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OPINION OF ADVOCATE GENERAL
 SZPUNAR
 delivered on 24 October 2024 ¹

Case C-517/23

-1308737-

Apothekerkammer Nordrhein
 v
DocMorris NV

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

(Reference for a preliminary ruling – Medicinal products for human use –
 Directive 2001/83/EC – Scope – Medicinal products subject to medical
 prescription – Advertising for a pharmacy’s entire range of medicinal products –
 Vouchers or percentage discounts for the subsequent purchase of other products –
 Direct rebates and payments)

¹ Original language: English.

I. Introduction

1. Are patients who rely on medicinal products prescribed by a doctor and who are attracted by a rebate offered by a foreign mail-order pharmacy primarily lured into consuming medicinal products or into contracting with the specific pharmacy offering the rebate? Is there a genuine need to protect such patients against incorrect and excessive consumption of medicinal products? Are they victims of the pharmaceutical industry and those selling their products or of their illnesses for which they seek a cure or from which they seek relief? Do patients suffering from, for example, a chronic disease, behave in an antisocial manner if they ‘cash in’ when purchasing a medicinal product for which they will be reimbursed?

2. These questions, posed in an illustrative manner, go straight to the heart of the subject matter of the present request for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany).

3. In the case at hand, DocMorris, a Dutch mail-order pharmacy, which has been a party to proceedings leading to a request for a preliminary ruling on a number of occasions already, is back, this time with rebates. Various practices of foreign companies offering rebates are a thorn in the side of the economic operators already firmly rooted in the national market, who claim that offering rebates on the sale of prescription-only medicines constitutes ‘advertising of medicinal products’ within the meaning of Directive 2001/83/EC.²

4. The Bundesgerichtshof (Federal Court of Justice), faced with the conflicting case-law of the German lower courts, seeks guidance on the definition of ‘advertising’, in particular in the context of a string of cases handed down by the Court of Justice in the last 10 years.

5. I shall argue in this Opinion that discount campaigns such as the ones at issue in the present case do not constitute advertising under Article 86(1) of Directive 2001/83, given that they are implemented upon purchase of prescription-only medicinal products.

II. Legal framework

A. European Union law

6. Title VIII, entitled ‘Advertising’, and Title VIIIa, entitled ‘Information and advertising’, of Directive 2001/83, contain, respectively, Articles 86 to 88 and Articles 88a to 100 of that directive.

² Directive 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’).

7. 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,
- 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,
- sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,
- sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

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.’

8. Article 87(3) of Directive 2001/83 provides:

‘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.’

9. Under Article 88(1) to (3) 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;

...

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.’

B. German law

10. The first sentence of Paragraph 7(1) of the Gesetz über die Werbung auf dem Gebiete des Heilwesens (Heilmittelwerbe-gesetz) (Law on the advertising of medicinal products; ‘the HWG’), in the version applicable to the main proceedings, provides:

‘It shall be prohibited to offer, announce or grant monetary advantages and other promotional gifts (goods or services) or to accept them, as a healthcare professional, unless:

1. those monetary advantages or promotional gifts are items of low value... Monetary advantages and other promotional gifts in respect of medicinal products are prohibited if they are granted in breach of the pricing rules applicable under the [Arzneimittelgesetz (Law on medicinal products)];

2. those monetary advantages and promotional gifts

(a) are granted as a specific sum of money or as a sum of money to be calculated in a specific way ...

...

The monetary advantages and promotional gifts in respect of medicinal products provided for in subparagraph (a) shall be prohibited if they are granted in breach

of the pricing provisions applicable on the basis of the Law on medicinal products. ...’

III. Facts, procedure and questions referred

11. DocMorris supplies prescription and non-prescription medicines by mail order to end customers in Germany. Apothekerkammer Nordrhein is the representative body for pharmacists in the North Rhine area in Germany.

12. Since 2012 DocMorris has run various discount campaigns where, upon purchasing prescription medicinal products, customers were offered a benefit in the form of an immediate cash discount, a voucher for a certain sum of money or a percentage reduction on the subsequent purchase of other products (non-prescription medicinal products or non-medicinal health or beauty products) from DocMorris.

13. Apothekerkammer Nordrhein considers that those advertising measures constitute an infringement of the system of fixed prices for prescription medicinal products under the Law on medicinal products and therefore – in so far as is relevant to the appeal on a point of law – obtained against DocMorris, during the period from 2013 to 2015, five interlocutory injunctions to cease those practices, in the context of interim measures issued by the Landgericht Köln (Regional Court, Cologne, Germany), which were each duly enforced.

