Case C-407/20

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:

31 August 2020

Referring court:

Oberlandesgericht Wien (Austria)

Date of the decision to refer:

29 July 2020

Applicant:

Österreichische Apothekerkammer

Defendant:

HA

Subject matter of the main proceedings

Free movement of goods – Quantitative restrictions – Measures having equivalent effect – Prohibition on mail-order sales of *in vitro* diagnostic medical devices for determining HIV status – Justification – Public health protection – Proportionality

Subject matter and legal basis of the reference

Interpretation of EU law, Article 267 TFEU

Question referred

Is Article 36 TFEU to be interpreted as meaning that a national prohibition on mail-order sales of *in vitro* diagnostic medical devices for determining HIV status intended by the manufacturer to be able to be used by lay persons in their home environment, that is a measure having equivalent effect within the meaning of Article 34 TFEU, is justified in order to protect the health and life of humans?

Provisions of EU law cited

A. Primary law:

Articles 34 and 36 TFEU

B. Secondary law

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices: Recitals 3, 5, 22, 23 and 31 and Articles 1, 2, 3, 4, 8 and 9(2)

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU: recital 1 and Articles 6 and 113

Provisions of national law cited

Verordnung der Bundesministerin für Arbeit, Soziales, Gesundheit und Konsumentenschutz über die Abgabe von HIV-Tests zur Eigenanwendung (Regulation of the Federal Minister for Labour, Social Affairs, Health and Consumer Protection on the supply of HIV tests for self-testing): Paragraphs 1, 2 and 3

Brief summary of the facts and procedure

1 The request for a preliminary ruling is made in the context of a dispute between the Österreichische Apothekerkammer (Austrian Chamber of Pharmacists) and HA concerning mail-order sales of HIV self-test kits.

2 The defendant, which is based in Germany, operates a pharmacy in Leipzig and also sells medicinal products via an online shop (https://www.apotheke.at). The online shop also sells HIV tests for self-testing, including the HIV self-test kit ‘Exacto Test HIV’ marketed by Biosynex and the ‘autotest VIH’ marketed by ratiopharm, both of which are *in vitro* diagnostic medical devices for determining HIV status that are intended by the manufacturer to be able to be used by lay persons in a home environment. The defendant also sells and supplies these HIV self-test kits to customers in Austria.

3 Each HIV self-test kit contains a package leaflet describing in detail, with diagrams, each individual step that must be followed in order to complete the self-test. The package leaflet expressly explains how the user is to interpret a negative or a positive test result. It emphasises in particular that a negative test result does not mean that infection with HIV can be ruled out, if the person was exposed to risk in the last three months before the test. The product description on the defendant’s website includes specific information about how the test works and is

to be prepared and carried out and about its reliability. It states, regarding the interpretation of test results, that infection with HIV can only be ruled out 12 weeks (3 months) after the last exposure to risk, and that all positive quick-test results must be confirmed by special laboratory testing. The defendant also provides advice, at the customer's request, on its HIV self-test kits which are available online. It operates a pharmaceutical help desk manned by pharmacists and trained assistants. The website also has a chat function via which customers can refer questions to the defendant's pharmaceutical help desk before purchasing or using a test kit. However, customers can also order HIV self-test kits via the defendant's website without first having to obtain advice from the help desk or check the product details.

4 The applicant requested that the defendant be ordered to cease selling and/or supplying mail-order HIV self-test kits in breach of the prohibition enacted in Paragraph 2 of the Regulation of the Federal Minister for Labour, Social Affairs, Health and Consumer Protection on the supply of HIV tests for self-testing, and also to publish the decision granting that injunction on its website and in various Austrian print media.

5 The Handelsgericht Wien (Commercial Court, Vienna), sitting as court of first instance, essentially adopted the defendant's line of argument and dismissed that request on 23 April 2020. The applicant lodged an appeal against that judgment with the referring court, the Oberlandesgericht Wien (Higher Regional Court, Vienna).

Principal arguments of the parties to the main proceedings

6 The **applicant** argues that the prohibition on mail-order sales in Paragraph 2(2), read in conjunction with the binding explanation in Paragraph 3 of the regulation, ensures that a consultation necessarily takes place, thereby preventing uncontrolled supply and use. This means that the pharmacist can – and must – supply (rather than the customer being able to demand) the product in conjunction with the necessary (follow-up) questions, information and advice. Where an HIV test for self-testing is obtained from the defendant's online shop, however, the mandatory explanation or advice is not given.

7 It contends that, as the objective of stopping the spread of HIV is undermined if there is no guarantee that all the necessary and requisite measures are taken to prevent error in the use of and/or a false diagnosis from an HIV test for self-testing, there is a specific public interest in having the supply of HIV self-test kits controlled by trained health workers within the framework of a personal consultation.

8 It argues that the fact that HIV self-test kits for *in vitro* diagnostics are included in List A in Annex II to Directive 98/79/EC on *in vitro* diagnostic medical devices illustrates that there is a significant risk of user error in the handling of the product

and in the interpretation of the test result. A false negative HIV test result puts persons with whom the user has intimate contact at high risk.

