



Transparency wins: third parties can access the documents of a marketing authorization application file

Judgements of the General Court of the European Union, of 5 February 2018, in the Cases T-235/15, T-718/15 and T-729/15

Background

In these three Judgements, the General Court analyzed the decisions of the European Medicines Agency (EMA) to grant access to a third party to the documents submitted in the context of applications for marketing authorizations (MA). The pharmaceutical companies who provided such documents to the EMA and then became MA holders, separately brought actions before the General Court against such decisions of EMA.

Specifically, the documents to which EMA was willing to provide access were a clinical study report (Case T-718/15); the assessment reports issued by the Committee for Medicinal Products for Human Use on the similarity and clinical superiority of an orphan medicinal product for which a MA was requested, compared to another orphan medicinal product available in the market (Case T-235/15); and to safety study reports (Case T-729/15).

General presumption of confidentiality

In the three cases, the appellants argued that, under Regulation (EC) No 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, the EMA must refuse access to a document where disclosure would undermine the protection of private commercial interests, unless there is an overriding public interest in disclosure. According to the appellants, there is in the regulation a general presumption of confi-

dentiality based on the protection of their commercial interests, under which the EMA shall refuse access to the documents.

The General Court considers that there is no presumption with respect to the documents of a file of a MA application and, in particular, regarding the specific documents requested in each of these cases.

Furthermore, the Court outlined that, as exposed in numerous case-law, the general rule is that the right to access the documents must be as wide as possible; and that although there are certain exceptions on reasons of public or private interest, these exceptions must be interpreted and applied strictly.

Overriding public interest

The appellants considered that the EMA justified the existence of an overriding public interest that justified providing the information of the appellants, to third party applicants.

The Court concludes that EU institutions must not permit access to documents where their disclosure is justified by an overriding public interest, even if it could undermine private commercial interests. Moreover, in these cases, the documents were found to be not confidential, which led the Court to state that the EMA was not required to weigh the particular interest in confidentiality against the overriding public interest in disclosure.