14. On 8 May 2013 (ref. 84 O 90/13), on 26 September 2013 (ref. 84 O 220/13) and on 4 November 2014 (ref. 84 O 208/14), Apothekerkammer Nordrhein obtained an interlocutory injunction from the Landgericht Köln (Regional Court, Cologne) against advertising by DocMorris. These three injunctions were each duly enforced. By two judgments of 22 March 2017, the Landgericht Köln (Regional Court, Cologne) annulled the interlocutory injunctions of 8 May 2013 and of 4 November 2014.

15. On 5 November 2013, Apothekerkammer Nordrhein obtained an interlocutory injunction from the Landgericht Köln (Regional Court, Cologne) (ref. 84 O 256/13), which was enforced on 21 January 2014, against the following advertising by DocMorris:

‘Send in your prescription now! ... Unfortunately we can’t save you a trip to the post box but to compensate for the cost of your journey by bus and train, new customers will receive 10 euro from us, which will be immediately deducted from the invoice amount when the prescription is sent in’.

The discount is offered as a reward for orders of prescription medicines with an order value of EUR 50 or more. The Landgericht Köln (Regional Court, Cologne) annulled this interlocutory injunction by judgment of 22 March 2017.

16. On 29 September 2015, Apothekerkammer Nordrhein obtained an interlocutory injunction from the Landgericht Köln (Regional Court, Cologne) (ref. 81 O 82/15), which was enforced on 26 May 2016, against the following advertising by DocMorris:

‘5 euro voucher for your next prescription order[.]’

That sum was to be deducted directly from the invoice amount. The Landgericht Köln (Regional Court, Cologne) annulled this interlocutory injunction by final judgment of 21 March 2017.

17. The referring court stresses that the reason for each of the abovementioned annulments was the change in circumstances in the light of the judgment of the Court in *Deutsche Parkinson Vereinigung*.³

18. Administrative fines were imposed on DocMorris in the context of the enforcement of some of the interlocutory injunctions at the request of the defendant.

19. DocMorris is claiming compensation for damage from Apothekerkammer Nordrhein on the ground that the interlocutory injunctions were unjustified from the outset.

20. The Landgericht Köln (Regional Court, Cologne) dismissed the action. On appeal DocMorris claimed, in essence, that the court should order Apothekerkammer Nordrhein to pay it compensation for damage in the amount of at least EUR 18 476 648.12 plus interest and declare that Apothekerkammer Nordrhein is liable to pay compensation in respect of any further damage.

21. By its appeal on a point of law, Apothekerkammer Nordrhein maintains its claim that the action should be dismissed in its entirety.

22. It is in those circumstances that, by order of 13 July 2023, received at the Court on 10 August 2023, 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) Does advertising for the purchase of prescription medicinal products from the entire range of products of a pharmacy fall within the scope of the rules on the advertising of medicinal products in Directive 2001/83 (Titles VIII and VIIIA, Articles 86 to 100)?
- (2) If Question 1 is to be answered in the affirmative, is it consistent with the provisions of Title VIII of Directive 2001/83, in particular Article 87(3), if a national rule (here: letter (a) of the first clause of point 2 of the second half

³ Judgment of 19 October 2016 (C-148/15, ‘the judgment in *Deutsche Parkinson Vereinigung*’, EU:C:2016:776).

of the first sentence of Paragraph 7(1) of the HWG) is interpreted as prohibiting the advertising of the entire range of prescription medicinal products of a mail-order pharmacy established in another Member State using promotional gifts in the form of vouchers for a monetary amount or a percentage discount for subsequent purchases of other products?

- (3) Furthermore, if Question 1 is to be answered in the affirmative, is it consistent with the provisions of Title VIII of Directive 2001/83, in particular Article 87(3), if a national rule (here: letter (a) of the first clause of point 2 of the second half of the first sentence of Paragraph 7(1) of the HWG) is interpreted as permitting the advertising of the entire range of prescription medicinal products of a mail-order pharmacy established in another Member State using promotional gifts in the form of immediately effective price reductions and payments?’

23. Written observations were submitted by the parties to the main proceedings, by the Estonian and Polish Governments and by the European Commission. The parties to the main proceedings and the Commission attended the hearing, which was held on 27 June 2024.

IV. Assessment

A. First question: on the scope of Directive 2001/83

24. By its first question, the referring court seeks, in essence, to ascertain whether discount campaigns, run by a pharmacy, that offer customers, upon purchasing prescription medicinal products, a benefit in the form of an immediate cash discount, a voucher for a certain sum of money or a percentage reduction on the subsequent purchase of other products (non-prescription medicinal products or non-medicinal health or beauty products), constitute ‘advertising of medicinal products’ within the meaning of Article 86(1) of Directive 2001/83.

