Capsulas

Finally, the Spanish reference pricing system becomes more flexible

Law 7/2025, which establishes the National Public Health Agency, published in the Official State Gazette (BOE) on 29 July, amends Article 98 of the LGURMPS

The new Article 98 of Royal Legislative Decree 1/2015 (LGURMPS) allows certain medicinal products to be excluded from the reference pricing system or to benefit from a price increase.

Products that objectively improve patient outcomes or offer a strategic advantage to the National Health System (NHS) - such as a new indication, lower dosage, new pharmaceutical form, pharmacokinetic benefit, or any other relevant feature - may benefit from one of these two options. Strategic medicinal products may also qualify for a price increase. Applying these measures requires a decision by the Interministerial Committee on Medicine Prices ("CIPM", by its Spanish acronym), with the participation of the Autonomous Regions.

This legal change is a long-awaited development, given the negative side effects caused by a rule that, until now, had been excessively strict. From a legal standpoint, we believe it is important to make two comments.

Effects on the 2025 Reference Price Order

This new provision takes effect the day after its publication. Currently, pursuant to Article 5 of Royal Decree 177/2014, the MOH is working on the 2025 Order updating reference prices, based on the information in its database (Nomenclator) as of April 1st. The new Article 98 of the LGURMPS can, and should, be applied to this 2025 Order, regardless of the fact that the process for its approval was initiated using the April 1st data in the Nomenclator data. That fact is not relevant in this context.

Companies that wish to benefit from the new mechanisms should file a motivated request for the application of Article 98. In addition, the MOH could also initiate the procedure ex-officio.

The role of the CIPM

It is noteworthy that the new provision grants the CIPM the authority to decide whether a product should be excluded from the reference pricing system or benefit from a price increase.

The CIPM's decision-making process should not be viewed as a mere procedural formality, but rather as a full administrative procedure, in which interested parties are entitled to the rights provided under Law 39/2015. These include the right to make allegations, which must be considered when drafting the proposed resolution. It is also possible that the Directorate-General of the MOH will continue managing this procedure, since it is empowered to provide technical and administrative support to the CIPM in all matters related to setting maximum ex-factory prices for medicinal products, as well as reviewing the prices of those already on the market.