Health Law, Data Protection

Third-Party Access to Marketing Authorization Files

Three EU Judgments in Favor of Transparency

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I. Introduction

Pharmaceutical companies applying for a marketing authorization (MA) for their medicinal products must provide ample documents to support the safety and efficacy of their product. To decide whether such an authorization can be granted, the drug agency – in the EU, the European Medicines Agency (EMA) under the centralized procedure – assesses these documents and produces corresponding documents. These documents are of significant interest to third parties. Researchers may want to access them to make their own assessments of the data. Health care professionals may want to access these documents to gain a better understanding of the products they will use. Patient organizations may have an interest in using the information to support their members. Lawyers may use these documents to support product liability claims. Competitors may wish to study them to develop their own original or generic products.[1]

EMA annual reports reveal that it receives some 800 requests for access to such documents every year.[2] Over the last ten years, the EMA has developed an increasingly generous policy of granting access to documents. Many documents are proactively being made public.[3] Moreover, the EMA often responds positively to requests for access to specific additional documents. However, for the last several years, the legal validity of the EMA policy has been challenged before EU Courts.

On February 5, 2018, the E.U. General Court[4] issued three judgments[5] – referred to as "landmark rulings"

1 According to the EMA's 2017 annual report (p. 95), a large majority of requests are made by pharmaceutical companies, followed by (in descending order) patient or consumer organizations, consultants and academic or research institutions.

2 According to this same report (p. 94), 683 requests for documents were filed with the EMA in 2015, 817 requests for 2016 and 844 for 2017. In 2017, the EMA released nearly half a million pages of documents. Id.

3 According to this annual report (p. 38), "20 October 2017 marked the first anniversary of EMA's groundbreaking transparency initiative to publish clinical reports underpinning the market authorization of new medicines for human use. This enables citizens, including researchers and academics, to access these reports directly via EMA's clinical data publication (CDP) website (https://clinicaldata.ema.europa.eu/home). EMA is the first regulatory authority to provide such broad access to clinical reports. As of the end of 2017, clinical reports on 55 medicines, including orphan, biosimilar and generic medicines, as well as medicines for use in children, are publicly available on the CDP website. This amounts to 3,583 clinical documents, totaling more than 1.3 million pages. Published data ha attracted a total of 2,361 new users (1,877 general and 484 non-commercial research users), resulting in 29,232 document views and 96,977 document downloads for non-commercial research purposes. A 2017 survey of the website users, including researchers, healthcare professionals, patients and industry, showed that three quarters of responders agreed that the publication of clinical data builds public trust and confidence in EMA's scientific and decision-making processes. Two out of three responders agreed that the data made available help researchers to reassess the clinical data."

4 The General Court has jurisdiction to hear and determine: actions brought by natural or legal persons against acts of the institutions, bodies, offices or agencies of the European Union (which are addressed to them or are of direct and individual concern to them)". Description of the General Court at https://curia.europa.eu/jcms/jcms/Jo2_7033/en/.

5 These three judgments were issued by the Second Chamber, one of them in extended composition. See T-235/15 (Pari Pharma v EMA); T-729/15 (MSD Animal Health Innovation and Intervet international v EMA) and T-718/15 (PTC Therapeutics International v EMA against Decision EMA/722323/2015). They were preceded by multiple orders for interim measures (Order of the President of the General Court of 1 September 2015 – T-235/15 R; Order of the Vice-President of the Court of 17 March 2016 – C-550/15 P(R); Order of the Vice-President of the Court

by the EMA[6] – addressing this controversial issue of third-party access to MA files for medicinal products. In all three cases, access was granted over the strenuous objections of the MA holders. The documents requested were clinical study reports, including similarity and superiority reports to overcome orphan exclusivity, survey reports, and toxicology tests for a veterinary medicine. The reasoning in all three rulings is essentially similar. At least two of the three judgments have been appealed to the Court of Justice, which has yet to decide them.[7] Some legal uncertainty therefore lingers.

Despite their non-final status, these judgments are well-reasoned[8] and hence worth the present summary. The remarks here will be kept brief, with a fuller analysis to be made after the EU Court of Justice will have confirmed or annulled them.

