Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

21 May 2026*

(Reference for a preliminary ruling – Medicinal products for human use – Directive 2001/83/EC – Article 85c(1) and (2) – Non-prescription medicinal products – Prohibition of the sale at a distance to the public, by means of information society services, of a category of non-prescription medicinal products – Protection of public health)

In Case C-604/24,

REQUEST for a preliminary ruling under Article 267 TFEU from the Symvoulio tis Epikrateias (Council of State, Greece), made by decision of 16 July 2024, received at the Court on 16 September 2024, in the proceedings

Farmakeio YZ & Sia OE

v

Ypourgos Anaptyxis kai Ependyseon,

Ypourgos Ygeias,

intervening parties:

Panellinios Farmakeftikos Syllogos,

THE COURT (Fifth Chamber),

composed of M.L. Arastey Sahún, President of the Chamber, J. Passer, E. Regan, D. Gratsias and B. Smulders (Rapporteur), Judges,

Advocate General: M. Szpunar,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Farmakeio YZ & Sia OE, by K. Chrysogonos, dikigoros,

* Language of the case: Greek.

– Panellinios Farmakeftikos Syllogos, by I. Dimitrellos, dikigoros,

– the Greek Government, by K. Georgiadis, V. Karra and K. Konsta, acting as Agents,

– the Italian Government, by S. Fiorentino, acting as Agent, and by E. Cicatelli, procuratore dello Stato, and M. Russo, avvocato dello Stato,

– the European Commission, by M. Konstantinidis, E. Mathieu, A. Spina and J. Szczodrowski, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 18 December 2025,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 85c(1) and (2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 (OJ 2011 L 174, p. 74) ('Directive 2001/83').

2 The request has been made in proceedings between Farmakeio YZ & Sia OE, a company established in Greece, on the one hand, and the Ypourgos Anaptyxis kai Ependyseon (Minister for Development and Investment, Greece) and the Ypourgos Ygeias (Minister for Health, Greece), on the other hand, concerning an action for annulment brought by that company against a ministerial decision defining the categories of medicinal products which may be sold at a distance by certified online pharmacy establishments to the public by means of information society services.

Legal context

European Union law

Directive 2011/62

3 Recitals 21 to 24 of Directive 2011/62 state:

'(21) The illegal sale of medicinal products to the public via the Internet is an important threat to public health as falsified medicinal products may reach the public in this way. It is necessary to address this threat. In doing so, account should be taken of the fact that specific conditions for retail supply of medicinal products to the public have not been harmonised at [EU] level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the [FEU Treaty].

(22) When examining the compatibility with [EU] law of the conditions for the retail supply of medicinal products, the Court of Justice of the European Union ("the Court of Justice") has recognised the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods. The Court of Justice has also held that health and life of humans rank foremost among the assets and interests protected by the [FEU Treaty] and that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved. Since that level may vary from one Member State to another, Member States must be allowed discretion … as regards the conditions for the supply on their territory of medicinal products to the public.

(23) In particular, in the light of the risks to public health and given the power accorded to Member States to determine the level of protection of public health, the case-law of the Court of Justice has recognised that Member States may, in principle, restrict the retail sale of medicinal products to pharmacists alone …

(24) Therefore, and in the light of the case-law of the Court of Justice, Member States should be able to impose conditions justified by the protection of public health upon the retail supply of medicinal products offered for sale at a distance by means of information society services. Such conditions should not unduly restrict the functioning of the internal market.'

Directive 2001/83

4 According to recitals 2 to 5 of Directive 2001/83:

'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

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

(4) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products …, and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.'

5 Under Title VIIA of that directive, entitled 'Sale at a distance to the public', Article 85c(1) and (2) thereof provides:

'1. Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of information society services as defined in Directive 98/34/EC of the European

Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services [OJ 1998 L 204, p. 37], under the following conditions:

(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established;

(b) the person referred to in point (a) has notified the Member State in which that person is established of at least the following information:

…

(c) the medicinal products comply with the national legislation of the Member State of destination in accordance with Article 6(1);

(d) without prejudice to the information requirements set out in Directive 2000/31/EC 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], the website offering the medicinal products contains at least:

…

2. Member States may impose conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services.

…'

