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Transparency of the documents submitted in the context of a marketing authorization application for a medicinal product

Judgments of the European Court of Justice of 20 January 2020, PTC Therapeutics v EMA, Case C-175/18 P; and MSD Animal Health Innovation and others v EMA, Case C-178/18 P

Background

In these judgments, the European Court of Justice analyzes the decisions of the General Court which confirmed the validity of the resolutions of the European Medicines Agency (EMA) that granted partial access to certain documents submitted in the context of an application to obtain a marketing authorization (MA) for a medicinal product.

Such documents were a clinical study report and several toxicology reports; and the requesters requested access on the basis of the regulations on transparency of the EU institutions work. The MA holders opposed to the disclosure and filed an appeal before the General Court. After the first judgment of the General Court rejecting the appeal, further appeals were submitted before the Court of Justice. These judgments decide on such appeals.

General presumption of confidentiality

The EMA could only refuse the access to the documents if any of the exceptions laid down in Regulation 1049/2001, such as the protection of commercial interests, was deemed applicable.

As occurs with the Spanish Law on Transparency, in such cases it should be weighed whether the public interest of granting access to the documents overrides the private commercial interests of the owner of such documents.

The appellants claimed that the EMA should refuse access to the documents on the basis of a general presumption of confidentiality. Further, they argued that the requesters and the EMA should be the ones proving the existence of a superior public interest justifying the disclosure of the documents. The General Court and the Court of Justice understand that the EMA is not obliged to accept the existence of a general presumption of confidentiality regarding the documents submitted in the context of a marketing authorization application for a medicinal product. Therefore, the EMA should be free to disclose such documents to any requester (some specific parts may be hidden if needed) unless (a) the owner of the documents is able to prove that granting access to such documents undermines the protection of its commercial interests, and (b) there is no overriding public interest in the disclosure.

¿How does it work in Spain?

In Spain, article 15 of Royal Decree 1345/2007 provides that the documentation submitted in the context of a marketing authorization application must be deemed confidential. Therefore, such documents are not only covered by a presumption of confidentiality but also by a legal guarantee of confidentiality. Holders of MA's granted by the AEMPS can rely on this article to refuse disclosure. However, we shall wait and see how this disposition will be applied by the Spanish Council on Transparency if it receives a request of this nature.