Access to the data regarding the cost of medicinal products and clinical trials data

Resolution No 149/2017 of 28 of June of 2017 of the Council for Transparency and Good Governance (CTBG)

Background

In March 2017, under Law 19/2013, on Transparency, Access to Public Information and Good Governance, an association of consumers and users requested the Spanish Ministry of Health, Social Services and Equality (MOH) to provide them with statistics of prescription and annual cost of certain medicinal products (price, number of prescriptions, total annual cost, financed cost); as well as with the raw data of the clinical trials on the basis of which their marketing authorisation was granted. Given the refusal of the MOH to provide such information, Scabelum exercised its right to submit a complaint before the CTBG.

Access to economic data

In its allegations before the CTBG, the MOH pointed out that the information could not be provided since it could be detrimental to legitimate economic and commercial interests, invoking therefore one of the limits that permit refusal of access in accordance with Law 19/2013.

The CTBG, in its resolution, criticizes the fact that the MOH refuses access without properly explaining the reasons for which it understands that providing access could be detrimental to the economic and commercial interests of a company, reiterating its doctrine in the sense that, in order to benefit from this derogation foreseen in Law 19/2013, the administration must apply criteria of proportionality and must properly analyse the circumstances of each specific case.

The CTBG understands that providing the association with the requested information cannot cause any harm to the companies involved due to its statistical nature and because the MOH publishes, on its web page, statistics of consumption and pharmaceutical expenditure based on prescriptions of the National Health System.

On the other hand, we should recall that the doctrine of the CTBG (Resolution of 5 of November of 2015) is that the MOH must not provide access to the economic and financial data that the pharmaceutical company has offered to the administration when requesting the authorisation for the price of the product.

Access to the clinical trials data

Regarding the clinical trials that justify the marketing authorisation, the CTBG establishes that it must be the AEMPS who must respond to the request as it is the competent body, highlighting that the MOH should have transferred the request to the AEMPS for processing. Likewise, the CTBG recalls that the Spanish registry for clinical trials exists since January 2016 and that it contains information about the way the trial is conducted and also information regarding its results.