Greek law

6 The ypourgiki apofasi G.P. oik. 22609 'Tropopoiisi tou arthrou 116 tis ypo stoicheia D.YG3a/G.P.32221/2013 koinis apofaseos ton Ypourgon Anaptyxis, Antagonistikotitas, Ypodomon, Metaforon kai Diktyon kai Ygeias …' (Ministerial Decision G.P. oik. 22609, 'Amendment of Article 116 of Joint Ministerial Decision D.YG3a/G.P.32221/2013, of the Minister for Development, Competitiveness, Infrastructure, Transport and Networks, and the Minister for Health …'), of 19 April 2022, adopted jointly by the Minister for Development and Investments and the Minister for Health (FEK B' 1965/20.4.2022) ('the ministerial decision'), sets out the categories of medicinal products which may be sold at a distance by certified online pharmacy establishments to the public by means of information society services. Under Article 1 of that ministerial decision, it is stated as follows:

'The sale at a distance to the public of medicinal products subject to medical prescription shall be prohibited. For other medicinal products, sale at a distance to the public by means of information society services is permitted, by online pharmacy establishments that have been certified in that regard by the [Panellinios Farmakeftikos Syllogos (Pharmaceutical Association)], pursuant to [the koini apofasi G5(b)/G.P.oik. 20293 ton Ypourgon Oikonomias, Anaptyxis kai Tourismou kai Ygeias "Orismos armodias Archis gia tin Pistopoiisi ilektronikon katastimaton farmakeion" (Joint Decision G5(b)/G.P. Oik. 20293 of the Minister for the Economy, Development and Tourism and the Minister

for Health, designating the competent authority for the certification of online pharmacy establishments) of 15 March 2016 (FEK B' 787/23.3.2016)], only for medicinal products which, in accordance with their marketing authorisation, are classified as or have been placed in the subcategory of medicinal products for general sale (over-the-counter medicinal products …) within the category of non-prescription medicinal products (NMPs), pursuant to the provisions of [the apofasi G5(a)51194 tou Ypourgou Ygeias (Decision G5(a)51194 of the Minister for Health) of 14 July 2016 (FEK B' 2219/18.7.2016)].

Those infringing those provisions shall be subject to a fine of twenty thousand euro (EUR 20 000) to one hundred thousand euro (EUR 100 000) and, in the event of a repeated offence, of fifty thousand euro (EUR 50 000) to two hundred thousand euro (EUR 200 000), by decision of the Board of Directors of the [Ethnikos Organismos Farmakon (National Organisation for Medicines)].

Those penalties shall be imposed together with any other penalty provided for.'

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

7 The applicant in the main proceedings operates a physical pharmacy in Greece and also sells goods from the pharmacy online, as permitted by national pharmaceutical legislation.

8 On 25 May 2022, the applicant brought an action before the Symvoulio tis Epikrateias (Council of State, Greece), which is the referring court, for annulment of the ministerial decision, which amends the previous national legislation, on the ground that that decision henceforth authorises the sale at a distance by certified online pharmacy establishments to the public by means of information society services of only a subcategory of non-prescription medicinal products, namely over-the-counter medicinal products, to the exclusion of other non-prescription medicinal products. According to the information provided by the referring court, the subcategory of over-the-counter medicinal products includes non-prescription medicinal products which may also be offered at points of sale other than pharmacies, without the presence of a pharmacist or an auxiliary pharmacist being required. Furthermore, it is apparent from the account of the national regulatory framework in force before the adoption of that ministerial decision, as presented by the referring court, that certified online pharmacies were previously authorised to sell to the public, online, without distinction, all non-prescription medicinal products and medicinal products which are not reimbursed by social security bodies.

9 In support of its action, the applicant in the main proceedings submits that the restriction introduced by the ministerial decision as regards the previous national legislation is contrary, inter alia, to Article 85c(1) of Directive 2001/83. Furthermore, according to the applicant, such a measure cannot be justified under Article 85c(2) of that directive on the ground of public health protection. The applicant adds that the new national legislation introduced by the ministerial decision remains, in practice, ineffective since no medicinal product has been classified to date on the Greek market by the competent national authority in the subcategory of over-the-counter medicinal products.