9 The **defendant** argues that the prohibition on mail-order sales is a measure having equivalent effect within the meaning of Article 34 TFEU that cannot be justified on the grounds of the protection of health of humans within the meaning of Article 36 TFEU, as the absolute prohibition on mail-order sales is disproportionate, and less restrictive measures are available which could achieve the objective pursued equally well. It contends that, when selling by mail order, it provides adequate opportunity for users to obtain information about the consequences of the test results and the time window for diagnosis, and that the regulation therefore infringes EU law and should be disapplied.

10 It argues that Directive 98/79/EC on *in vitro* diagnostic medical devices includes special provisions on *in vitro* diagnostic medical devices for self-testing which manufacturers must comply with in order to obtain certification and which take account of the fact that the tests are for use, in a home environment without any specialist instruction or supervision, by lay persons who (initially) have no one to rely on for an interpretation of test results; that the Austrian legislature has already transposed those provisions in the Medizinproduktegesetz (Law on Medicinal Devices, 'the MPG'); and that there is therefore no margin for national legislation restricting the sale of *in vitro* diagnostic medical devices which have been duly certified in accordance with those provisions.

11 It contends that their inclusion in List A in Annex II to the Directive is based solely on the risk in terms of the reliability of the test results and is therefore directed at the manufacturer; that that classification implies nothing in terms of the potential risk to users which, even assuming there is an enhanced potential risk, could be addressed by less stringent measures, such as mandatory online customer services.

12 According to the defendant, a local pharmacy offers no advantage whatsoever. In fact, given the situation in a pharmacy, with other staff or customers present, it may even be a disadvantage, as the psychological barrier is substantially higher in such circumstances.

Brief summary of the basis for the reference

13 The referring court has doubts as to whether Paragraph 2(2) of the cited regulation is consistent with EU law.

14 The concept of a measure having equivalent effect within the meaning of Article 34 TFEU covers all measures, other than purely quantitative restrictions, which undermine the free movement of goods, that is all cases in which the equivalent effect arises in some other way (not defined in the TFEU).

15 In its judgment of 2 December 2010, *Ker-Optika* (C-108/09, EU:C:2010:725), the Court found that legislation applicable to all traders (in that case) selling contact lenses does not affect in the same manner the selling of contact lenses by (in that case) Hungarian traders and such selling as carried out by traders from other Member States, and that the prohibition on selling contact lenses by mail order deprives traders from other Member States of a particularly effective means of selling those products and thus significantly impedes access of those traders to the market of the Member State concerned (see paragraph 54 and the case-law cited).

16 At paragraph 74 of its judgment of 11 December 2003, *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664), the Court classified a prohibition on online sales of non-prescription medicines (authorised in the Member State) as a measure having equivalent effect.

17 The referring court is of the opinion that the measure at issue in this case is likewise a measure having equivalent effect within the meaning of Article 34 TFEU. Consequently, the restriction in the Regulation of the Federal Minister for Labour, Social Affairs, Health and Consumer Protection on the supply of HIV tests for self-testing is a measure having equivalent effect to the quantitative restrictions fundamentally prohibited under Article 34 TFEU, unless it can be justified.

18 Such measures by the Member States may be justified in accordance with Article 36 TFEU. Article 168 TFEU states that the EU and the Member States must ensure a high level of human health protection. Thus, the health and life of humans rank foremost among the objects of protection mentioned in Article 36 TFEU. In the absence of harmonisation at EU level, it is for the Member States themselves to decide on the extent to which that protection is to be provided within the limits laid down by the Treaty, and by what measures. Permissible national measures in fully harmonised areas must primarily be consistent with secondary EU law. Only in the absence of EU legislation does Article 36 TFEU apply.

19 The referring court is of the opinion that the Regulation of the Federal Minister for Labour, Social Affairs, Health and Consumer Protection on the supply of HIV tests for self-testing must be examined in terms of its permissibility under Article 36 TFEU, as full harmonisation has not (yet) been achieved in the area of *in vitro* diagnostic medical devices and the question that arises in this case cannot be answered unequivocally in light of secondary law.

20 Article 8 of Directive 98/79/EC on *in vitro* diagnostic medical devices (safeguard clause) refers – including in light of the relevant recitals – to devices which may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, and therefore does not regulate specific distribution channels. Also, the referring court is of the opinion that the classification in Annex II to the directive only allows conclusions to be drawn concerning the procedure enacted in Article 9 (conformity assessment), which

concerns stricter quality assurance of devices, but does not concern the distribution method.

21 According to Article 113(2) of Regulation 2017/746 of 5 April 2017 on *in vitro* diagnostic medical devices, the regulation, or at least the parts which are relevant here, does not enter into force until 26 May 2022. Nor does that regulation enact any general prohibition on mail-order sales.

