Summary C-517/23 – 1

#### Case C-517/23

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

**Date lodged:** 

10 August 2023

**Referring court:** 

Bundesgerichtshof (Germany)

Date of the decision to refer:

13 July 2023

Defendant and appellant in the appeal on a point of law:

Apothekerkammer Nordrhein

Applicant and respondent in the appeal on a point of law:

DocMorris NV

## Subject matter of the main proceedings

Interpretation of Directive 2001/83/EC in respect of the extent to which advertising of prescription medicinal products from the entire range of products of a pharmacy falls within the scope of the directive

## Subject matter and legal basis of the request

Interpretation of EU law, Article 267 TFEU, in particular

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 ('Directive 2001/83')

## Questions referred 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 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?

## Provisions of European Union law relied on

TFEU, in particular Article 34

Directive 2001/83, in particular Titles VIII and VIIIa (Articles 86 to 100), Article 87(3) and Article 88(1)(a)

#### Provisions of national law relied on

Gesetz über die Werbung auf dem Gebiete des Heilwesens (Law on the advertising of medicines) (HWG)

Zivilprozessordnung (Code of Civil Procedure) (ZPO)

#### Succinct presentation of the facts and procedure

- The applicant is a Dutch mail-order pharmacy which supplies prescription and non-prescription medicines by mail order to end customers in Germany.
- 2 The defendant is the representative body for pharmacists in the North Rhine area.

- Since 2012 the applicant has advertised using various discount campaigns where, upon purchasing prescription medicinal products, customers were offered a benefit in the form of a cash discount, a voucher to be used against the purchase of another medicine, a hotel voucher or annual membership of a motoring association.
- 4 The defendant considers that these advertising measures constitute an infringement of the system of fixed prices for prescription medicinal products under the law on pharmaceuticals and therefore in so far as is relevant to the appeal on a point of law obtained against the applicant, from 2013 to 2015, the five interlocutory injunctions mentioned below, which were each duly enforced.
- On 8 May 2013 (ref. 84 O 90/13), on 4 November 2014 (ref. 84 O 208/14) and on 26 September 2013 (ref. 84 O 220/13), the defendant obtained an interlocutory injunction from the Landgericht Köln (Regional Court, Cologne) against advertising by the applicant. These three injunctions were each duly enforced. By two judgments of 22 March 2017, the Landgericht Köln annulled the interlocutory injunctions of 8 May 2013 and of 4 November 2014.
- On 5 November 2013, the defendant obtained an interlocutory injunction from the Landgericht Köln (ref. 84 O 256/13), which was enforced on 21 January 2014, against the following advertising by the applicant:
  - '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',
  - with the discount being offered as a reward for orders of prescription medicines with an order value of EUR 50 or more. The Landgericht Köln annulled this interlocutory injunction by judgment of 22 March 2017.
- On 29 September 2015, the defendant obtained an interlocutory injunction from the Landgericht Köln (ref. 81 O 82/15), which was enforced on 26 May 2016, against the following advertising by the applicant
  - '5 euro youcher for your next prescription order',
  - with that sum to be deducted directly from the invoice amount. The Landgericht Köln annulled this interlocutory injunction by final judgment of 21 March 2017.
- 8 The reason for each of the abovementioned annulments was the change in circumstances in the light of the judgment of the Court of Justice of the European Union ('Court of Justice') of 19 October 2016, *Deutsche Parkinson Vereinigung* (C-148/15, EU:C:2016:776).

- 9 High administrative fines were imposed on the applicant in the context of the enforcement of some of the interlocutory injunctions at the request of the defendant.
- 10 The applicant is claiming compensation for damages from the defendant on the ground that the interlocutory injunctions were unjustified from the outset.
- The Landgericht dismissed the action. On appeal the applicant claimed, in essence, that the court should order the defendant to pay the applicant compensation for damages of at least EUR 18 476 648.12 plus interest and declare that the defendant is liable to pay compensation in respect of any further damage.
- By its appeal on a point of law, the defendant maintains its claim that the action should be dismissed in its entirety.