II. A General Presumption of (Full) Confidentiality?

In all three cases, the first and central argument against access made by MA holders was that, because of a general presumption of confidentiality, all information and documents related to a MA procedure should be automatically held fully confidential. In other words, Regulation 1049/2001, which outlines the right of access to documents held by EU authorities, should *not* apply to documents in a MA file *at all*. Hence, the EMA should not have even attempted to analyze the content of each document, since they all should have been considered beyond the scope of the right of access.

The General Court flatly rejected this line of argument. It first observed that general presumptions of confidentiality are the exception because they derogate to the principle of access laid down by Article 15 TFEU[9] and by Regulation 1049/2001.[10] Therefore, they must be "considered strictly".[11] General presumptions of confidentiality have been recognized only in a few situations, typically when a procedure is still pending.[12] The General Court had already denied that a general presumption of confidentiality covered documents pertaining to the registration of new chemicals.[13] In this case, a marketing authorization had already been granted when the request for access had been made. Moreover, nothing in the Regulation(s) governing the grant of MA suggested that the legislature had wanted to remove MA documents from the general right of access of Regulation 1049/2001.[14] On the contrary, Article 73 of Regulation 726/2004[15] explicitly states: "Regulation (EC) No 1049/2001 [...] shall apply to documents held by the Agency". The fact that the EMA already proactively published several documents, notably the European Public Assessment Report (EPAR), does not imply that other documents must remain confidential.[16] On the contrary, these obligations to publish proactively underline the importance given to transparency of

of 18 October 2016 – Case C-406/16 P(R); Order of the Vice-President of the Court of 17 March 2016; Order of the President of the General Court of 20 July 2016 – Case T-729/15 R; Order of the Vice-President of the Court of 1 March 2017- C-512/16 P(R)). Previously, two other companies had challenged the EMA's policy of wide access but later withdrew their appeals (C-389/13 P(R) – EMA v AbbVie; C-390/13 P(R) – EMA v InterMune UK and Others; T-73/13 – InterMune UK and Others v EMA). The decisions in this field of the Ombudsman, though certainly worth analyzing, are beyond the scope of this article.

6 See its press release of February 6, 2018, titled "General Court confirms EMA approach to transparency", available at http://www.ema.europa.eu/ema/index.jsp;curl=pages/medicines/pips/EMEA-001743-PIP01-14/pages/about_us/general/index.jsp?curl=pages/news_and_events/news/2018/02/news_detail_002899.jsp&mid=WC0b01ac058004d5c1.

7 See C-178/18 P – MSD Animal Health Innovation and Intervet International v EMA, at http://curia.europa.eu/juris/liste.jsf?num=C-178/18&language=en; C-175/18 P – PTC Therapeutics International v EM at http://curia.europa.eu/juris/liste.jsf?num=C-175/18&language=en. No appeal information has been found on-line regarding judgment T-235/15 (Pari Pharma v EMA).

8 Together, the three judgments run some 100 pages; they cite over twenty former cases: C-353/99; T-144/05; C-39/05; C-52/05; C-431/05; C-514/07; C-528/07; C-532/07; T-250/08; T-437/08; T-439/08; C-506/08; C-365/10; C-404/10; C-477/10; T-245/11; T-516/11; T-534/11; C-415/11; C-514/11; C-605/11; T-306/12; C-350/12; C-365/12; C-365/12; T-496/13; C-612/13; C-615/13; T-189/14.

9 According to Article 15(1) TFEU: "[i]n order to promote good governance and ensure the participation of civil society, the Union's institutions, bodies, offices and agencies shall conduct their work as openly as possible." As per its paragraph 3: "Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have a right of access to documents of the Union's institutions, bodies, offices and agencies, whatever their medium, subject to the principle to be defined in accordance with this paragraph. General principles and limits on grounds of public or private interest governing this right of access to documents shall be determined by the European Parliament and the Council, by means of regulations, acting in accordance with the ordinary legislative procedure."

10 Regulation 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents; this regulation was "applicable from 3 December 2001." (Article 19).

