Borderline products and the precedence of medicinal product legislation

Recently the Court of Justice of the European Union handed down a judgment interpreting the rule of precedence laid down in Article 2(2) of Directive 2001/83/EC, systematising and elaborating on a number of aspects that it had already addressed in previous rulings. It is the Judgment of the Court (Ninth Chamber) of 4 September 2025, *Kwizda Pharma II*, C-451/24 (ECLI:EU:C:2025:663).

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1. The precedence of medicinal product legislation

1.1. European Union law uses a dual criterion to define the legal concept of a *medicinal product*, according to which there are medicinal products by presentation or by function. Thus, in the current wording of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Art. 1(2)), a *medicinal product* is defined as "*a*) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or *b*) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or

modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis".

The Court of Justice has repeatedly stated[1] that the concept of *medicinal product by function* covers all products intended to restore, correct or modify physiological functions and which, therefore, may have consequences for health in general, whether they are products having properties for treating or preventing disease or products that alter physiological functions without there being any disease. If the substance has these properties, it is irrelevant that it is not presented as such a medicinal product, since, even if the product does not fall within the definition of a medicinal product by presentation, it would be a medicinal product by function. On that basis, in order to determine whether a product falls within the definition of a *medicinal product by function*, the national authorities, under the supervision of the courts, must decide on a case-by-case basis, taking into account all the characteristics of the product, including its composition, its pharmacological, immunological or metabolic properties (to the extent that these can be determined in the current state of scientific knowledge), its method of administration, the extent of its dissemination, consumer awareness of it, and the risks associated with its use.

For its part, a product is considered a *medicinal product by presentation* when it is presented as having properties for the treatment or prevention of human diseases. The classification as a medicinal product of products presented as such, regardless of whether or not they have therapeutic effects, is intended to protect consumers. For this reason, the Court of Justice maintains that this criterion must be interpreted broadly[2], so that all products presented as medicinal products are subject to the strict controls and requirements applicable to medicinal products.

In this regard, an express statement, description or recommendation is not essential for a product to be considered a medicinal product by presentation. On the contrary, it is sufficient for there to be an indirect presentation as a medicinal product. What is relevant is that the average consumer may obtain the impression that the product has properties suitable for the treatment or prevention of diseases. According to the Court of Justice, a product is presented as a medicinal product whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in

[1] See, among the most recent, its judgment of 13 October 2022 (*M2Beauté Cosmetics*, C-616/20, ECLI:EU:C:2022:781) and its judgment of 27 October 2022 (*Orthomol*, C-418/21, ECLI:EU:C:2022:831).

[2] See, for example, the Judgment of 21 March 1991, *Jean Monteil and Samanni*, C-60/89, ECLI:EU:C:1991:138, paragraph 23.

question should, having regard to its presentation, have the aforementioned properties for treating or preventing disease[3].

1.2 Having set out these criteria for defining the legal concept of a medicine, Article 2(2) of Directive 2001/83/EC provides that in "cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply". With such provision, introduced by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC, the European legislator - as expressly recognised in the seventh recital of Directive 2004/27/EC — sought to provide clarity in relation to so-called "borderline" products between the medicinal product sector and other sectors, such as food, food supplements, medical devices, biocides or cosmetics.

Recently, the Court of Justice handed down a judgment interpreting this precedence clause, systematising and elaborating on a number of aspects that it had already addressed in previous rulings. It is the Judgment of the Court (Ninth Chamber) of 4 September 2025, *Kwizda Pharma II,* C451/24, ECLI:EU:C:2025:663.

2. The interpretative guidelines set out in the Court of Justice judgment of 4 September 2025

2.1. The Court of Justice emphasises that the rule of precedence referred to above is based on public health considerations, "by reason of the higher requirements that EU law relating to medicinal products provides for the placing of medicinal products on the market".

On that basis, the Court of Justice clarifies that the application of the aforementioned rule of precedence requires two conditions to be met. Firstly, a given product must fall within the legal definition of a *medicinal product,* whether it is a medicinal product by function or by presentation. Secondly, there must be doubts as to whether it also falls within the legal concept of other types of products (food supplements, cosmetics, etc.), as expressly provided for in Article 2(2) of Directive 2001/83/EC.

2.2. In accordance with the above, the provision does not apply when it is abundantly clear that a given product does not fall within the legal definition of those other regulated products. Therefore, the Court of Justice states (paragraph 67 of the judgment) that:

> [...] in a situation such as that described by the referring court, where there is no doubt that the

[3] See, among the most recent, the Judgment of 19 January 2023, *Bundesrepublik Deutschland (Nasal drops),* C495/21 and C496/21, EU:C:2023:34, paragraphs 45 and 46.

products concerned, first, are medicinal products by presentation and, second, are not food for special medical purposes, the rule of precedence laid down in Article 2(2) of Directive 2001/83 as amended is irrelevant. That directive is applicable to those products by reason solely of the fact they are clearly medicinal products by presentation and therefore fall within the scope of that directive.

Where a product comes clearly under the definition of other product categories, medicinal product legislation does not apply

Similarly, Article 2(2) of Directive 2001/83/EC does not apply either when there is no doubt, because it is clear that the product in question fits the legal definition of those other regulated products. In fact, recital 7 of Directive 2004/27/EC, amending Directive 2001/83/EC, already states that where "a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics, this Directive should not apply".

In the same vein, the Court of Justice emphasises (paragraph 65) that "several instruments of EU law relating to those other categories of regulated products contain rules which exclude medicinal products from their respective scope". This is the case, for example, with Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (Article 2(3)(d)); Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (Article 1(2)), or Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products (recital 6).

Finally, the Court of Justice concludes (paragraph 83) that it is not possible for a given product to be considered both a medicinal product and another type of regulated product, because "a product which is unequivocally a medicinal product must be subject only to the rules relating to medicinal products" and, consequently, "a product may be covered by other legislation only if it is not considered to be a medicinal product".

2.3. Having established the above guidelines for interpretation, the Court of Justice examines whether, in cases where a national authority responsible for authorising the marketing of a type of regulated product other than medicinal products refuses to grant authorisation (on the grounds that the product in question does not fall within the legal definition of that regulated

product, but is a medicinal product), it may prohibit its marketing.

According to the Court, it is for national law to determine whether the authority responsible for authorising the marketing of medicinal products must be the same as the authority responsible for authorising those other products. On that basis, there may be different national authorities or agencies depending on the type of product. That being the case, "if an administrative authority of a Member State, which does not have jurisdiction to apply the legislation on medicinal products, considers that a product which is the subject of a procedure before it is a medicinal product which was placed on the market without having the authorisation required by that legislation, it must immediately inform the competent authority thereof", because only "in that way can that competent authority take the necessary measures as quickly as possible to guarantee the protection of public health" (para. 84).

Furthermore, "where the administrative authority which is not competent to enforce the legislation on medicinal products has not considered that the product which is the subject of the proceedings before it could be a medicinal product, but the court before which its decision is challenged reaches such a conclusion, it is for the legal system of the Member State concerned to establish whether that administrative authority, following the annulment of its decision on the ground of lack of competence, must inform the competent authority, or whether that court may itself inform it" (para. 86).