# Succinct presentation of the reasoning in the request for a preliminary ruling

- 13 Under Paragraph 945 of the ZPO, the party which obtained an interlocutory injunction which was unjustified from the outset is obliged to compensate the opponent for damage incurred by him or her as a result of enforcement.
- When the German legislation on the advertising of medicines here: Paragraph 7(1) of the HWG is applied, three of the five advertising measures prohibited by the interlocutory injunctions prove to be unlawful. That is the case for the advertising measures to which the interlocutory injunctions of 8 May 2013 (ref. 84 O 90/13), of 26 September 2013 (ref. 84 O 220/13) and of 4 November 2014 (ref. 84 O 208/14) relate. No claim for compensation for damages under Paragraph 945 of the ZPO arises in respect of those three injunctions.
- The appeal court rightly held that the system of fixed prices for medicinal products may not be applied to the detriment of the applicant because, according to the case-law of the Court of Justice, a system of fixed sales prices has a greater impact on the applicant a pharmacy established in a Member State other than the Federal Republic of Germany than on those which are established within German territory, a fact which could impede market access for products from other Member States more than it impedes such access for domestic products, which means that there is an infringement of Article 34 TFEU (see judgment of the Court of Justice of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraph 26 et seq.).
- Under the first half of the first sentence of Paragraph 7(1) of the HWG, it is unlawful to offer, announce or grant rewards and other promotional gifts (goods or services) or to accept these as a healthcare professional unless one of the exceptions regulated by law in the second half of the first sentence of Paragraph 7(1) of the HWG applies. Under that provision, exceptions to the prohibition include small objects of low value and rewards or promotional gifts in a specific monetary amount or a monetary amount to be calculated in a specific

manner. However, in the case of both exceptions, rewards or other promotional gifts for medicinal products remain unlawful if they are granted in breach of the rules on pricing which apply inter alia on the basis of the Arzneimittelgesetz (Law on medicinal products).

- 17 The rewards and vouchers to be assessed in the present case constitute promotional gifts within the meaning of the first sentence of Paragraph 7(1) of the HWG, but not small objects of low value. Furthermore, they are only to some extent rewards or promotional gifts which are granted in a specific monetary amount or a monetary amount to be calculated in a specific manner within the meaning of the exception in letter (a) of the first clause of point 2 of the second half of the first sentence of Paragraph 7(1) of the HWG and are therefore lawful.
- The rewards or promotional gifts to which the interlocutory injunctions of 5 November 2013 (ref. 84 O 256/13) and of 29 September 2015 (ref. 81 O 82/15) relate are lawful.
- 19 The appeal on a point of law unsuccessfully challenges the appeal court's assessment that those two interlocutory injunctions were unjustified from the outset.
- Both of these relate to monetary discounts which are lawful under letter (a) of the first clause of point 2 of the second half of the first sentence of Paragraph 7(1) of the HWG and which directly reduce the invoice amount for the order. They do infringe the second clause of point 2 of the second half of the first sentence of Paragraph 7(1) of the HWG because they are granted in breach of the rules on pricing which apply inter alia on the basis of the Arzneimittelgesetz. They concern prescription medicinal products which are subject to the system of fixed prices for medicinal products. The grant of a monetary discount which directly reduces the invoice amount for the order runs counter to the system of fixed prices for medicinal products. The appeal court rightly held, however, that this proviso of compliance with the system of fixed prices for medicinal products may not be applied to the detriment of the applicant.
- The success of the appeal on a point of law depends on the interpretation of EU law here: Directive 2001/83. Questions of EU law requiring clarification arise in the case at issue in connection with the application of Paragraph 7 of the HWG.
- The rules of the HWG relating to the advertising of medicinal products must be interpreted in conformity with EU law having regard to the rules of Directive 2001/83. Within the scope of that directive, the advertising of medicinal products has been completely harmonised (judgment of the Court of Justice of 8 November 2007, *Gintec*, C-374/05, EU:C:2007:654, paragraphs 20 to 39).

