

CJEU Rules that EU Member States Cannot Restrict Online Sale of Non-Prescription Medicinal Products to Single Subcategory on Public Health Grounds

On 21 May 2026, the Court of Justice of the European Union (the **CJEU**) ruled that national legislation which prohibits the sale at a distance to the public by online pharmacy establishments of non-prescription medicinal products (**NMPs**) – with the exception of a single subcategory – is incompatible with Article 85c(1) and (2) of Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (**Directive 2001/83/EC**) (CJEU, 21 May 2026, Case C-604/24, *Farmakeio YZ & Sia*, EU:C:2026:418 – the **Judgment**, available [here](#)).

Article 85c(1) of Directive 2001/83/EC (**Article 85c(1)**) requires EU Member States to ensure that medicinal products – other than prescription medicinal products, the online offer for sale of which may be prohibited – are offered for sale at a distance to the public by means of information society services, in compliance with the conditions set out by Article 85c(1). Article 85c(2) of Directive 2001/83/EC (**Article 85c(2)**) permits EU Member States to impose conditions on such sales, provided that they are justified on public health grounds.

Background and Facts

The applicant, Farmakeio YZ & Sia OE, is a Greek company operating both a physical pharmacy and an online sales channel. In April 2022, the Greek Ministers for Development and Investment and for Health adopted Ministerial Decision G.P. oik. 22609, which narrowed the previously unrestricted authorisation to sell all NMPs online to a single subcategory: over-the-counter (**OTC**) medicinal products classifiable as such under their marketing authorisation and available for sale outside pharmacies, without the presence of a pharmacist or an auxiliary pharmacist being required (the **Decision**). The measure amounted in practice to a ban of online sales of NMPs because no product had been classified in the OTC subcategory on the Greek market.

The applicant challenged the Decision before the Greek Council of State (*Symvoulío tis Epikrateias*), which stayed the proceedings and referred four questions to the CJEU. Those questions asked, in essence: (i) whether Article 85c(1) precludes national legislation which permits sales by online pharmacy establishments only of OTC products, to the exclusion of other NMPs; (ii) or, conversely, whether Article 85c(2) permits an EU Member State to prohibit the online sale of certain NMPs on public health grounds; (iii) if so, whether the grounds relied on by the Greek authorities – combating overmedication and the trafficking of counterfeit or inappropriate medicinal products – fall within the meaning of public health protection under Article 85c(2); and (iv) if so, whether the applicable standard of judicial review is negative (manifest inappropriateness or manifest unreasonableness) or positive (appropriate and strictly necessary measure).

CJEU Judgment

The CJEU examined the first and second questions together, as two sides of the same issue, and given the conclusions it reached on those questions, declined to answer the third and fourth questions.

The CJEU held that the general wording of Article 85c(1) – reinforced by the use of the definite article in multiple linguistic versions – makes clear that the obligation for EU Member States to ensure the online availability of NMPs extends to all NMPs. The only limitation in Article 85c(1) concerns prescription medicinal products. National legislation authorising online sales of only a subcategory of NMPs, in this case OTC products, is therefore incompatible with Article 85c(1) (*see also*, CJEU, 29 February 2024, Case C-606/21, *Doctipharma*, EU:C:2024:179, paragraph 41).

Moreover, the CJEU rejected the argument that the restriction could be justified as a "condition" under Article 85c(2). Legislation that only partially authorises online sales of NMPs cannot be classified as a condition for their retail supply. To hold otherwise would deprive Article 85c(1) of its effectiveness (*see, Doctipharma*, paragraphs 55–56). Recital 24 of Directive 2011/62/EU, which inserted Article 85c(1) and (2) in Directive 2001/83/EC, confirms that EU Member State conditions must not unduly restrict the functioning of the internal market. The CJEU further observed that in *Deutscher Apothekerverband* (CJEU, 11 December 2003, Case C-322/01, EU:C:2003:664), it had already held that an absolute prohibition on the online sale of NMPs could not be justified on public health grounds.

The CJEU additionally clarified that Article 85c(2) is limited to conditions governing the terms of online sales – for example, per-consumer order limits or consumer identification mechanisms to combat overmedication – and does not permit the exclusion of entire product categories from the obligation contained in Article 85c(1).

Assessment

The Judgment is the latest in a developing line of CJEU authority – following *Deutscher Apothekerverband* (2003) and *Doctipharma* (2024) – that progressively restricts Member States' ability to curtail the online sale of NMPs. The Judgment makes clear that Article 85c(1) creates an inviolable floor: all NMPs must be available through certified online pharmacies, and Article 85c(2) cannot be used to circumvent that obligation, however genuine the underlying public health concerns.

Of immediate practical significance is the CJEU's guidance on permissible Article 85c(2) conditions. Member States retain meaningful regulatory space to address risks of overmedication or counterfeit products, but must do so through positive and targeted interventions – such as order limits or digital health registration systems – rather than by restricting access to product categories. Any existing national measure limiting online NMP sales to a defined subset of products should now be considered presumptively incompatible with EU law and open to challenge before national courts.

The CJEU's refusal to engage with the substantive public health justifications advanced by Greece – treating the matter as resolved at the threshold stage – signals that no case-by-case balancing exercise is available to Member States once a measure is found to deprive Article 85c(1) of its effectiveness. Online pharmacies across the EU should take note of this ruling when assessing the compatibility of the regulatory frameworks in which they operate. This advice will remain valid after the entry into force of the pharmaceutical package (*see*, Van Bael & Bellis Life Sciences News & Insights of [6 March 2026](#) and [20](#)

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[May 2026](#)), as Articles 172(1) and (2) of the proposed Directive on the Union code relating to medicinal products for human use reproduce in near-identical terms the wording of Articles 85c(1) and (2).

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