The classification as a "medical device" in a Member State is not an obstacle for it to be reclassified as a "medicinal product"

Judgment of the Court of Justice of the European Union (ECJ), of 3 October 2013, in case C-109/12

Background

In 2008, the Finnish healthcare authority in Finland decided to reclassify "Gynocaps" (vaginal capsule containing live lactobacilli and that is intended to restore balance to bacterial flora in the vagina) as a "medicinal product". Until then, such product had been marketed in Finland as "medical device" bearing a CE marking. The Finnish authority based its decision on the fact that a similar product was being marketed in Finland as a "medicinal product". It also took into account the fact that the European Medicines Agency (EMA) has considered that a gynaecologic tampon containing live lactobaccili satisfied the conditions to be classified as "medicinal product" on the basis of its intended use and effects.

Subsequently, the decision of the Finnish authority was notified to the European Commission because it believed that until then the CE marking had been wrongly affixed. The manufacturer of Gynocaps challenged such decision claiming that the action performed by Gynocaps has no pharmacological effect and therefore it should not be classified as a "medicinal product", in accordance with the definition established in Directive 2001/83.

Position of the ECJ

The Supreme Administrative Court of Finland, before which the appeal was heard, decided to stay the proceedings and to refer three questions to the ECJ.

In its judgment, the ECJ decided as follows:

1. The classification as a "medical device" in one Member State does not preclude the competent national authorities of another Member State from classifying the product concerned as a "medicinal product", on the basis of its pharmacological, immunological or metabolic effects. The classification of a product as a "medicinal product" falls within the competence of national authorities after a case-by-case analysis.

2. National authorities that intend to reclassify as a "medicinal product" a product that is being marketed as a "medical device" must previously apply the procedure of "wrongly affixed CE marking" and, in case it is compromising the health and/or the safety of the persons, they must follow the "safeguard clause" procedure according to the provisions of Directive 93/42.

3. Finally, the ECJ highlights that in cases of doubt regarding whether to classify a product as a "medicinal product" or as a "medical device", the *vis atractiva* of the classification as "medicinal product" must prevail according to article 2.2 of Directive 2001/83.

Likewise, the ECJ declares that, in principle, within the same Member State a product cannot be marketed as a "medical device" when there is another one classified as a "medicinal product" if they both have in common an identical substance and the same mode of action, even if they are not strictly identical.