ARTICLE

COMMUNICATION OF MA FILES: A RELATIVE CONFIDENTIALITY BEFORE THE EMA - QUESTIONS AND ANSWERS ON THE TEACHING OF TWO RECENT CJEU JUDGMENTS

Technologies - Media - IP | 09/09/20 | Océane Millon de La Verteville

Two judgments of the CJEU[1] delivered on 22 January 2020 have shed new light on the scope of the confidentiality of marketing authorisation (MA) dossiers for medicinal products. In both cases, a third party had requested disclosure of certain documents in the marketing authorisation file held by the European Medicines Agency (EMA). The marketing authorisation holders (MSD and PTC) objected on the grounds that the documents were covered by confidentiality. The EMA finally released the requested documents after the secret information had been removed. The ECJ upheld the EMA's decisions.

What type of documents were involved in the access requests?

These were toxicology test reports[2] in the MSD case and a clinical trial report in the TPC case.

The occultation: proposed by the MA holder or by the EMA?

Both!

In the MSD case, the third party requested the disclosure of five documents. The EMA considered that only three of these documents could be disclosed. Of these three documents, EMA invited MSD to submit its proposals for redaction, which it accepted only in part.

In the PTC case, the third party was requesting disclosure of a document. After consultation with the MA holder, the EMA granted access to the document on the condition that certain passages, determined by the EMA itself, be redacted.

What kind of information was redacted?

In the PTC clinical trial report, the information suppressed was: references to protocol design discussions with the Food and Drug Administration, batch numbers, materials and equipment, exploratory assays, the quantitative and qualitative description of the method for drug concentration measurement, and the start and end dates of treatment and further dates that could lead to the identification of the patients.

In MSD's toxicological test reports, the redacted parts included the concentration range of the active substance, details on the internal reference standard used for the analytical tests and references to future development plans.

The EMA, however, refused to release two of the toxicological test reports (reasons are not mentioned, as the decisions do not relate to those reports).

When were the requests for access to documents submitted?

In both cases, the third party requested access to the documents a few months after the MA (or conditional MA) containing the data was granted. The decisions do not mention whether these "third parties" were generic companies (however, the PTC decision mentions that the third party is a pharmaceutical company).

What were the MA holders' arguments to support the confidentiality of their documents?

MSD and PTC invoked a "general presumption of confidentiality". They relied on Regulation 726/2004, stating that this regulation contains a series of disclosure obligations to ensure sufficient transparency of EMA's decision-making process but does not provide for a general right of access to the file. They also invoked Regulation 1049/2001: it lays down the principle of transparency between the EU institutions and citizens, which translates into wide public access to documents of the EU institutions, including EMA (art. 1). However, exceptions to this principle are provided for (art. 4) and should be applied, according to MSD and PCT.

MSD and TPC also cited the presence of commercially sensitive information in the documents sought to be disclosed, and the fact that the court imposed too high a standard of proof on this test. Among their arguments, MSD and PTC developed the risk that the reports could be misused by a competitor (and give him a competitive advantage), or the fact that the reports presented an innovative strategy on how to plan a toxicology program (MSD).

What is the CJEU's reasoning on the general presumption of confidentiality?

The CJEU considers that the EMA can consider that certain categories of documents are "in principle" excluded from public disclosure, but that, even in that case, the EMA retains the possibility of examining each document and considering its confidentiality[3]. The CJEU unambiguously overturns the common view that the documents in a MA file are, by their nature, confidential. The EMA always retains the possibility of carrying out a concrete and individual examination of each document to determine whether it is protected by exceptions, in whole or in part.

What is the CJEU's reasoning on commercially sensitive information?

The CJEU recognises (§ 80 et seq. of the MSD case) that the disclosure of certain data may harm commercial interests. These data must meet cumulative criteria as they must :

- be identified,

- involve an identified, "concrete and reasonably foreseeable" risk of being used in at least one third country to obtain a marketing authorisation by a competitor ("thus taking unfair advantage of the work done" by the original marketing authorisation holder);
- not have been published, and
- not falling within the general knowledge of the pharmaceutical industry.

On the latter point, in the PTC case, the CJEU upheld the court's interpretation that PTC had " that the assembly of the publicly accessible data together with the data which is not publicly accessible [constituted] a commercially sensitive item of data', forming an 'inseparable whole with economic value ", and that " the models and methodologies used in the clinical study concerned were based on know-how that is widely available in the scientific community " (§ 97-100 of the TPC case).

In both cases, the CJEU confirms that the marketing authorisation holder did not sufficiently identify which parts of the documents would harm its commercial interests if disclosed, but also that it did not show either the existence of a risk of unfair use of its data or the inadequacy of the redactions carried out by the EMA.

The Court also specified that, in order to conclude that a document is not confidential, the EMA is not required to determine or assess the public interest in the disclosure of that report, or to weigh that interest against the MA holders's interest in keeping the report confidential (§ 85 of the MSD case, 84 et seq. of the PTC case).

Thus, the CJEU gives the MA holder guidelines on the conduct to be followed if he intends to avail himself of an exception to the right of communication: it is up to him, on the one hand, to set out in concrete terms the objections he intends to invoke (confidentiality, communication liable to harm his commercial interests, etc.) and, on the other hand, to do so before the administrative authority (in this case the EMA) and not *ex post,* during the judicial phase of the proceedings.

Could the data held by French human and veterinary health agencies [4] **be disclosed, like those held by EMA?**

Yes, that could happen. The right to the communication of administrative documents, including documents held by the ANSM or the ANMV, is governed by Articles L.300-1 et seq. of the Code on Relations between the Public and the Administration, on which the European Regulation is based.

Hence the importance for the marketing authorisation holder, as also noted in the PTC case (§ 105), to indicate to the administrative authority in a complete and detailed manner the elements which he considers covered by a secret (including commercial and industrial secrecy, which includes the secrecy of processes protected by Article L.311-6 of the said Code) of the document whose communication is requested by a third party.

The control by laboratories of the scientific publications of their teams, generally very well monitored, could allow them to tip the balance of confidentiality: private laboratories publish very little, demonstrating the confidentiality attached to their studies.

This recommendation of course only works if the public authority asks its opinion to the MA holder...

[1] C-178/18 P: MSD animal health innovation & Intervet International v. EMA (hereinafter "MSD")

and C-175/18 P: PTC therapeutics international v. EMA and Eucope (hereinafter "PTC")

[2] In this case, the 5 toxicology test reports in the dossier, including the following three reports (described in T-729/15 R): C 45151/ 28-day dermal toxicity study (6-hour semi-occlusive application) in Wistar rats, C 45162/ 28-day oral toxicity study in Wistar rats and C 88913/ 28-day dermal toxicity study (6-hour semi-occlusive application) in Wistar rats.

[3] (§56 et seq. of the MSD case, §60 et seq. of the PTC case)

[4] ANSM (agence nationale de sécurité du médicament et des produits de santé) and ANMV (agence nationale du médicament vétérinaire)