11 T-729/15, para. 11; T-235/15, para. 41; T-718/15, para. 36.

12 T-729/15, para. 26–30; T-235/15, para. 43–48; T-718/15, para. 37–43.

13 T-729/15, para. 31 and T-235/15, para. 49, T-718/15, para. 44, citing to judgment T-189/14.

14 T-729/15, para. 33; T-235/15, para. 53; T-718/15, para. 46–48 and 56 (with respect to Regulation 536/2014).

15 Regulation 726/2004 of the European parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; this regulation entered into force on 20 May 2004 (Article 90).

16 T-729/15, para. 35 and 36; T-235/15, para. 54–55 and 98–99; T-718/15, para. 49–51.

the EMA procedure.[17] Former judgments had not directly ruled on the issue,[18] while judgments granting interim measures of protection were not decisive in that respect.

The General Court refused to infer a general presumption of confidentiality from Article 39 of the TRIPS Agreement.[19] This provision of this multilateral agreement protects, against unfair use, test and clinical data which were generated by companies in order to obtain drug marketing authorizations. The Court agreed that Regulation 1049/2001 should be given a meaning that does not contradict Article 39 TRIPS, but the latter cannot invalidate the second outright.[20] It found that the exceptions introduced by Article 4 of Regulation 1049/2001, together with the grant of data marketing exclusivity, were enough to ensure compliance with the provision of the TRIPS agreement.[21] In other words, compliance with the TRIPS agreement did not require a general presumption of confidentiality, because commercially confidential information was protected under Article 4(2) of Regulation 1049/2001 and because unfair use by competitors was made impossible, or at least unlikely, by data and marketing protection/exclusivity.[22]

III. Confidentiality Under Article 4(2) of Regulation 1049/2001?

The Court next had to decide whether the exception of Article 4(2) of Regulation 1049/2001 on commercial interests[23] resulted in shielding the entire MA file from disclosure. Once again, the answer was a firm "no". First, the Court reiterated that exceptions to the principle of access must be interpreted strictly.[24] For this exception to apply, the authority intending to refuse access had to ensure that the following conditions were met: "access [would] specifically and actually undermine the interest protected" by the Article 4(2) exception and this specific and actual risk was "foreseeable and not purely hypothetical".[25] An MA holder wishing to show that its competitive interest would be unduly undermined must be able to demonstrate how this risk could actually materialize. Not all business information produced by a company satisfies this test.[26] Information that revealed business strategies, commercial relations or the company's expertise would indeed meet these conditions.[27] In the three affairs it had to decide, the EMA, and then the General Court, took the view that no such serious risk was present if documents were to be disclosed. The MA holders could not point to circumstances that made this risk foreseeable, especially given that the information about the manufacturing process was redacted.[28] Because MA holders retain the protection of data marketing exclusivity (for 10–11 years), competitors are in any case obliged to conduct their own clinical studies if they want to obtain a non-generic MA.[29]

The next step was to decide whether individual documents could be kept confidential based on Article 4(2) of Regulation 1049/2001. The documents in the three cases requested were: animal toxicity studies, clinical studies, and literature review and marketing survey data, respectively. The EMA concluded that, except for specific pieces of information regarding the manufacturing process, all these documents were to be made public. The reasons put forth by the EMA were of three kinds:

- The documents contained already publicly-available information – the fact that it had been assembled from different sources and structured appropriately (the "inseparable whole with economic value" argument and the "road-map" argu-

17 T-729/15, para. 36; T-235/15, para. 56 and 99; T-718/15, para. 52 and 59. Further, the Court writes: "the transparency of the process followed by the EMA and the possibility to obtain access to the documents used by that agency's experts to prepare their scientific assessment contribute to such an authority acquiring greater legitimacy in the eyes of the persons to whom that measure is addressed and increasing their confidence in that authority and to ensuring that the authority is more accountable to citizens in a democratic system" (T-729/15, para. 44; T-718/15, para. 83).

18 T-729/15, para. 44; T-718/15, para. 59. The Biogen case C-181/95 had often been cited, but it was delivered before the entry into force of the Regulation 1049/2001.

19 Word Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Right, in effect since 1 January 1995.

20 T-729/15, para. 48; T-235/15, para. 111; T-718/15, para. 62.

21 T-729/15, para. 50–52; T-718/15, para. 64–65.

22 T-235/15, para. 89. As per Article 14(11) of Regulation 726/2004, "Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with the provisions of this Regulation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection, in which connection the latter period shall be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies."

