Capsulas

Medicinal products' price and reimbursement decisions are confidential

The Spanish National High Court endorses the legal arguments presented by the Faus Moliner team in its Judgment of 23 April 2025

The confidentiality of the ex-factory price (PVL) and reimbursement conditions for medicinal products has been intensely debated in recent years. Since the Spanish Law on Transparency, Access to Public Information and Good Governance (LTAIBG) came into force, requests for access to this information have risen.

Until now, both the Spanish Council for Transparency and Good Governance (CTBG) and some lower courts have taken an inconsistent stance. The judgment discussed provides clarity on this issue, offering a comprehensive analysis of the merits of the case.

Background

The judgment stems from a request for access to the price and reimbursement decision of a medicinal product. Following the Ministry of Health's refusal to grant access, the applicant filed a complaint with the CTBG, which ruled in the applicant's favour and ordered the Ministry to provide the requested information.

In response to the CTBG decision, both the Ministry and the local representative of the marketing authorisation holder filed a contentious administrative appeal, which was dismissed at first instance. This judgment stated that the confidentiality of the information provided by companies to the Ministry when submitting their price and reimbursement request should not prevent the disclosure of the final decision on the product's inclusion in pharmaceutical provision and the setting of its PVL. The court further noted that disclosing this information would not compromise the economic interests of either the company or the National Health System.

In the appeal phase, the National High Court (Audiencia Nacional) upholds the appeals filed by both the Ministry and the company. Below, we briefly outline the arguments presented by Faus Moliner's team, which were fully accepted in the judgment.

Specific confidentiality regime

First, the judgment points out that the confidentiality guarantee established in article 97.3 of the Law on Medicinal Products and Medical Devices (LGURMPS), which covers all technical, economic and financial data provided by companies during the price and reimbursement process, constitutes a specific access regime that must prevail over the LTAIBG.

The Court accepts that for a specific regime of access to public information to take precedence over the LTAIBG, it need not provide a "global and systematic" regulation. It is sufficient for it to be a sectorial regulation addressing relevant aspects. In such cases, the judgment states, "this special regime is applied in preference to the provisions of the law on transparency, the latter serving as a supplementary regulation."

Confidentiality of the PVL and reimbursement conditions

The judgment concludes that disclosure of the PVL and the reimbursement decision would compromise the confidentiality guaranteed by article 97.3

of the LGURMPS. It points out, following a detailed analysis, that disclosure of the PVL would make it possible to infer information on the technical, economic and financial aspects of the medicinal product, as well as to provide a significant insight into the company's activity.

Public interests

The judgment emphasises that any decision to grant access to public information under the LTAIBG must be based on a proper balancing of the interests at stake, assessing whether there is a public or private interest that justifies granting or denying access to the requested information.

In this case, the Court finds no public or private interest that justifies disclosing the reimbursement price. It considers that maintaining confidentiality is convenient and necessary to protect the interests of companies and the public interest. In a highly competitive global pharmaceutical market, it is in the Administration's interest to keep the PVL and the related decisions confidential. In short, confidentiality is a strategic tool that enables the Administration to secure the best possible economic conditions, particularly for innovative medicinal products, thereby benefiting the National Health System.

Conclusion

The judgment discussed is not final and can be appealed before the Supreme Court. However, it is worth noting that the National High Court has conducted a thorough and rigorous analysis of the issue, taking into account the relevant legal and economic context, and establishes a general criterion that should be applicable to similar future access requests.