25. *In casu*, DocMorris offered such discounts to its customers.

26. Given that this constitutes a cross-border activity within the internal market, the present case potentially concerns both the Treaty fundamental freedoms, notably the free movement of goods (medicinal products) and the freedom to provide services (the commercial activity of running a pharmacy), and the specific rules adopted by the EU legislature in the domain of advertising of medicinal products.

27. Indeed, as the referring court carefully explains in its request for a preliminary ruling, while the disputes before the national courts, in the context of which it has been called upon to rule on a point of law, have as their background the application of the case-law of the Court of Justice in the context of the free

movement of goods, namely the judgment in *Deutsche Parkinson Vereinigung*,⁴ it seeks guidance on (the Court's case-law interpreting) Directive 2001/83, namely the judgments in *DocMorris*⁵ and *EUROAPTIEKA*.⁶

28. This calls for a brief recapitulation, to the extent necessary for the present case, of the Court's case-law mentioned.

29. As a matter of fact, this is not the first time that the Court has been seised with questions regarding the matter of prices charged and rebates offered (primarily) by mail-order pharmacies and it is indeed against that background that the referring court seeks further clarification as to what is imposed or permitted under EU law when it comes to pharmacists offering customers rebates on medicinal products.

1. The Court's case-law to date

30. There are two complementary lines of case-law.

(a) Free movement under the FEU Treaty

31. In the judgment in *Deutsche Parkinson Vereinigung*, the Court was faced with the question whether the prohibition, based on national law,⁷ of a rebate system under which various bonuses would be provided to patients when purchasing, from DocMorris, prescription-only medicinal products for Parkinson's disease available only from pharmacies, was contrary to the fundamental freedom of free movement of goods under Articles 34 and 36 TFEU.

32. The Court found this to be the case, the measure in question constituting a measure having equivalent effect to a quantitative restriction under Article 34 TFEU, which could not be justified under Article 36 TFEU as it went beyond what was appropriate for attaining the objectives relied on.⁸ and was therefore not proportionate.⁹ In this connection, the Court stressed that there was no evidence to substantiate the contention that it is necessary to ensure a uniform supply of prescription-only medicinal products for essential medical purposes throughout

⁴ See, in particular, points 4, 6, 7, 9, 10, 17 and 64 of the request for a preliminary ruling.

⁵ Judgment of 15 July 2021 (C-190/20, 'the judgment in *DocMorris*', EU:C:2021:609). See, in particular, points 53, 54, 62 and 64 of the request for a preliminary ruling.

⁶ Judgment of 22 December 2022 (C-530/20, 'the judgment in *EUROAPTIEKA*', EU:C:2022:1014). See, in particular, points 54 and 59 of the request for a preliminary ruling.

⁷ Paragraph 78 of the Law on medicinal products ('*Arzneimittelgesetz*'), in the version applicable at the time.

⁸ Namely, the protection of health and life of humans.

⁹ See the judgment in *Deutsche Parkinson Vereinigung* (paragraph 46 and operative part of the judgment).

Germany that satisfies the conditions under Article 36 TFEU.¹⁰ Crucially, the Court held that there were certain factors that suggested that increased price competition between pharmacies would be conducive to a uniform supply of medicinal products by encouraging the establishment of pharmacies in regions where the scarcity of dispensaries allows for higher prices to be charged;¹¹ that price competition from mail-order pharmacies could lead to traditional pharmacies being encouraged to improve certain activities in the general interest, such as producing prescription medicinal products or maintaining a given stock and selection of medicinal products;¹² and that 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 in Germany at more attractive prices than those currently imposed by that Member State.¹³

(b) Advertising under Directive 2001/83

33. In its judgment in *A (Advertising and sale of medicinal products online)*,¹⁴ which concerned the activity of a pharmacy established in a Member State that consisted in it 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 does 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/EC.¹⁵

34. Subsequently, in the judgment in *DocMorris*,¹⁶ which concerned an 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, the Court held that that advertising campaign sought to influence not the customer's choice of a given medicinal product but the choice, which takes place 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.

¹⁰ See the judgment in *Deutsche Parkinson Vereinigung* (paragraph 37).

¹¹ See the judgment in *Deutsche Parkinson Vereinigung* (paragraph 38).

¹² See the judgment in *Deutsche Parkinson Vereinigung* (paragraph 40).