## First question referred for a preliminary ruling

- The first question is intended to clarify whether the contested advertising for the purchase of prescription medicinal products from the entire range of products of a pharmacy falls within the scope of the rules on the advertising of medicinal products in Directive 2001/83 (Titles VIII and VIIIa, Articles 86 to 100).
- The contested advertising in the present case concerns the purchase of unspecified medicinal products from the entire range of products, while the pleas raised by the defendant relate to the advertising of prescription medicinal products contained therein.
- As the Court of Justice first ruled, Title VIII of Directive 2001/83, regarding the advertising of medicinal products, is intended to regulate the advertising of certain medicinal products (the content of the advertising message and the manner of advertising for particular medicinal products), but governs neither advertising of online sales services relating to medicinal products nor advertising for the entire range of medicinal products subject to a medical prescription offered for sale by the pharmacy in question (judgments of the Court of Justice of 1 October 2020, *A (Advertising and sale of medicinal products online)*, C-649/18, EU:C:2020:764, paragraphs 49 and 50, and of 15 July 2021, *DocMorris*, C-190/20, EU:C:2021:609, paragraphs 20 to 22).
- The Court of Justice has now ruled that, notwithstanding what is stated in paragraph 50 and in paragraph 20 of the abovementioned judgments, the scope of application of provisions of Directive 2001/83 is not limited to advertising of a specific medicinal product only (judgment of the Court of Justice of 22 December 2022, *EUROAPTIEKA*, C-530/20, EU:C:2022:1014, paragraph 51).
- 27 It follows from a literal, contextual and teleological interpretation of Article 86(1) of Directive 2001/83 that the concept of 'advertising of medicinal products' covers any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of unspecified medicinal products (judgment of the Court of Justice of 22 December 2022, *EUROAPTIEKA*, C-530/20, EU:C:2022:1014, paragraph 47).
- 28 It is possible that advertising for the purchase of prescription medicinal products only should be regarded as advertising of sales services, which is not covered by Directive 2001/83 according to the case-law of the Court of Justice, and not advertising of medicinal products, because in the case of such advertising the patient is no longer able or intended to choose the already prescribed medicinal product, but only a pharmacy.

## Second question referred for a preliminary ruling

In the event that advertising for the purchase of prescription medicinal products from the entire range of products of a pharmacy, which is at issue in the present

- case, falls within the scope of the rules on advertising in Directive 2001/83, the second question arises.
- 30 By that question, the court wishes to know whether it is 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 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.

### Compatibility with Directive 2001/83

- 31 The court takes the view that such an interpretation is consistent with the abovementioned rules of the directive.
- The Court of Justice has ruled that Article 87(3) and Article 90 of Directive 2001/83 must be interpreted as not precluding a national provision that prohibits the inclusion, in advertising to the general public of medicinal products that are neither subject to medical prescription nor reimbursed, of information which encourages the purchase of medicinal products by justifying the need for that purchase on the basis of the price of those medicinal products, by announcing a special sale, or by indicating that those medicinal products are sold together with other medicinal products, including at a reduced price, or with other types of products (judgment of the Court of Justice of 22 December 2022, *EUROAPTIEKA*, C-530/20, EU:C:2022:1014, paragraph 73).
- It held that, in that they prevent the use of advertising material that encourages the irrational and excessive use of medicinal products that are neither subject to medical prescription nor reimbursed, prohibitions such as those laid down in the provision at issue in the main proceedings meet the essential aim of safeguarding public health (judgment of the Court of Justice of 22 December 2022, *EUROAPTIEKA*, C-530/20, EU:C:2022:1014, paragraph 69).
- The Court of Justice noted in this connection that those prohibitions do not cover the dissemination of merely informative statements, which lack any promotional intent, about those medicinal products but rather they cover the dissemination of content that seeks to encourage the purchase of those medicinal products, whether by reference to their price, to a special sale or a sale bundled with other medicinal products, including at a reduced price, or with the sale of other products (judgment of the Court of Justice of 22 December 2022, *EUROAPTIEKA*, C-530/20, EU:C:2022:1014, paragraph 70).
- 35 These considerations would appear to apply *a fortiori* to advertising to the general public of prescription medicinal products and also, in principle, to advertising to the general public by a mail-order pharmacy established in another Member State.

