

APPLICATION OF THE SPANISH TRANSPARENCY ACT IN RELATION TO MEDICINES (2013-2023)

- Spanish Law 19/2013, of 9 December, on transparency, access to public information and good governance [*Ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno*] (the "Transparency Act") was approved in 2013. The Transparency Act establishes and regulates the right of individuals and legal entities to access public information, as well as the procedure for complaining to the Spanish Transparency and Good Governance Council (CTBG).
- The public authorities that receive access-to-information requests are obliged to resolve them. If they fail to do so within the established period (in which case the request is considered denied) or the requester does not find the response satisfactory, a complaint can be filed with the CTBG or directly apply for a judicial review.
- Complaints before the CTBG replace any administrative proceedings/appeals, and its resolutions are binding for public authorities.
- The CTBG's resolutions can be appealed before the Administrative Chamber of the National Court.
- Since the Transparency Act was approved, numerous requests have been made related to information on medicines (among others, ex-factory prices, P&R decisions, purchase price paid by hospitals).
- In relation to ex-factory prices or P&R resolutions, the Ministry of Health's stance has been to reject access to this information based on the following:
 - o Giving access to reimbursement prices of medicines in Spain would hinder the MoH's negotiating position to obtain more competitive prices based on Spain's less privileged economic-financial situation compared to other countries.
 - o Public reimbursement of medicines comes after a negotiation process with the pharmaceutical companies on which costs of manufacturing the medicine, profit margin and the therapeutic utility of the product are assessed. Data on companies' costs and margins are confidential and their publication could seriously affect companies' capacity to compete effectively, given that it is information relating to, among others, costs of products, storage and transformation; commercial costs; sales forecasts, market shares, economic analysis and pharmacological costs. All this information is under trade secret protection, and its disclosure could seriously affect economic and commercial interests of impacted companies.
 - o Section 97(3) of the Spanish Medicines Act establishes the confidentiality of all information on "technical, economic and financial aspects" provided by pharmaceutical companies to the Ministry of Health.

- The CTBG's stance on this has been erratic. However, in recent years, it has established a clear position in favour of giving access to information such as ex-factory prices, P&R resolutions or purchase prices based on the following grounds:
 - The confidentiality warranty under section 97(3) of the Medicines Act only affects the information that pharmaceutical companies provide during negotiations but does not affect P&R resolutions.
 - The ex-factory price is information that contributes to generate a public debate on the use of public resources.
 - Pharmaceutical companies have not proved what impact would have on their economic and commercial interests the provision of access to ex-factory prices and P&R decisions.
- To date, most of CTBG's decisions that have been appealed before the courts have been overturned based on formal grounds.
- However, with regard to the position taken by the courts, three judgments should be highlighted:
 - Supreme Court Judgment of 8 March (315/2021). This judgment confirmed the CTBG and MoH's duty to give audience to MAHs when access-to-information requests are made in relation to them.
 - Judgment of the Administrative Chamber of the National Court of 30 March (55/2020). This judgment confirmed MoH's position of denying access requested on prices of all medicines paid by public hospitals in 2018. The Ministry of Health argued that providing such information would cause clear, real and effective harm to the economic and commercial interests of pharmaceutical companies (section 14(1)(e) of the Transparency Act). Furthermore, the MoH also justified that granting access to ex-factory prices of medicines in Spain to third parties would hinder MoH's negotiating position to obtain more competitive prices. The Court ratified MoH's position and endorsed the refusal to provide the requested information.
 - Judgment of the Administrative Chamber of the High Court of Justice of the Canary Islands of 28 March 2023 (119/2023). This judgment ratified the position maintained by the MoH that pharmaceutical companies have a legitimate interest in relation to the reimbursement price of their medicines, as this is based on confidential information. The High Court of Justice ruled that disclosing this information could seriously hinder the company's capacity to compete and that this price should be considered a trade secret subject to protection. Furthermore, it stated that the Spanish Public Sector Contracts Act does not require the publication of the unitary price of the medicines purchased, and that it is acceptable to publish only the total price of the contract, without a breakdown of the units purchased.