Decision on the European Medicines Agency's (EMA) refusal of public access to documents relating to the manufacturing of mRNA vaccines against COVID-19 (case 1458/2021/MIG)

Decision
Case 1458/2021/MIG - **Opened on** 20/08/2021 - **Decision on** 10/11/2021 - **Institution concerned** European Medicines Agency (No maladministration found) |

The case concerned a request for public access to the parts of an application for a marketing authorisation for an mRNA vaccine against COVID-19 containing detailed explanations regarding how the vaccine is manufactured. EMA refused to grant access to the documents because it considered that their disclosure would undermine the manufacturer's commercial interests and because there was no overriding public interest in disclosing the documents.

The Ombudsman agrees that the information in the requested documents is commercial information under EU law, since knowledge of it would help competing manufacturers. As regards whether there is an overriding public interest in disclosing the documents, while there are reasons why information relating to the safety and efficacy of a medicine (for example the results of clinical trials) should always be disclosed, the same does not normally apply to detailed information relating to how a medicine is manufactured.

In assessing the public interest in the disclosure of the manufacturing information in this case, the Ombudsman notes that EMA does disclose summaries of the manufacturing information.

The Ombudsman recognises the sentiment of the complainant in this case of the wider public interests involved, however she feels these are largely political questions which need be addressed by those politically responsible.

The Ombudsman thus found that EMA's position was in line with EU case law and closed the inquiry finding no maladministration.

Background to the complaint
1. In December 2020 and January 2021 respectively [1] , EMA recommended granting

conditional marketing authorisations for two 'messenger-RNA' vaccines against COVID-19, that is, Comirnaty and COVID-19 vaccine (Moderna). [2]

2. In January 2021, the complainant asked EMA [3] to give him public access [4] to *Module 3 of the 'Common Technical Document' (CTD)* **[5]** *concerning the two novel vaccines Comirnaty (Biontech/Pfizer) and COVID-19 vaccine (Moderna)* . The complainant clarified that he was not interested in obtaining information regarding the manufacturing process for these vaccines.

3. EMA identified ten documents and refused to give the complainant access to them.

4. In March 2021, the complainant asked EMA to review its decision (by making a 'confirmatory application').

5. EMA then split the complainant's request into batches and started processing those batches consecutively.

6. In June 2021, EMA issued a confirmatory decision on batch 1, that is, document '3.2.S/2/3 control-of-materials-raw', informing the complainant that it intended to grant him access to those parts of the document which it did not consider to be commercially sensitive. However, it said, it had consulted the manufacturer concerned as regards its intentions and was awaiting the outcome of that consultation.

7. In July 2021, after it had received additional information from the manufacturer, EMA issued an amended confirmatory decision on batch 1 and a separate confirmatory decision on batch 2 (document '3.2.S.2.3 control-of-materials-starting-lonza-visp'), refusing access to both documents in their entirety, relying on the need to protect the commercial interests of the manufacturer [6] .

8. Dissatisfied with this reply, the complainant turned to the Ombudsman in August 2021.

9. By way of relevant background, the Ombudsman notes that during the COVID-19 pandemic, EMA is implementing exceptional measures to try and maximise the transparency of its regulatory activities on treatments and vaccines for COVID-19 that are approved or are under evaluation. EMA is doing this by shortening its standard publishing timeframes and publishing information it does not normally publish for other medicines. Detailed information regarding the safety and efficacy of all the COVID-19 vaccines approved by EMA is available on EMA's website. [7]

The inquiry

10. The Ombudsman opened an inquiry into EMA's refusal to disclose two of the documents at issue in the complainant's access request, both originating from the same manufacturer, namely Moderna.

11. In the course of the inquiry, the Ombudsman received EMA's reply on the complaint and, subsequently, the comments of the complainant in response to EMA's reply. The

Ombudsman's inquiry team also inspected the two documents to which EMA had refused to give access, and the reply of the manufacturer that EMA had consulted.

Arguments presented

At the confirmatory stage

12. In his confirmatory application, the complainant argued that there is a public interest in verifying the quality of medicines authorised by the EU as well as of the raw materials used to manufacture them. He also raised a number of concerns pertaining mainly to one of the excipient components [8] used to store the vaccine. The complainant also asked for additional information on the authorising procedure.

