



Medicinal products' price confidentiality and the implementation of Transparency Law

Executive summary of Joan Carles Bailach's presentation at the Pharmaceutical Law Course organized by Fundació CEFI

The right of access to public information was regulated, in general terms, by Law 19/2013, of 9 December 2013, on transparency, access to public information and good governance (LTAIBG). LTAIBG defines public information as the contents or documents held by public administrations, which have been prepared or acquired in the exercise of their functions, regardless of their format or support.

The Council for Transparency and Good Governance (CTBG) is the public body responsible for ensuring that this right is correctly exercised as well as for resolving any potential complaints that may arise. Since its creation, the CTBG has solved various complaints with notable impact on the pharmaceutical and biomedical sector, namely, complaints regarding manufacturer pricing, and price and funding resolutions. For the most part, the CTBG has been in favor of granting access to this type of information.

On the other hand, the Ministry of Health has defended the need to keep medicinal products' prices confidential based on the following three reasons: (i) the underlying public interest in obtaining economic conditions for financing medicinal products makes it advisable to keep medicine prices confidential; (ii) considering that companies provide numerous documents that can be classified as trade secrets throughout price negotiation procedures of a given product, the disclosure of this information could harm the economic and commercial interests of these companies; and (iii) article 97(3) of the Law on Guarantees and Rational Use of Medicinal products and Medical Devices (LGURMPS)

guarantees that the information provided by companies throughout price negotiation procedures be kept confidential. The position of the Ministry of Health is in line with that of the European Commission regarding price confidentiality of Covid-10 vaccines.

What else can the Ministry of Health do to defend the confidentiality of medicine prices?

Firstly, considering that the LGURPMS is being amended, this opportunity could be taken to include a specific regime for access to information on the pharmaceutical provision of the NHS, detailing the entitled parties and/or the content and limits of the information that can be provided.

Secondly, article 97(3) of the LGURMPS could be amended to contemplate that the guarantee of confidentiality set out in this article covers both the information obtained by the General State Administration throughout price negotiation procedures of medicinal products, as well as manufacturer prices, economic conditions of financing and price and funding resolutions.

Finally, the Ministry of Health could expressly include clauses on the confidentiality of manufacturer prices as well as the financing conditions in the price and funding resolutions.