



# Capsulas

## Ratification of the principle of primacy of application of the legal regime on medicinal products

*Judgment of the Court of Justice of the European Union of 19 January 2023 in cases C-495/21 and C-496/21*

### Background

On 19 January 2023, the Court of Justice of the European Union (CJEU) issued a new judgement answering some questions on the definitions of medicinal product and medical device, at the request of the German Supreme Administrative Court.

The case concerned two products (nasal drops and nasal spray) marketed in Germany as medical devices. In both cases, the German health authorities declared that they should have the regulatory status of medicinal products and therefore require an administrative authorisation for their marketing.

In particular, they stated that both products met the definition of a medicinal product both “by function” (in both cases the effect on the symptoms of nasal congestion was achieved by a pharmacological action) and “by presentation” (the products were presented in such a way that a “reasonably well-informed and observant” consumer could associate them with medicinal products).

The marketing companies appealed the administrative decisions before the referring courts. Their arguments were initially rejected, and, in the context of these proceedings, four questions were referred to the CJEU for a preliminary ruling. These questions raise doubts as to the scope of European legislation on medical devices and medicinal products for human use, in particular as regards:

- the definition of a medicinal product (medicinal product by function vs. medicinal product by presentation);
- the priority of application of the status of medicinal product (primacy of application) to products which meet both the definition of a medicinal product and the definition of other products.

### Definition of medicinal product: primacy of application of the legal regime applicable to medicinal products also in medicinal products “by presentation”

According to Directive 2001/83/EC, a product is a medicinal product if it achieves its intended effect through pharmacological, immunological or metabolic action (medicinal product by function) or if it presents itself as having therapeutic properties characteristic of medicinal products (medicinal product presentation).

However, even if it may seem more robust to consider a medicinal product “by function” than “by presentation”, the CJEU considers that the primacy of application of the legal regime applicable to medicinal products applies equally to those “by presentation”. This is because the legislator’s intention is to reconcile the requirements of legal certainty for economic operators with those of quality, safety and efficacy of these products.

In this respect, the Court states that where the principal mode of action of a product has not



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been scientifically proven (i.e., it has not been possible to determine whether the principal mode of action of the product is pharmacological, immunological or metabolic), it cannot be classified as “medical device”, or meet the definition of “medicinal product by function”. It will be for the national courts to assess, on a case-by-case basis, whether the conditions relating to the definition of the concept of “medicinal product by presentation” are satisfied.

A medicinal product “by presentation” is qualified as such when the product is presented for treating or preventing disease whenever any averagely well-informed consumer gains the impression, that the product in question should have the properties concerned. This formal aspect does not only relate to the external form of a product itself. According to the Court of Justice, attention must also be paid to its packaging, references to interactions with other medicinal products and side effects, or even to the fact that the product is distributed exclusively in pharmacies. All of these elements, when taken together, are likely to lead the average consumer to consider the product as a “medicinal product” and are, therefore, relevant elements when classifying a borderline product.

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