23 According to this provision, "[t]he institutions shall refuse access to a document where disclosure would undermine the protection of: commercial interests of a natural or legal person, including intellectual property".

24 T-235/15, para. 67.

25 T-729/15, para. 66; T-235/15, para. 69; T-718/15, para. 82.

26 T-235/15, para. 70; T-718/15, para. 84.

27 T-729/15, para. 68.

28 T-718/15, para. 90 (was redacted "information on the composition or manufacturing of the medicinal product Translarna, [...] discussions on protocol design with the US Food and Drug Administration, batch numbers, materials and equipment, explanatory assays, quantitative and qualitative description of the method for drug concentration measurement as well as start and end dates of treatment and further dates that could lead to the identification of the patients").

29 T-718/15, para. 91.

ment) did not affect this outcome.[30] The Court noted that currently available search tools make it easy to locate publicly-available information.[31] The next step of assembling and structuring the gathered information did not require any inventiveness.[32] The overall result did not reveal the company's (secret) expertise or know-how.[33]

- The documents did not contain commercially confidential information – the fact that the studies were designed in accordance with guidelines, or with requests from the EMA, was a factor negating a special expertise or know-how of the MA holder.[34] The Court seems to imply that the outcomes (results) of the studies can never be protected under Article 4(2), whereas the design of the studies can only be protected if the MA holder has itself independently conceived and implemented an innovative design.[35] Moreover, when none of the exceptions of Article 4 applies, the authority must *not* weigh the interests in presence; no proportionality assessment takes place.[36] In other words, the MA holder cannot ask that its interest in confidentiality be weighed against the interest in favor of transparency.
- Even if some information could be deemed confidential, the fact that, despite the granting of access, the information would remain protected against generic use by data/marketing protection (for ten to eleven years) made it highly unlikely that the MA holder would incur a competitive injury through disclosure.[37] Concrete evidence of competitive harm (i.e., the undermining of commercial interests) is a requirement under Article 4(2) of Regulation 1049/2001.[38]
- Even if some documents could be said to contain commercially confidential information (as per Article 4(2) of Regulation 1049/2001), the public interest in favor of disclosure was held to prevail over the MA holder's interest to keep the information confidential.[39]

30 T-729/15, para. 81; T-235/15, para. 76; T-718/15, para. 89.
31 T-235/15, para. 78 and 115.
32 T-235/15, para. 113–115.
33 T-235/15, para. 116.
34 T-235/15, para. 82–83.
35 T-718/15, para. 55 ad 90.
36 T-729/15, para. 122 and 136; T-718/15, para. 106–112.
37 T-729/15, para. 88; T-718/15, para. 92.
38 According to para. 84 of judgment T-718/15, "the joint guidance document of the EMA and the Heads of Medicines Agencies on the identification of commercially confidential information and personal data within the structure of the MA procedure defines 'commercial confidential information' as any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information."
39 T-235/15, para. 143 and 163.

IV. Other Key Holdings

This section highlights some additional points that can be inferred from these judgments.

First, it is interesting to point out the issues that, according to the General Court, are *not* decisive (to decide on requests for access to documents). Are thus here *irrelevant:*

- The nature of the medicine at issue (in these three cases: an orphan medicine, a veterinary medicine, respectively a hybrid product).
- The identity of the party requesting access to MA documents.
- The fact that the MA granted is a conditional authorization.[40] Even though the MA holder will have to submit additional information to secure an ordinary authorization, the procedure concerning the condition authorization is now considered closed and the documents that were evaluated in support of such authorization can be made public.[41] Similarly, the fact that the MA was granted in a hybrid procedure which required reliance on documents of a reference medicinal product does not affect the conclusion.
- The fact that the MA holder may intend to submit future applications extending the use of its authorized medicinal product. The EMA's future decision-making process will not be undermined by release.[42] However, information regarding its future plans – if they are mentioned in this MA file – will be redacted.[43]
- The fact that the requested report was submitted in order to overcome a legal obstacle (here another medicine's orphan exclusivity)[44] – and not directly to prove the new product's positive benefit-risk balance.
- The financial value of the information produced by the MA holder as well as the time and resources its generation required.[45]
- The administrative burden that redacting commercially confidential information places on the authority and on MA holders.[46]
- The risk of competitors making *illegal* use of the information contained in the documents, notably to unduly tarnish the reputation of the MA holder.[47]
- The fact that the EMA deliberately chooses not to assume any liability for third-parties' possible illicit use of the disclosed information.[48]

40 T-718/15, para. 56.
41 T-718/15, para. 101–102.
42 T-729/15, para. 110.
43 T-729/15, para. 46 and 90.
44 T-235/15, para. 102.
45 T-729/15, para. 89.
46 T-718/15, para. 66.
47 T-729/15, para. 91.
48 T-718/15, para. 72.