22 In its judgment of 2 December 2010, *Ker-Optika* (C-108/09, EU:C:2010:725), the Court examined whether a prohibition on selling contact lenses was justified under Article 36 TFEU; however, it did not apply the e-Commerce Directive to that process, even though recital 18 of the directive expressly refers to selling goods online as an example of an information society service. The Court emphasised at paragraph 31 that national rules on the sale of contact lenses are covered by the directive only in so far as they relate to the process of selling contact lenses via the internet, whereas national rules on the supply of contact lenses fall outside the scope of the directive. On the basis of the criteria established in the judgment of 2 December 2010, *Ker-Optika* (C-108/09, EU:C:2010:725), the supply of tests in this case likewise falls outside the scope of the e-Commerce Directive. The referring court is therefore of the opinion that the entire process should be judged within the framework of Article 36 TFEU.

23 Any measure adopted by the Member States to restrict the free movement of goods must be in the general interest (to protect assets recognised under primary law), must be capable of attaining that interest, must satisfy the principle of proportionality, that is it must be proportionate to the objective pursued, and must be the least onerous means of achieving the objective.

24 The Court held in its judgment of 2 December 2010, *Ker-Optika* (C-108/09, EU:C:2010:725) that reserving the supply of contact lenses to opticians was appropriate for securing the attainment of the objective of ensuring protection of the health of those users (paragraph 64), but it found that the legislation went beyond what was necessary in order to attain that objective, because it was equally possible to provide for mandatory advice via interactive features or to obtain mandatory advice interactively from a qualified optician (see paragraphs 65 to 75).

25 In its judgment of 11 December 2003, *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664), the Court classified a prohibition on mail-order sales of non-prescription medicines (authorised in the Member State) as not justified for the effective protection of human health in accordance with Article 36 TFEU, as a 'virtual pharmacist' can provide the same advisory services (see paragraphs 113 to 116).

26 By its judgment of 28 October 2004, *Commission* v *Austria* (C-497/03, not published, EU:C:2004:685), the Court found that Austria's prohibition on mail-

order sales of food supplements infringed the Treaty, as supplements generally present less of a potential risk than non-prescription medicines.

27 The following arguments undermine the assumption that the prohibition on mail-order sales enacted in the regulation at issue is justified in accordance with Article 36 TFEU:

28 *The findings made by the Court in its judgments of 2 December 2010, *Ker-Optika* (C-108/09, EU:C:2010:725), and of 11 December 2003, *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664) can also be applied to the present case. According to those judgments, online advice is equivalent to advice given in person. Less onerous measures, such as mandatory online advice, can attain the objective pursued just as well as an absolute prohibition on mail-order sales.

29 *HIV testing is a highly personal matter which is easier to address within the framework of online advice than in a pharmacy in front of other people.

30 *The handling of the test and the (direct) interpretation of the test results, which were raised in order to assert a specific potential risk, are a matter for the customer alone, even where the test is purchased in a pharmacy.

31 The following arguments support the assumption that the prohibition on mail-order sales enacted in the regulation at issue is justified in accordance with Article 36 TFEU:

32 *The Court has on numerous occasions held in connection with national measures coming within the field of public health that health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since that level may vary from one Member State to another, Member States should be allowed a measure of discretion (judgment of 19 October 2016, *Deutsche Parkinson Vereinigung*, C-148/15, EU:C:2016:776, paragraph 30 and the case-law cited). The regulation at issue is intended to implement appropriately the strategies to stop the spread of HIV by 2030 to which Austria is committed in accordance with the United Nations' sustainable development goals. One of the primary objectives of those strategies is to reduce late diagnosis of HIV ('late presenter'). Almost 9 000 people in Austria are currently living with an HIV infection. It is estimated that approximately 9-14% of them are unaware of their HIV status. The antiretroviral treatment of HIV infections used today can bring the viral load below the limit of detection in most cases, at which point the patient is no longer infectious. The earliest possible diagnosis of HIV infection is therefore essential: first, so that treatment can be started promptly and, second, to prevent onward transmission of the HI-virus.

33 *Potential problems with the handling of HIV tests for self-testing can be explained in person by the pharmacist before the test is supplied to the customer.

34 *The personal relationship of trust which is important with such a sensitive issue is more likely to exist between the customer and a pharmacist he or she may in some cases already know, or is, at the very least, easier to establish in a personal conversation.

35 *The customer's reactions and needs can be perceived directly in a pharmacy but may not be noticed to the same degree online.

36 It is entirely possible that prohibitions on mail-order sales of certain categories of products may be justified on the ground of the public interest in the protection of health and consumer protection, for example where the application of the product harbours health risks that can only be mitigated through personal specialist advice or where the product needs to be adjusted individually to the patient's requirements.

37 Overall, therefore, the referring court has doubts as to whether the prohibition enacted in the Regulation of the Federal Minister for Labour, Social Affairs, Health and Consumer Protection on the supply by mail order of HIV tests for self-testing is justified in accordance with Article 36 TFEU. The answer to this question will enable judgment to be given in the main proceedings.

Higher Regional Court, Vienna, 29 July 2020