10 The national authorities which adopted the ministerial decision and the Panellinios Farmakeftikos Syllogos (Pharmaceutical Association, Greece) claim, for their part, that the public interest reasons relating to public health protection required the adoption of that new national legislation, in accordance with Article 85c(2) of Directive 2001/83. They submit, in particular, that the right, provided for in the previous national regime, of online pharmacies to sell, without distinction, all non-prescription medicinal products and non-reimbursed medicinal products had

the effect of making more than 1 000 types of medicinal products available on the internet, which makes it more difficult to monitor overmedication, that is to say, the excessive consumption of medicinal products, and to combat the trafficking of counterfeit or non-compliant medicinal products. The online sale of medicinal products, including non-prescription medicinal products, poses risks to public health since it essentially deprives the pharmacist of the possibility to identify the end user. According to the national authorities and the Pharmaceutical Association, the ministerial decision also limits interference with the 'guarantee of safety' that comes with a pharmacist manually dispensing medicinal products, since that risk does not exist in relation to over-the-counter medicinal products on account of their particular characteristics. Furthermore, the provision, by online pharmacies, of all non-prescription medicinal products and non-reimbursed medicinal products does not meet any particular need in Greece in view of the excellent and rational geographical distribution of pharmacies on national territory. Lastly, in support of its arguments, the Pharmaceutical Association relies on the legislation in force in Cyprus and Portugal, which, it submits, restricts the supply of non-prescription medicinal products online.

11 The referring court considers that the question whether EU law precludes national legislation which authorises the online sale at a distance to the public of only a subcategory of non-prescription medicinal products must be assessed, inter alia, in the light of the judgments of 11 December 2003, *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664), and of 29 February 2024, *Doctipharma* (C-606/21, EU:C:2024:179). The referring court concludes from that case-law that Article 85c(1) of Directive 2001/83 cannot be interpreted as allowing the national legislature to prohibit the online sale of non-prescription medicinal products. Accordingly, it considers that the ministerial decision should be annulled.

12 However, in the absence of unequivocal case-law from the Court in that connection and taking into account the arguments of the Pharmaceutical Association based on the relevant Cypriot and Portuguese legislation, the referring court asks whether Article 85c(2) of that directive should be interpreted as meaning that Member States are permitted to prohibit, on grounds of public health protection, sales at a distance to the public of certain medicinal products not subject to medical prescription, by means of information society services.

13 In those circumstances, the Symvoulio tis Epikrateias (Council of State) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Must Article 85c(1) of Directive [2001/83] be interpreted as precluding a national provision which permits the sale at a distance to the public by means of information society services, by [online] pharmacy establishments, not of all non-prescription medicinal products …, but of one subcategory only thereof (in the present case, [over-the-counter] medicinal products …)?

(2) Or, on the contrary, does Article 85c(2) of Directive [2001/83] permit the national legislature to prohibit sales at a distance to the public by means of information society services, by [online] pharmacy establishments, of certain medicinal products not subject to medical prescription, on grounds of public health protection?

(3) If the answer to [the second question] is in the affirmative, are the grounds relied on in the present case by the Greek [Government] and the Panhellenic Pharmaceutical Association to justify the restriction in question (combating overmedication and the trafficking of counterfeit or inappropriate medicinal products, and so forth) grounds of public health protection within the meaning of Article 85c(2) of Directive [2001/83]?

(4) If the answer to [the third question] is in the affirmative, is the national court to review the proportionality of the restrictive measure by carrying out negative screening, that is to say, is it to assess only whether the restriction appears to be manifestly inappropriate or manifestly unnecessary, or, conversely, is the court to carry out positive screening, that is to say, is it to assess whether the restriction appears to be an appropriate and strictly necessary measure for public health protection?'

Consideration of the questions referred

The first and second questions

14 By its first and second questions, which it is appropriate to examine together, the referring court asks, in essence, whether Article 85c(1) and (2) of Directive 2001/83 must be interpreted as precluding national legislation which, on grounds of public health protection, prohibits the sale at a distance to the public, by online pharmacy establishments using information society services, of non-prescription medicinal products, with the exception of a subcategory thereof.

15 In that connection, it should be borne in mind that Article 85c(1) of Directive 2001/83 provides that 'without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of information society services … under the … conditions [set out in points (a) to (d) of paragraph 1]'.

