



The price of medicinal products in Europe cannot be used to reduce their prices in Spain

Judgment of the Supreme Court of 28 October 2015 annulling the Second Additional Provision of Royal Decree 177/2014

Background

In 2014, with the enactment of Royal Decree 177/2014 regulating the reference pricing system and homogenous groups of medicinal products within the Spanish Health System, it was established that reference prices could not fall beneath the minimum threshold of €1.60. The regulation also stipulated that, in some instances, the reference price could not be different from the cost of medicinal products with the lowest cost of treatment/day, but that a weighted average would be employed. However, the Second Additional Provision of the Royal Decree stated that if any such medicinal product was sold in any EU country at a lower price than in Spain, the government could reduce the Spanish price to match the European price.

The judgment in question, rendered in proceedings brought by Farmaindustria (Spanish Business Association of the Pharmaceuticals Industry), annuls the aforementioned Second Additional Provision.

Using European prices as a reference

Before the passing of Royal Decree-Law 16/2012, the law allowed the Ministry of Health, when fixing the price for drugs, to consider "the prices of medicinal products in European Union Member States that, without being subject to exceptional or transitional measures in terms of intellectual property, would have implemented the corresponding EU legislation in their respective legal systems".

This criterion was no longer foreseen in the law after the entry into force of Royal Decree-Law 16/2012. Specifically, it is the inapplicability of this criterion that has resulted in the Supreme Court cancelling the Second Additional Provision in question. In Spain, pursuant to this ruling, prices charged in other European countries can no longer be taken into account given that this is not an objective criterion provided for by the law.

Furthermore, the judgment adds that "it would be inappropriate to arithmetically transfer the wholesale price at which the product is sold in any EU Member State to the Spanish system without exhaustively assessing the circumstances or specific features of the different countries involved and without considering parameters such as per capita income, the characteristics of the corresponding public health system and possible fluctuations in currencies, which are by no means trivial aspects".

Requests for Information

On the same grounds, as part of the procedures to request the initial price or an increase in price, the administration cannot ask for information regarding the prices charged in other European countries to be provided, much less extend the deadline for providing an answer in order to seek this type of information.