



Transparency news regarding prices of medicinal products and marketing authorization applications

Resolutions 193, 194, 239, 257 and 266 of 2018 by the Council of Transparency and Good Governance

Introduction

This last summer the Council of Transparency and Good Governance (CTBG), an independent public body promoting transparency of public activities and ensuring compliance of the regulations on transparency and good governance, has settled various complaints bringing important updates in terms of access to public information concerning the prices of medicinal products and the applications for marketing authorizations ("MA") of medicinal products.

Access to the date of MA application

Through Resolutions 193 and 194 of 2018, the CTBG has settled two complaints against certain decisions issued by the Spanish Agency of Medicinal Products (AEMPS) denying access to certain information about MA applications for homeopathic medicinal products.

AEMPS denied access to such information arguing that it was part of the "documentation of the marketing authorization application", which is considered as confidential according to Article 15 of Royal Decree 1345/2007. The CTBG decided to grant access to the information related to the date of MA application because it considered that the confidentiality obligation covers all the information in the dossier of the MA application, but not the application form itself.

Access to the CIMP's minutes and to the approved ex-factory price

In Resolution 239 of 2018, the CTBG responded to a complaint against the decision of the Ministry of Health denying access to the minutes of meet-

ings of the Inter-Ministerial Commission of Prices of Medicinal Products ("CIMP") held between 2007 and 2017, considering that they contained information that could harm the economic and commercial interests of the affected pharmaceutical companies. The CTBG determined that the content of such minutes did not affect the above-mentioned interests of the companies and that, therefore, such minutes should be delivered to the claimant after redacting any classified information as well as any information the disclosure of which is legally prohibited, according to the reasonable and loyal judgement of the Administration.

In Resolutions 257 and 266 of 2018, the CTBG settled certain complaints against the refusal of the Ministry of Health (MoH) to grant access, on the one hand, to all the authorized ex-factory prices of medicinal products approved by the CIMP in 2017 and, on the other hand, to the authorized ex-factory price of a specific medicinal product. The MoH denied access to such information arguing that it implied a previous rework process and that such disclosure could affect the economic and commercial interests of the affected companies.

The CTBG decided to grant the complainant access to the requested information based mainly on two arguments. First, the CTBG understands that the MoH cannot rely on the need of reworking because the CIMP, when deciding about prices, must act in a reasoned manner and in accordance with objective criteria. Secondly, the CTBG points out that the accountability principle inspiring the transparency legislation, can hardly be guaranteed if there is no transparency on the prices of medicines, which is a significant matter from a social point of view.