¹³ See the judgment in *Deutsche Parkinson Vereinigung* (paragraph 43).

¹⁴ Judgment of 1 October 2020 (C-649/18, EU:C:2020:764, paragraphs 50 and 59). See also the judgment in *EUROAPTIEKA* (paragraph 49).

¹⁵ Directive 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).

¹⁶ Paragraph 21 et seq. See also the judgment in *EUROAPTIEKA*, paragraph 50.

35. Finally, in its judgment in *EUROAPTIEKA*, which concerned a promotion by which pharmacies and companies distributing medicinal products for retail offered a 15% reduction on the purchase price of any medicinal product where at least three products were purchased, the Court held that such a practice comes within the concept of ‘advertising of medicinal products’ within the meaning of Article 86(1) of Directive 2001/83. The Court stressed that this was so even where the information in question does not refer to a specific medicinal product, but to unspecified medicinal products.

(c) Taking stock

36. While the judgments in *A (Advertising and sale of medicinal products online)*¹⁷ and in *DocMorris* were handed down in cases in which there was a cross-border element in the main proceedings, this was not the case as regards the judgment in *EUROAPTIEKA*. In that case, the main proceedings constituted what is known as a ‘purely internal situation’.

37. As the Commission correctly stresses in its written observations, two essential points can be inferred from the case-law on Directive 2001/83 for the purposes of the present case.

38. First, it follows from the judgment in *EUROAPTIEKA* that the concept of advertising of medicinal products under Directive 2001/83 is not limited to advertising for individual medicinal products. That concept also includes circumstances where information is provided about unspecified medicinal products. Ergo, the fact that the information in the present case relates, inter alia, to all prescription-only medicinal products from a pharmacy’s entire product range does not, as such, prevent that directive from being applicable.

39. Secondly, it follows from the judgment in *DocMorris* that, in the case of advertising by a pharmacy that uses information on unspecified medicinal products, it must be examined whether the advertising is aimed at encouraging the purchase of medicinal products or rather at influencing the later decision regarding the choice of pharmacy from which the medicinal product is purchased. In the latter case, the advertising does not fall within the scope of Directive 2001/83.

40. On the basis of these precedents, I shall now proceed with the analysis under Directive 2001/83.

¹⁷ Judgment of 1 October 2020 (C-649/18, EU:C:2020:764).

2. *Article 86(1) of Directive 2001/83*

(a) *Textual interpretation*

41. At the outset, it should be recalled that Directive 2001/83 brought about complete harmonisation in the field of advertising of medicinal products and expressly lists the situations in which Member States are authorised to adopt provisions departing from the rules laid down by that directive.¹⁸

42. Pursuant to Article 86(1) of Directive 2001/83, ‘advertising of medicinal products’ includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.¹⁹

43. It is apparent from the wording of that provision, in particular from the expression ‘any form’, that the concept of advertising of medicinal products adopted by the EU legislature is very broad.²⁰

44. Nevertheless, it is equally clear from the very wording of a number of provisions contained in Titles VIII and VIIIa of Directive 2001/83 that many of the provisions on advertising are, by their very nature, geared more towards manufacturers,²¹ marketing authorisation holders, wholesale distributors,²² medical sales representatives and importers, rather than pharmacies selling the medicinal products to end customers, that is to say, to patients. By way of

¹⁸ See judgment of 8 November 2007, *Gintec* (C-374/05, EU:C:2007:654, paragraph 39). Situations in which Member States may adopt such provisions can be found, in particular, in Article 88(3), Article 89(1)(b), Article 89(2), Article 91 and Article 96(2) of Directive 2001/83. On the difference between advertising and promotion, see Grzybczyk, K., in Ogiegło, L. (ed.), *Prawo farmaceutyczne – Komentarz*, 2nd ed., Warsaw, 2015, Art. 52.

¹⁹ This definition results directly from the terms of Article 86(1) of Directive 2001/83 and not, as the Court appears to imply in the judgment in *EUROAPTIEKA* (paragraph 47), ‘from a literal, contextual and teleological interpretation of Article 86(1) of Directive 2001/83’. On the concept of advertising, see also Czyżewska, K., Dziurawicz, J., Łoś, K., Lukawska, N. and Piekarczyk, K., in Czyżewska, K., Dziurawicz, J., Łoś, K., Lukawska, N. and Piekarczyk, K. (eds), *Reklama produktów leczniczych. Komentarz do art. 52-64 ustawy – Prawo farmaceutyczne*, Warsaw, 2020, Art. 52.

