



## Balancing transparency and confidentiality

*Opinions of the Advocate General, Mr. Gerard Hogan, of 11 September 2019, on Cases C-175/18 and C-178/18; and resolution of the CTBG of 26 September 2019*

### Background

In our Capsulas newsletter of March 2018, we addressed the important judgements of the General Court of the European Union (TGUE) of 5 February 2018 in which third parties were granted access to documents submitted before the European Medicines Agency (EMA) in the context of applications for marketing authorizations. The title we used then for our Capsulas was “Transparency wins”.

Nowadays, administrative doctrine and the case law are progressing to gain clarity in this matter. Two good examples are the decision of the Supreme Court of 18 January 2019 which declares that the interpretation of article 14.1.k of the Spanish Law on Transparency is a matter of interest for the Court; or the appeals submitted against the mentioned judgements of the TGUE. In this context, the Opinions of the Advocate General and the resolution of the Council of Transparency and Good Governance (CTBG) which we will discuss below, were recently published. In our view, they point towards the good direction: a balance between the unquestionable need of transparency and the preservation of confidentiality of certain documents.

### Opinions of the Advocate General

The Advocate General Opinions refer to two appeals submitted before the Court of Justice against two of the three judgements of the TGUE of 5 February 2018. The Advocate General positions himself in favour of the recognition of a general presumption of confidentiality in respect of a clinical study

report and certain toxicity study reports included in applications for marketing authorizations submitted before the EMA. The Advocate General focuses on the legislation on medicinal products and on the high level of protection that is offered to innovator companies to conclude that the disclosure of the documents would foreseeably damage the commercial interests of the applicants.

### Resolution of the CTBG

In its resolution of 26 September 2019, the CTBG denies an individual access to a resolution of the General Directorate of Basic Services Portfolio of the National Health System and Pharmacy where the price & reimbursement of a medicinal product is decided. The CTBG considers that such access might cause reasonable damage, and not purely hypothetical, to the economic and commercial interests of the marketing authorization holder.

Additionally, the CTBG endorses the arguments of the Ministry of Health and of the marketing authorization holder which state that preserving the confidentiality of prices permits “maximizing patients’ access to innovative medicinal products” and allows “each country to obtain the best possible price depending on their circumstances”. The position of the CTBG is especially relevant as it recognizes the importance to preserve the confidentiality of certain documents, not only to protect private interests, but also to favour public ones. This way, medicinal products’ prices may be adapted to the circumstances of each specific case and access to such products can be improved.