16 It is apparent from the second part of that provision that Member States are required to ensure that 'medicinal products' are offered for sale at a distance to the public by means of information society services. The general nature of that wording and the use of the definite article in certain linguistic versions, such as the Spanish-, Greek-, French-, Italian- and Portuguese-language versions, indicates that the obligation thereby imposed on Member States covers all medicinal products. That second part of the provision offers no reason to believe that the intention of the EU legislature was to distinguish between possible categories of medical products.

17 However, the first part of that provision allows an exception to that obligation inasmuch as the sale at a distance to the public of prescription medicinal products may be prohibited under national legislation (see, to that effect, judgment of 27 February 2025, *Apothekerkammer Nordrhein*, C-517/23, EU:C:2025:122, paragraph 74).

18 It therefore follows from the wording of Article 85c(1) of Directive 2001/83 that the obligation provided for therein relates to the offer for sale at a distance to the public, by means of information society services, of all non-prescription medicinal products (see, to that effect, judgment of 29 February 2024, *Doctipharma*, C-606/21, EU:C:2024:179, paragraph 41).

19 It follows that national legislation that prohibits the sale at a distance to the public, by means of information society services, of non-prescription medicinal products, with the exception of a subcategory thereof, fails to fulfil the obligation arising from Article 85c(1) of Directive 2001/83.

20 Such national legislation cannot, moreover, be based on Article 85c(2) of that directive, under which Member States may impose conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services.

21 While, on account of the use of the term 'condition' in both paragraphs 1 and 2 of Article 85c of that directive, it can be considered that Member States may make the sale at a distance to the public of all non-prescription medicinal products subject to conditions additional to those expressly listed in points (a) to (d) of Article 85c(1), it should be noted that national legislation prohibiting the offer for sale online to the public of non-prescription medicinal products, with the exception of a subcategory thereof, such as the national legislation at issue in the main proceedings, cannot be classified as a 'condition' for the retail supply of medicinal products within the meaning of Article 85c(2) of that directive.

22 Such legislation only partially authorises the offer for sale at a distance to the public by means of information society services of non-prescription medicinal products. The conditions referred to in Article 85c(2) of Directive 2001/83 cannot have the effect of rendering meaningless the obligation on Member States, under Article 85c(1), to ensure that medicinal products, at least all non-prescription medicinal products, are offered for sale at a distance to the public, by means of information society services, in compliance with the conditions set out by that provision (see, to that effect, judgment of 29 February 2024, *Doctipharma*, C-606/21, EU:C:2024:179, paragraphs 55 and 56).

23 That interpretation is supported both by the origin of Article 85c of Directive 2001/83 and by the objectives pursued by that directive.

24 In the first place, as regards that origin, it should be noted that Directive 2011/62 inserted, within Directive 2001/83, Title VIIA, entitled 'Sale at a distance to the public', which includes, inter alia, Article 85c of that directive.

25 It follows from recital 24 of Directive 2011/62, in the light of which Article 85c(1) and (2) of Directive 2001/83 must be interpreted, that, while Member States must be able to impose conditions justified on grounds of public health protection in relation to the retail supply of medicinal products offered for sale at a distance by means of information society services, those conditions cannot however unduly restrict the functioning of the internal market. As the Advocate General noted, in essence, in point 35 of his Opinion, such a restriction could occur if the scope of the obligation to authorise the online sale of non-prescription medicinal products were unilaterally called into question by a Member State.

26 In that context, it should be noted that, in paragraphs 76 and 124 of its judgment of 11 December 2003, *Deutscher Apothekerverband* (C-322/01, EU:C:2003:664), the Court classified the prohibition provided for by national legislation on the sale of medicinal products by mail order, in that case via the internet, as a 'measure having an effect equivalent to' a quantitative restriction on imports within the meaning of Article 28 EC, now Article 34 TFEU. It also held that, while such a measure could be justified on grounds of public health protection, referred to in Article 30 EC, now Article 36 TFEU, in so far as it relates to prescription medicinal products, that article could not be relied on to justify an absolute prohibition on the sale by mail order of non-prescription medicinal products in the Member State concerned.

27 It is apparent that the EU legislature intended to take into account, when adopting Article 85c(1) of Directive 2001/83, the case-law of the Court relating to the online marketing of medicinal products. By that provision, the EU legislature further limited the discretion conferred on Member States in the area, by introducing the obligation to offer all non-prescription medicinal products for sale at a distance to the public, by means of information society services.