²⁰ See judgment of 5 May 2011, *MSD Sharp & Dohme* (C-316/09, EU:C:2011:275, paragraph 29), and my Opinion in *EUROAPTIEKA* (C-530/20, EU:C:2021:993, point 45). See also Streinz, R. and Klaus, B., ‘C.V. Arzneimittelrecht’, point 130, in Dausen, M.A. and Ludwigs, M., *Handbuch des EU-Wirtschaftsrechts*, Vol. I, EL 53 (2021), C.H. Beck, Munich, 2024.

²¹ On the general duties of manufacturers and importers, see Title IV of Directive 2001/83.

²² Article 1(17) of Directive 2001/83 defines ‘wholesale distribution of medicinal products’ as ‘all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in the Member State concerned’.

example, the advertising of medicinal products to persons qualified to prescribe or supply them (second indent of Article 86(1) of Directive 2001/83) or visits by medical sales representatives to persons qualified to prescribe medicinal products (third indent of Article 86(1) of that directive) seem to me to target not pharmacies selling to patients, but entities further up the distribution chain. The same goes for Article 89(1)(b) of Directive 2001/83:²³ if the 15% reduction on the purchase price of *any* medicinal product is offered, where at least three products are purchased, then, as the Court held in the judgment in *EUROAPTIEKA*, by definition a pharmacy selling to a patient cannot be expected to include the *name* of a medicinal product.

45. The Court consistently holds that while the definition contained in Article 86(1) of Directive 2001/83 explicitly emphasises the *purpose* of the message, it does not provide any indication as to the people who disseminate such information.²⁴ The purpose of the message constitutes the fundamental defining characteristic of advertising within the meaning of Article 86(1) of that directive and the decisive factor for distinguishing advertising from mere information.²⁵ The Court has, accordingly, applied this provision *ratione personae* to ‘independent third part[ies]’²⁶ as well as to pharmacies and companies distributing medicinal products.²⁷

46. On the activities of a pharmacy in particular, where the purpose of the message is 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, this message does not come within the concept of ‘advertising of medicinal products’ within the meaning of Article 86(1) of Directive 2001/83.²⁸

47. Applying these criteria to the case in hand, it emerges that the purpose of the message conveyed by the commercial practices employed by DocMorris is to encourage the patient to come to the DocMorris pharmacy specifically. By means of the message ‘come to us’ instead of ‘buy these (specific or unspecified)

²³ According to that provision, without prejudice to Article 88 of Directive 2001/83, *all* advertising to the general public of a medicinal product is to include the following minimum information: the name of the medicinal product, as well as the common name if the medicinal product contains only one substance; the information necessary for correct use of the medicinal products; and an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.

²⁴ See judgment of 2 April 2009, *Damgaard* (C-421/07, EU:C:2009:222, paragraph 20 et seq.). See also my (additional) Opinion in *EUROAPTIEKA* (C-530/20, EU:C:2022:450, point 30).

²⁵ See judgment of 5 May 2011, *MSD Sharp & Dohme* (C-316/09, EU:C:2011:275, paragraph 31).

²⁶ See judgment of 2 April 2009, *Damgaard* (C-421/07, EU:C:2009:222, paragraph 22).

²⁷ See the judgment in *EUROAPTIEKA* (paragraph 55).

²⁸ See, to that effect, the judgment in *DocMorris* (paragraph 21).

medicinal products’, DocMorris focuses on the sale *to* the patient rather than the sale *of* a (specific or unspecified) medicinal product.

48. This finding applies, in my view, both to immediate rebates and to rebates offered in respect of future purchases.

49. Regarding immediate rebates, crucially, in the present case, the patient already knows which product to buy. This product has been prescribed by a professional qualified to do so. The rebates are offered uniquely in relation to the sale of prescription medicinal products. Once a patient has received a prescription, the only parameter left for him or her to choose is from which pharmacy to procure the product. Everything else has already been decided by a doctor: whether a medicinal product is prescribed and the quantity prescribed, as well as the dosage and the intervals at which the medicinal products are to be taken by the patient.

50. Regarding future rebates, the same message as the one described above is conveyed to the patient. There is no focus on persuading a patient to buy a certain number of medicinal products. The rebates apply to a pharmacy’s entire product range of non-prescription medicinal products and non-medicinal health or beauty products. Therefore, as will be explained in more detail below (second and third questions), medicinal products are only one part of that product range.

