How the reference price system may apply for products with the same active ingredient but different potency

Judgement of the Supreme Court of 27 October 2021

Background

We are approaching the 25th anniversary of the reference pricing system (RPS), which was first introduced in Spain by Law no. 13/1996. Hindsight allows us to draw one conclusion, among others: while the RPS has proved to be a useful tool to control pharmaceutical expenditure and ensure sustainability of the public healthcare system, applying automatic and purely mathematical mechanisms has often had negative effects on all operators, including the Ministry of Health (see Report no. 1891/2018 of the State Attorney's Office on the legal viability of solutions aimed at avoiding the withdrawal of essential medicines), the industry and, mostly importantly, patients. It is vital and urgent to reform Royal Decree no. 177/2014, which regulates the RPS. This should be a top priority.

Undertaking a regulatory reform requires having clear goals to guide and inspire the negotiations and the technical work involving drafting the final text. In this particular case, one of these goals should be to avoid automatic mechanisms as much as possible and to introduce mechanisms that may differentiate medicines in view of their differential characteristics.

In order to allow for adequate comparison of costs between elements of a reference group and to set the reference price, consistency across the products included in a reference group must be ensured. Without consistency, the RPS collapses. This is why automatic systems that treat different cases as "equals" should be reviewed. The judgment under analysis clearly reflects this approach.

The Judgement of the Supreme Court

The matter that is settled in this judgement is, essentially, whether the fact that a medicine included in a group is not equipotent to the rest of the products included in the same group (i.e., its efficacy is equal or greater with fewer quantity of active substance) must be considered when setting the defined daily dose. The Court's answer is clear: "*in the case of medicinal products that are not equipotent with respect to other medicinal products included in the same reference group, their efficacy will be taken into account to determine the defined daily doses*".

Conclusion

In our opinion, this judgment sets an excellent precedent and should be considered throughout the regulatory reform of the RPS which, in short, should treat equal products equally and unequal products unequally. The judgment is also relevant for the revision of Reference Price Order of 2021: companies whose medicines that are not equipotent to others in the same reference price group should pay close attention and may benefit from this judgement.