



Capsulas

Price increases of medicinal products that are not reimbursed

The Judgment of the High Court of Justice of Madrid of 10 May 2023 limits the authority of the administration in this matter

Background

This judgement deals with the power of the Ministry of Health to oppose, based on Article 93 of the Law on Guarantees and Rational Use of Medicines and Healthcare Products (LGURMPS), the price increase of a medicinal product that is not reimbursed by the National Health System (NHS).

In our opinion, this is one of the cases in which the regulation of medicinal product prices generates some confusion.

Currently, the Law states that the Administration has the authority to establish, based on motivated and objective criteria, the prices for prescription medicinal products dispensed in the Spanish territory that are reimbursed by the NHS (Art. 94.5).

The Law also provides that these medicinal products, when not reimbursed, can be marketed under a notified pricing regime, which means communicating the price to the Ministry of Health so that it may object to it for reasons of public interest (Art. 94.4).

Finally, Article 93 stipulates that the Administration, by means of reasoned resolution, may update the list of medicinal products that are not reimbursed. The responsible parties of the products excluded from reimbursement will communicate to the competent authority the prices at which they will market these medicinal products (and their revisions). In these cases, the Administration will decide whether or not

they agree with the proposed prices based on reasons of protection of public health, equal access by patients, or real or potential harm to the interests of disadvantaged groups.

In this analyzed case, the company received a resolution against the desired price increase for a non-reimbursed product, as the Ministry deemed that the increase exceeded the variations of the annual CPI (Consumer Price Index).

Position of the High Court of Justice

The Court upholds the claim based on the following arguments.

Firstly, the Court considers it relevant that other medicinal products with the same composition were being marketed at a lower price than the one the company intended to apply. For this reason, the Court understands that the interests of patients or disadvantaged groups would not be affected, as they could purchase these other medicinal products at a lower price.

On the other hand, the Court does not accept that the price increase is prevented because it exceeds the annual CPI increase. In this regard, it points out that even if the CPI was admitted as an indicative criterion (not provided for by the Law), the proposed increase should be analyzed based on the multi-year variation of the CPI since the price was last revised.





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Furthermore, the judgment states that it is the Administration's responsibility to provide the reasons for rejecting the proposed new price and that, in order to act correctly, the Administration should have provided an economic study of the evolution of actual manufacturing prices (raw materials, energy, personnel, etc.) that would allow deducing whether the proposed increase was disproportionate and inadequate, without being sufficient a generic reference to the annual CPI.

Finally, the Court states that the decision of the Administration to use the CPI variation as a cap for price increases without properly justifying such approach "could cause greater harm to citizens, as laboratories could decide to stop producing medicinal products if manufacturing them is not profitable." In conclusion, the judgment advocates for the need of each case to be individually analyzed based on particular circumstances and for each decision to be sufficiently justified.

Based on the above, the appeal is upheld, and the price increase communicated by the company to the Administration authorized; all of the foregoing on the basis that the Administration did not demonstrate that the price increase was disproportionate or inappropriate.

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