51. Moreover, it is in this regard that the present case is markedly different from that giving rise to the Court’s judgment in *EUROAPTIEKA*. In the latter case, where a pharmacy offered a 15% reduction on the purchase price of any medicinal product where at least three products were purchased, that pharmacy directly and unequivocally persuaded a customer to buy more (of an) unspecified medicinal product(s). The patient could not benefit from the promotion without buying a certain number of medicinal products. Obviously, as summarised above, such a practice clearly constitutes, in my view, ‘advertising of medicinal products’ within the meaning of Article 86(1) of Directive 2001/83. This was, moreover, what I proposed to the Court in my two Opinions in that case.

52. A textual interpretation of Article 86(1) of Directive 2001/83 accordingly leads me to the intermediate conclusion that commercial practices employed by a pharmacy such as those at issue in the present case do not constitute advertising of a medicinal product within the meaning of that provision.

53. That finding is supported by a systematic and teleological interpretation of Article 86(1) of Directive 2001/83.

(b) Systemic and teleological interpretation

54. I shall now allow myself to take a step back and focus on Article 86(1) of Directive 2001/83 within the scheme and the overall rationale of that directive.

55. Directive 2001/83 is a classic example of a harmonising measure²⁹ in the domain of the internal market, as clearly illustrated by the recitals of that directive.

56. The starting point for the political institutions of the European Union³⁰ was the consideration that, while the essential aim of any rules governing the production, distribution and use of medicinal products is to safeguard public health,³¹ 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.³² They detected that trade in medicinal products within the European Union was hindered by disparities between certain national provisions relating to medicinal products³³ and that such disparities directly affected the functioning of the internal market.³⁴ In order to remove such hindrances, it was decided to proceed to an approximation of the relevant provisions.³⁵

57. The legal basis for pursuing this endeavour is Article 114 TFEU, which is arguably the most important of all harmonising competences in the TFEU. Under that provision,³⁶ in order to achieve the objectives set out in Article 26 TFEU, the EU legislature, under the ordinary legislative procedure,³⁷ can adopt harmonising measures ‘which have as their object the establishment and functioning of the internal market’. The Court understands that provision to require the harmonising measures *genuinely* to *improve* the conditions for the establishment and functioning of the internal market.³⁸

²⁹ I have argued elsewhere that the terms ‘coordination’, ‘approximation’ and ‘harmonisation’ are used interchangeably throughout the TFEU. See my Opinions in Joined Cases *Trijber and Harmsen* (C-340/14 and C-341/14, EU:C:2015:505, point 52), and in Joined Cases *X and Visser* (C-360/15 and C-31/16, EU:C:2017:397, point 108). See also, on this issue, Ignatowicz, Z., in Olszewski, W.L. (ed.), *Prawo farmaceutyczne – Komentarz*, Warsaw, 2016, Art. 52.

³⁰ For the purposes of this Opinion, I understand the political institutions of the European Union to comprise the European Parliament, the Council of the European Union and the Commission.

³¹ See recital 2 of Directive 2001/83.

³² See recital 3 of Directive 2001/83.

³³ Excluding substances or combinations of substances which are foods, animal feeding-stuffs or toilet preparations.

³⁴ See recital 4 of Directive 2001/83.

³⁵ See recital 5 of Directive 2001/83. See also judgment of 8 November 2007, *Gintec* (C-374/05, EU:C:2007:654, paragraph 19).

³⁶ See Article 114(1) TFEU.

³⁷ And after consulting the Economic and Social Committee.

³⁸ See judgments of 5 October 2000, *Germany v Parliament and Council* (C-376/98, EU:C:2000:544, paragraph 83 et seq.); of 12 December 2006, *Germany v Parliament and Council* (C-380/03, EU:C:2006:772, paragraph 24); of 8 June 2010, *Vodafone and Others*

58. Any harmonising measure seeks to align national levels of protection of (in the present case) health with an EU level of protection. That is the very purpose of harmonisation. The rationale of harmonising national provisions on advertising of medicinal products is therefore that of creating a level playing field for economic operators, allowing them to trade freely, within the confines, obviously, of the very rules adopted by the EU legislature. In this connection, as regards the level of protection at EU level, this must be high, as is apparent from Article 114(3) TFEU.³⁹

59. Since, as is repeatedly stressed by Apothekerkammer Nordrhein, medicinal products are not products like any other, the specificity of the market of such products requires that public health be taken into account at all stages. Ergo, recital 2 of Directive 2001/83, referred to above and also referred to by the Court,⁴⁰ confirms that the essential aim pursued by that directive is to safeguard public health.

