedly, Directive 2001/83 also acknowledges that both pharmacists and doctors, in order properly to practise their profession, need to be informed about the medicinal products they prescribe or supply, and that the advertising of medicinal products contributes to the information available to them.[29] However, I reiterate that excluding pharmacists from the specific form of advertising represented by the free distribution of samples of medicinal products, following a balancing exercise by the EU legislature, does not mean that pharmacists are excluded from all forms of advertising or deprive them of any information that may be provided at the same time as a given advertising measure that is simply in a different form from the free distribution of samples.

41. I would add that the justification given for distributing the medicinal product at issue in the main proceedings is that the pharmaceutical company that distributes it changed the consistency and odour of the product after it had been criticised by pharmacists. Giving pharmacists information about the scientific properties of the medicinal product seems to have been a very secondary purpose in this particular situation. I do not believe that the aim of providing information for health professionals, as conceived by the EU legislature, is to improve commercial competition by pharmaceutical companies. In the same vein, the argument that pharmacists need free samples of medicinal products to test before recommending them is to my mind completely unrealistic, if not actually dangerous. Is it seriously believed that each pharmacist personally tests all the medicinal products in his pharmacy? That is quite clearly not the meaning to be given to acquiring experience in dealing with medicinal

25 See, for example, recital 45 of Directive 2001/83. As regards the case-law of the Court, see judgment of 22 April 2010, *Association of the British Pharmaceutical Industry* (C-62/09, EU:C:2010:219, paragraph 30 and the case-law cited).

26 Judgment of 5 May 2011, *Novo Nordisk* (C-249/09, EU:C:2011:272, paragraphs 38 and 39).

27 Judgment of 22 April 2010, *Association of the British Pharmaceutical Industry* (C-62/09, EU:C:2010:219, paragraph 29).

28 See recital 46 of Directive 2001/83.

29 See recital 47 of Directive 2001/83. See also Articles 91 and 92 of that directive. See, lastly, judgment of 5 May 2011, *Novo Nordisk* (C-249/09, EU:C:2011:272, paragraph 38).

products as referred to in recital 51 of Directive 2001/83. In contrast, it seems more reasonable to find that for doctors, who in principle are not in contact with the medicinal products, the distribution of free samples provides a useful, albeit regulated, means of obtaining information about and familiarising themselves with what is newly available on the market.

42. It emerges from the foregoing that Article 96(1) of Directive 2001/83 must be interpreted as meaning that pharmaceutical companies may distribute free samples of medicinal products, on the conditions laid down by that article, only to persons qualified to prescribe them.

C. The second question referred

43. In the light of the reply I propose that the Court should give to the first question referred, it is, prima facie, unnecessary to examine the second. For the sake of completeness, I will nevertheless address that question, although only in the alternative, and therefore more briefly than the foregoing analysis.

44. Article 96(2) of Directive 2001/83 provides that 'Member States may also place further restrictions on the distribution of samples of certain medicinal products.' On the hypothesis that Article 96(1) of that directive did authorise the distribution of free samples of medicinal products to pharmacists, the referring court asks whether the German legislation at issue in the main proceedings, which prohibits such distribution, could be construed as a restriction within the meaning of Article 96(2) of Directive 2001/83.

45. It can be seen from the wording of that article that the restriction that Member States are indeed entitled to impose on the distribution of free samples of medicinal products must be imposed on the basis of the medicinal product in question rather than on the basis of the category of persons to whom they are to be distributed.

46. One of the conditions for distributing free samples in fact already excludes one category of medicinal product from that distribution.[30] However, Article 96(2) of Directive 2001/83 allows the Member States to go further in terms of excluding certain categories of medicinal product. Those categories of medicinal product could be determined, for example, on the basis of the active substances they contain, the type of conditions treated or according to whether or not they must be supplied on medical prescription. Nevertheless, given that the Court has already held that Directive 2001/83 brought about complete harmonisation of the common rules on advertising medicinal products,[31] and that Article 96(1) of that directive governs who can be recipients of free samples of medicinal products, I do not believe that Article 96(2) can serve as the basis for a national provision that restricts such distribution in terms of the persons to whom they are to be distributed.

30 These are medicinal products containing psychotropic or narcotic substances (see Article 96(1)(g) of Directive 2001/83).

31 See judgment of 8 November 2007, *Gintec* (C-374/05, EU:C:2007:654, paragraphs 20, 33 and 39).

V. Conclusion

47. In the light of all the foregoing, I propose that the Court of Justice should reply as follows to the questions referred for a preliminary ruling by the Bundesgerichtshof (Federal Court of Justice, Germany):

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 meaning that pharmaceutical companies may distribute free samples of medicinal products, on the conditions laid down by that article, only to persons qualified to prescribe them.