



The Supreme Court dismisses the automatic review of reference prices

Supreme Court judgments of 10 and 11 November 2015, on Royal Decree 177/2014 on reference prices and homogeneous groups

Background

In 2014 the Spanish federation of wholesaler associations (FEDIFAR) challenged Royal Decree 177/2014, alleging that it failed to contemplate controls to guarantee the supply of lower-priced medicinal products, and that it would affect its commercial margin by not providing for sufficient periods of price coexistence. A second appeal from the Pharmacists Business Federation (FEFE) added that the model produced monthly price variations that were incompatible with the foreseeability that is needed to conduct a business. FEFE also alleged that the determination of prices by means of the defined daily dose criterion and their automatic review according to the prices approved in other countries lacked the necessary legal coverage.

Dismissed reasons for appeal

Both appeals were dismissed by the Spanish National High Court, so the federations took their appeal to the Supreme Court. On appeal, the Supreme Court dismissed most of the reasons in the understanding that the law does not contemplate controls in relation to the products with a lower price, so no regulatory omission is produced, and that failure to supply the market is already penalised as a very serious breach. Nor does it consider that the freedom to conduct a business or the right of wholesalers to a commercial margin is affected, insofar as the regulation does not impose monthly price variations, but rather these are

the consequence of voluntary decisions by the operators, and that the times of coexistence foreseen in the law allow the stock to be reasonably managed, and that there are provisions that regulate returns of medicinal products. Nor does it appreciate any breach of the principle of requirement of law in applying the criterion of "defined daily dose" as this is neither prohibited by law nor a "subjective" parameter, at least in its view.

Second Additional Provision of the Royal Decree

The allegations against the automatic system for reviewing reference prices based on the existence of a lower price in the EU were more successful. The Supreme Court maintains the criterion already indicated in a previous judgment and annuls this mechanism as not being provided in law and as contravening the principle that the decisions on prices must always be duly substantiated and taken in accordance with objective criteria. The court understands that it is entirely inappropriate to "automatically arithmetically transfer" the price approved in another country to our system "without bearing in mind the specific characteristics of the country in questions such as per capita income, the characteristics of the public health system or the exchange rate fluctuations". Therefore it does admit this reason and annuls and leaves without effect the requirements of the second additional Provision of the Royal Decree.