60. The rules on advertising contained in Title VIII⁴¹ and VIIIa⁴² of Directive 2001/83 are to be considered against this background. Recital 43 of that directive specifically concerns the advertising sector of medicinal products and states, in essence,⁴³ that the disparities between the measures adopted by the Member States in that field are likely to have an impact on the functioning of the internal market. It is therefore the stated intention of that directive to remove such disparities.⁴⁴

61. In this connection, I should like to stress that I have held elsewhere that when the purchase of a medicinal product is conditional on obtaining a medical prescription, under the control of persons authorised to prescribe such products, an

(C-58/08, EU:C:2010:321, paragraph 32); and of 3 September 2015, *Inuit Tapiriit Kanatami and Others v Commission* (C-398/13 P, EU:C:2015:535, paragraph 26).

³⁹ Pursuant to that provision, the Commission, in its proposals concerning health, safety, environmental and consumer protection, is to take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the Parliament and the Council will also seek to achieve this objective.

⁴⁰ See the judgment in *EUROAPTIEKA* (paragraph 39).

⁴¹ This title is headed 'Advertising'.

⁴² This title is headed 'Information and Advertising'.

⁴³ The wording of recital 43 is as follows: 'All Member States have adopted further specific measures concerning the advertising of medicinal products. There are disparities between these measures. These disparities are likely to have an impact on the functioning of the internal market, since advertising disseminated in one Member State is likely to have effects in other Member States.'

⁴⁴ See, to that effect, my (additional) Opinion in *EUROAPTIEKA* (C-530/20, EU:C:2022:450, point 40).

advertising campaign by a pharmacy is not such as to encourage the irrational use of medicinal products.⁴⁵

62. As regards the commercial practices at issue in the present case, I do not see how they would lead to abuse of the consumption of medicinal products.⁴⁶ Again, the decision to prescribe the product has already been taken. Such prescription already contributes to ensuring that the medicinal product will be used for its intended purpose.

63. To suggest otherwise, as Apothekerkammer Nordrhein did during the hearing, in so far as it claimed that patients could convince doctors to prescribe them specific products or larger quantities of specific products, not only reverses the standard assumptions underlying all the EU and national legislation at issue (doctors – as experts – prescribe, with patients literally being on the receiving end), but also attempts to portray others in a bad light: fuelled by greedy mail-order pharmacies which are typically foreign establishments, supposedly fragile patients convince unscrupulous doctors to prescribe an excessive amount of medicinal products. In this connection, we can furthermore rely on the previous findings of the Court where it held the following:⁴⁷ ‘It is admittedly possible that, because of a request by an informed patient, the doctor is led to prescribe a medicinal product other than that which he initially preferred and that, consequently, the factual information contributes, even marginally, to increasing sales. However, such a possibility is not sufficient to show promotional intent on the part of the manufacturer of the medicinal product. Furthermore, in principle it does not represent a specific danger to the health of the patient if the doctor takes the view that the prescription of one or other of the medicinal products may be envisaged and cannot compromise the objectivity with which, as noted in recital 50 in the preamble to Directive 2001/83, a doctor must act when issuing a prescription for a given patient. A prescribing doctor is required, from the point of view of professional conduct, not to prescribe a given medicinal product if it is not fitting for the therapeutic treatment of his patient.’⁴⁸

64. Finally, the reasoning set out above reflects the principles enshrined in Article 16 of the Charter of Fundamental Rights of the European Union (‘the Charter’), which recognises the freedom to conduct a business. It is only natural

⁴⁵ See my Opinion in *EUROAPTIEKA* (C-530/20, EU:C:2021:993, point 71), and my (additional) Opinion in *EUROAPTIEKA* (C-530/20, EU:C:2022:450, point 29).

⁴⁶ Article 1(16) of Directive 2001/83 defines ‘abuse of medicinal products’ as the ‘persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects’.

⁴⁷ The fact that these findings were made in the context of a case regarding the advertising of a specific medicinal product, which was also not aimed at the public, leads me to think that they apply a fortiori in the present case.

⁴⁸ See judgment of 5 May 2011, *MSD Sharp & Dohme* (C-316/09, EU:C:2011:275, paragraph 37 and the case-law cited).

for a pharmacy to try to promote its business, as opposed to encouraging its customers to consume medicinal products. Directive 2001/83 regulates, in principle, only the latter aspect. Article 16 of the Charter, in my view, requires that that directive be interpreted as proposed above, so that the former aspect, i.e. that of promoting a pharmacy, is not virtually excluded.