Compatibility with the free movement of goods under Article 34 TFEU

- In the view of the court, the interpretation described in the question referred is also not contrary to the free movement of goods under Article 34 TFEU.
- National provisions restricting or prohibiting certain selling arrangements are not such as to hinder, directly or indirectly, actually or potentially, trade between Member States on the twofold condition, first, that those provisions apply to all relevant traders operating within the national territory and, secondly, that they affect in the same manner, in law and in fact, the marketing of domestic products and that of products from other Member States. The application of such rules to the sale of products from another Member State meeting the requirements laid down by that State is not by nature such as to prevent their access to the market or to impede access any more than it impedes the access of domestic products. The Court has found provisions restricting, inter alia, the opportunities for an undertaking to advertise to be 'provisions governing selling arrangements' (judgment of the Court of Justice of 15 July 2021, *DocMorris*, C-190/20, EU:C:2021:609, paragraph 35 et seq. and the case-law cited).
- The national rule described in the question referred is a provision which applies without distinction to all pharmacies selling medicinal products in Germany, whether they are established in Germany or in another Member State, such that they affect in the same manner, in law and in fact, the marketing of domestic products and products from other Member States.
- In the view of the court, this assessment is not contrary to the judgment of the Court of Justice of 19 October 2016 (*Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776).
- The Court of Justice stated in the 'DocMorris' judgment, which was delivered in response to a reference from the court, that the prohibition of promotional competitions at issue in that case, which was likewise based on the first sentence of Paragraph 7(1) of the HWG did not unlike in the 'Deutsche Parkinson Vereinigung' case constitute the 'total prohibition on price competition'. A prohibition of competitions designed to promote the sale of medicinal products has far less significant consequences for mail-order pharmacies than the total prohibition on price competition (judgment of the Court of Justice of 15 July 2021, *DocMorris*, C-190/20, EU:C:2021:609, paragraph 44).
- 41 The prohibition at issue in the present case on advertising using vouchers for a monetary amount or a percentage discount for subsequent purchases of other products would likewise not appear to constitute the total prohibition on price competition. That would appear to mean only the prohibition of advertising using immediately effective price reductions.

## Third question referred for a preliminary ruling

- 42 By the third question, the court wishes to clarify whether it is 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.
- In the view of the court, a prohibition of the advertising of prescription medicinal products using monetary rewards cannot be considered to be justified on the basis of Article 88(1)(a) of Directive 2001/83, which in accordance with recital 44 of the directive obliges Member States to proscribe the advertising of prescription medicinal products to the general public.
- Even if advertising to the general public which as in the case of the contested advertising measures in this case is generally intended to promote the marketing of prescription medicinal products through the grant of monetary benefits constitutes the advertising of medicinal products to the general public within the meaning of Article 86(1) of Directive 2001/83, it does not, in the view of the court, constitute generally prohibited advertising to the general public of prescription medicinal products for the purposes of Article 88(1)(a) of Directive 2001/83.
- Article 88(1) of Directive 2001/83 is intended, with a view to safeguarding health, to prevent advertising to the general public creating inducements for patients to ask their doctor to prescribe them a prescription medicinal product. The purpose of advertising prices for prescription medicinal products, on the other hand, is so that patients can choose a certain pharmacy when purchasing a medicinal product already prescribed to them. Prices advertising in the marketing of prescription medicinal products is an aspect of competition and is not covered by Article 88(1) of Directive 2001/83.