28 It follows that Member States cannot rely on Article 85c(2) of Directive 2001/83 in order to impose conditions justified on grounds of public health protection as concerns the retail supply on their territory of non-prescription medicinal products offered for sale at a distance to the public by means of information society services, where such conditions have the effect of depriving the obligation set out in Article 85c(1) of its effectiveness.

29 In the second place, as regards the objectives pursued by Directive 2001/83, it follows from recital 2 of that directive that it is aimed at safeguarding public health, inter alia, through combating the illegal sale of medicinal products to the public by means of the internet, as set out in recital 21 of Directive 2011/62. However, as is apparent from recital 3 of Directive 2001/83, that objective of public health protection must be attained without hindering the trade in medicinal products within the European Union.

30 From that perspective, Article 85c(1) of Directive 2001/83 requires that Member States authorise the sale at a distance to the public, by means of information society services, of all non-prescription medicinal products. In the context of the objective of public health protection and while taking into account the judgment of 19 May 2009, *Apothekerkammer des Saarlandes and Others* (C-171/07 and C-172/07, EU:C:2009:316), cited, as a footnote, in recitals 22 and 23 of Directive 2011/62, by which the Court recognised that Member States have the power to determine the level of public health protection, that provision establishes, in points (a) to (d) thereof, the conditions relating to persons, medicinal products and websites to which the sale at a distance to the public of medicinal products by means of information society services is subject. In that connection, that provision reserves to the Member States, in accordance with that case-law, the power to determine the requirements which must be met by those persons.

31 It follows that, as the Advocate General noted in point 20 of his Opinion, where the conditions provided for in Article 85c(1) of Directive 2001/83 are satisfied, a Member State cannot prohibit the offer for sale at a distance to the public, by means of an information society service, of non-prescription medicinal products.

32 Accordingly, while it is true that Article 85c(2) of that directive allows Member States to impose, on grounds of public health protection, conditions relating to the retail supply on their territory of medicinal products offered for sale at a distance to the public by means of information society services, a ‘condition’ within the meaning of that provision cannot, however, be interpreted as allowing Member States to establish, on such grounds, a prohibition on the offer for sale at a distance to the public, by means of such services, of non-prescription medicinal products, with the exception of a subcategory thereof, since such a prohibition would have the consequence of compromising the objectives pursued by that directive, by depriving Article 85c(1) thereof of its effectiveness.

33 Accordingly, since the conditions referred to in Article 85c(2) of Directive 2001/83 cannot affect the scope of the obligation defined in Article 85c(1) of that directive, or the conditions set out in points (a) to (d) of that provision, the power conferred on Member States to determine the content of the ‘conditions, justified on grounds of public health protection, for the retail supply’,

within the meaning of Article 85c(2), is necessarily limited inasmuch as it can deal only with how those medicinal products are marketed to the public, that is to say, the conditions relating to the activities carried out with a view to the retail supply of those medicinal products on their territory.

34 Those conditions, which must be justified on grounds of public health protection, may apply to measures aimed at reducing the risks associated with the online sale of medicinal products. As the applicant in the main proceedings suggests, those conditions could consist, for example, of putting in place effective mechanisms to monitor the consumption of medicinal products, such as establishing order limits per consumer or the creation of an online system for identification and registration of consumer health data in order to combat overmedication.

35 In that context, it cannot be ruled out that Member States may make a specific category of non-prescription medicinal products subject to such conditions, for example, on account of their particular therapeutic characteristics, in so far as those conditions do not call into question the possibility of offering those medicinal products for such sale, as is apparent from Article 85c(1) of Directive 2001/83.

36 In the light of all the foregoing considerations, the answer to the first and second questions is that Article 85c(1) and (2) of Directive 2001/83 must be interpreted as precluding national legislation that, on grounds of public health protection, prohibits the sale at a distance to the public, by online pharmacy establishments using information society services, of non-prescription medicinal products, with the exception of a subcategory thereof.

The third and fourth questions

37 In view of the answer given to the first and second questions, there is no need to answer the third and fourth questions.

Costs

38 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fifth Chamber) hereby rules:

Article 85c(1) and (2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011,

must be interpreted as precluding national legislation that, on grounds of public health protection, prohibits the sale at a distance to the public, by online pharmacy establishments using information society services, of non-prescription medicinal products, with the exception of a subcategory thereof.

[Signatures]