Construction of the principle of mutual recognition in the marketing of food supplements

Judgment of the National High Court of 22 November 2021

Background

This judgement was published on 26 January. It resolves an appeal lodged against a decision of the Spanish Medicines Agency (AEMPS) that declared, in June 2019, that a product being marketed as a food supplement in Spain should be classified as a medicinal product.

The appellant relied on the principle of mutual recognition. The product was lawfully marketed in Portugal as a food supplement, which would allow it to be marketed in Spain.

On the application of the principle of mutual recognition

This judgment upholds the decision of the AEMPS regarding the prohibition to market the product. Although this decision is based on various merits, the rationale regarding the application of the principle of mutual recognition is nonetheless striking.

According to this principle, a Member State may not prohibit the sale of products that are legally marketed in another Member State, even if they have been produced according to different technical standards. States must clearly justify the grounds for restricting or refusing market access on the basis of "overriding reasons relating to the public interest". A restriction to market access may only be justified on reasons of public interest if there are legitimate differences between the technical rules across States.

This judgment denies the application of the principle of mutual recognition by arguing that, pursuant to article 2(2) of Regulation 764/2008 (which is incorrectly quoted, as it was repealed by Regulation 2019/515), a State may prohibit marketing a product that is legally marketed in another Member State on the basis of a technical rule "that prohibits marketing a product in Spanish territory". The judgment considers article 9(1) of RDL 1/2015 as a technical rule, whereby a marketing authorisation must be held for all medicinal products.

This interpretation, according to which RDL 1/2015 is a "technical rule" for the purposes of the application of Regulation 2019/515, is extraordinarily broad and allows the principle of mutual recognition to be artificially circumvented. In fact, Regulation 2019/515 states that prior authorisation procedures do not constitute technical rules and recalls that technical provisions are those covering aspects that have not been harmonised at Union level. This is clearly not the case of marketing authorisation requirements for medicinal products, which are set out in Directive 2001/83/EC.