3. *Conclusion*

65. The overriding purpose of the discount campaigns is to persuade patients to choose DocMorris as their pharmacy, instead of another one. Their purpose is not to persuade patients to consume more medicinal products than they would have otherwise. Rather, a foreign pharmacy is attempting to enter the German market by generating a steady flow of orders: since patients relying on prescription-only medicinal products often suffer from chronic and perhaps incurable illnesses, they will rely on such products for a considerable amount of time. Pharmacies naturally want to tap into this lucrative market where one prescription is often part of a bigger ‘subscription’.

66. My proposed reply to the first question is, accordingly, that discount campaigns, run by a pharmacy, that offer customers, upon purchasing prescription medicinal products, a benefit in the form of an immediate cash discount, a voucher for a certain sum of money or a percentage reduction on the subsequent purchase of other products (non-prescription medicinal products or non-medicinal health or beauty products), do not constitute ‘advertising of medicinal products’ within the meaning of Article 86(1) of Directive 2001/83.

B. *Further considerations*

67. As a result of my proposed reply to the first question, there is no longer any need to examine the second and third questions. I shall nevertheless examine them for the sake of completeness. Before doing so, I should like to stress that if the provisions of Directive 2001/83 do not apply, the referring court will have to have regard to the Treaty on the Functioning of the European Union, in particular the fundamental freedoms enshrined therein.⁴⁹

68. Prohibiting advertising such as that at issue in the case in the main proceedings constitutes a measure having equivalent effect to a quantitative restriction under Article 34 TFEU. Crucially, as in the judgment in *Deutsche Parkinson Vereinigung*, and in contrast to the judgment in *DocMorris*, the advertising in question in the present case does not constitute a selling arrangement, as the said prohibition impedes the access of pharmaceutical

⁴⁹ Unless the national court ruling on the facts should find that the commercial practice in question is predominantly carried out online, with physical advertising only constituting an ancillary element. In such a situation, the national court should have due regard to the judgment of 1 October 2020, *A (Advertising and sale of medicinal products online)* (C-649/18, EU:C:2020:764), and examine the possible application of Directive 2000/31.

products, lawfully marketed in other Member States. to the German market. Moreover, there is, based on the judgment in *Deutsche Parkinson Vereinigung*, no room for a justification.

C. Second and third questions

69. As stated above, the assessment that follows is undertaken for the eventuality that, in respect of the first question, the Court should reach a conclusion different from the one proposed in the present Opinion.

70. By its second and third questions, which ought to be examined together, the referring court seeks, in essence, to ascertain whether the provisions of Title VIII, and in particular Article 87(3), of Directive 2001/83 preclude the use, by a pharmacy, of discount campaigns that offer customers, upon purchasing prescription medicinal products, a benefit in the form of an immediate cash discount, a voucher for a certain sum of money or a percentage reduction on the subsequent purchase of other products (non-prescription medicinal products or non-medicinal health or beauty products).

71. This question calls for the following observations.

72. First, once we are within the scope of application of Directive 2001/83, Article 88(1)(a) of that directive applies, as a result of which advertising of medicinal products available on prescription only is prohibited.

73. Secondly, the *advertising* in question relates exclusively to the acquisition of a medicinal product available on prescription only. It is upon this acquisition that both the immediate and the future rebates are triggered. Accordingly, both types of rebates would be precluded by Article 88(1)(a) of Directive 2001/83.

74. Thirdly, I note that the referring court itself harbours doubts as to the application of Article 88(1)(a) of Directive 2001/83 to the case at issue in the main proceedings.⁵⁰ In my view, if it is found that the directive applies, such doubts are not in order. They rather prove that, as outlined in detail in the analysis of the first question, cases such as those at issue in the main proceedings do not fall within the scope of Directive 2001/83.

75. My proposed reply to the second and third questions is, therefore, that Article 88(1)(a) of Directive 2001/83 must be interpreted as precluding the use, by a pharmacy, of discount campaigns that offer customers, upon purchasing prescription medicinal products, a benefit in the form of an immediate cash discount, a voucher for a certain sum of money or a percentage reduction on the subsequent purchase of other products (non-prescription medicinal products or non-medicinal health or beauty products).

⁵⁰ See point 66 et seq. of the request for a preliminary ruling.

V. Conclusion

76. In the light of the foregoing considerations, I propose that the Court answer the question referred by the Bundesgerichtshof (Federal Court of Justice, Germany) as follows:

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

must be interpreted as meaning that discount campaigns, run by a pharmacy, that offer customers, upon purchasing prescription medicinal products, a benefit in the form of an immediate cash discount, a voucher for a certain sum of money or a percentage reduction on the subsequent purchase of other products (non-prescription medicinal products or non-medicinal health or beauty products), do not constitute ‘advertising of medicinal products’ within the meaning of that provision.