- The risk that, through disclosure of their studies, MA holders would incur a disadvantage in third countries where they would not enjoy data exclusivity. The Courts must apply EU Regulation to the benefit of EU citizens and cannot rely on the hypothetical risk of a disadvantage abroad.[49]

Additional important holdings of the General Court can be summarized as follows:

First, the General Court chose not to base its judgments directly on the EMA policy statements.[50] The EMA issues documents to clarify the scope of the right of access and to specify which documents are usually made available and which are typically kept confidential. These documents were mentioned by the General Court, but were not relied upon to reach the judgment.[51] The Court did not generally endorse or confirm these EMA documents.

Second, the risk that, fearing disclosure of their documents, pharmaceutical companies may decide to withhold certain information. when applying for marketing authorizations is viewed as minimal. The Court held that pharmaceutical companies would rather avoid having their applications rejected on grounds of insufficient data.[52]

Third, the burden of proof on MA holders is very high. To withhold documents, MA holders must be able to present concrete evidence that the documents requested would reveal otherwise unknown and unknowable expertise, which their competitors could then directly and rapidly put to use to advance their own interests, while directly undermining the commercial interests of the said MA holders. A general abstract possibility does not satisfy this demanding threshold. For medical/safety/clinical data, the applicable standard is therefore likely to remain that of general third-party access.

V. Impact for Switzerland?

Switzerland is not bound by EU judgments. Similarly, its therapeutic product agency, Swissmedic, is not bound by the EMA Policy. However, the Swiss Federal Act on Transparency[53] is similar to Regulation 1049/2001. Moreover, MA files in the EU and in Switzerland have similar content. When an MA document is made public by the EMA (either proactively or reactively), its information can also be exploited in Switzerland.

Recently, the Federal Tribunal confirmed a judgment by the Federal Administrative Tribunal granting broad access to MA files.[54] Until that final judgment of July 2018, it was uncertain whether the Federal Act on Transparency had similar effect on pharmaceutical transparency as the EU Regulation has had. Since similar arguments by MA holders were raised in the Swiss and the EU procedures and since these arguments were rejected based on similar grounds, it is likely that the practice of the EMA will now start influencing that of Swissmedic. Indeed, the Revised Swiss Therapeutic Products Act already significantly enhances the transparency of this industry.

49 T-729/15, para. 87; T-718/15, para. 94.

50 T-729/15, para. 39 and 40; T-235/15, para. 58–59; T-718/15, para. 54–55. Article 73(3) allows the EMA to enact implementing policy ("The Management Board shall adopt the arrangements for implementing Regulation (EC) No 1049/2001 within six months of entry into force of this Regulation"). See EMA, European Medicines Agency policy on access to documents (EMA/110196/2006; Policy/0043; 30 November 2010; soon to be superseded by document EMA/729522/2016); EMA, Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use (EMA/127362/2006; 30 November 2010).

51 T-235/15, para. 124.

52 T-729/15, para. 57 and 113.

53 Federal Act on Freedom of Information in the Administration (Freedom of Information Act, FoIA) of 17 December 2004 (152.3).

54 Judgment of the Swiss Federal Tribunal in case 1C_562/2017; previously judgments of the Federal Administrative Tribunal A-75/2009 of 16 April 2009; A-4356/2010 of 25 January 2011; A-4307/2010 of 28 February 2013, A-3621/2014 of 2 September 2015; A-6/2015 of 26 July 2017; Federal Tribunal's judgments 2C_234/2011, 2C_235/2011 of 23 August 2011, 1C_501/2013, 1C_502/2013, 1C-503/2013 of 12 February 2014. The author was the party requesting access in all these procedures.