13. In its confirmatory decisions, EMA said that the documents contain commercially confidential information, such as the identity of the materials used in the manufacturing of the vaccine, their quantity and other specifications. It added that the documents contain key elements of the manufacturing process that are novel and relevant not only to the manufacturing of the vaccine concerned but also possible similar vaccines. The information in the documents is the " *result of significant research and investment of human, time, and financial resources".* EMA also said that the structure of the documents reflects the number of manufacturing steps.

14. EMA concluded that access had to be refused, as disclosure of the documents would enable the manufacturer's competitors " *to benefit from this research and investment at no cost"* and to gain a competitive advantage. Disclosure would thus undermine the economic interest and the competitive position of the manufacturer concerned.

15. EMA also noted that the content of the documents does not address any of the health concerns raised in the complainant's confirmatory decision. EMA therefore replied to those concerns in a separate communication to the complainant.

16. As regards the proactive publication of information on authorised medicines, EMA referred to its relevant guidance [9] and said that it had published non-confidential information on the quality of the vaccine and on its assessment of the manufacturer's application for a marketing authorisation [10] .

Before the Ombudsman

17. In his complaint to the Ombudsman, the complainant stated that EMA was taking the side of the pharmaceutical industry and that it puts profits above patients' interests. The complainant also considered EMA's decision to be contradictory and in violation of the 'Helsinki Declaration' [11] , which provides for the publication of the results of studies on humans.

18. In reply, EMA clarified that the documents at issue do not concern studies on how a medicine affects humans, but rather constitute information on the starting materials for making a medicinal product. Accordingly, it said, the Helsinki Declaration is not applicable to these documents. EMA noted that it has, in fact, published proactively the studies on humans (clinical trials) that were submitted to it for the purpose of the authorisation of the vaccine at issue [12] , and that it has been publishing proactively all clinical data submitted for the purpose of the authorisation of COVID-19 medicines. [13]

19. The complainant replied, insisting on the application of the Helsinki Declaration.

The Ombudsman's assessment

20. The Ombudsman's inquiry team inspected the documents at issue. They contain information on the manufacturing process and the composition of the vaccine concerned. This includes, for example, information on the identity of the raw materials, their quantity and their concentration. The documents do not contain non-clinical or clinical data relating to the safety and efficacy of the vaccine. That information is contained in Modules 4 and 5 of the marketing authorisation application. EMA has proactively published the information from those modules.

21. When it refused to grant access to the documents, EMA relied on the need to protect the commercial interests of the manufacturer, saying that disclosure would give competitors insights into how to make the vaccine.

22. The EU courts have ruled that information on the quality and manufacturing of a medicinal product can be commercially confidential information. [14]

23. The vaccine at issue is based on a newly developed technology ('messenger-RNA' or 'mRNA') [15] . It is amongst the first vaccines against infectious diseases using this technology that have obtained a marketing authorisation. It appears that there are only a few companies worldwide that know how mRNA vaccines can be produced. It is therefore reasonable to consider that the information in the documents is novel and very valuable.

24. Having taken account of EMA's exchanges with the manufacturer concerned, the Ombudsman notes that EMA has verified with the manufacturer that this is indeed the case.

25. The Ombudsman therefore accepts EMA¤s argument that disclosure would allow a third party manufacturer to benefit from the commercial information of the manufacturer concerned. For example, a manufacturer of generic medicines could use the detailed information contained in the documents to produce their own drug. Makers of alternative vaccines could also gain insights from the information which might assist them in making their products.

26. The Ombudsman therefore considers that disclosure would very likely undermine the legitimate commercial interests of the manufacturer concerned.

27. However, the Ombudsman notes that this exemption can be overridden if there is a public interest in disclosure which is deemed more important than the interest invoked to justify not disclosing the document.

28. In this regard, the complainant has put forward that there is a public interest in being able to verify the quality of the medicines authorised by the EU, as well as of the raw materials used to manufacture them. The complainant, in that context, raised concerns regarding certain excipient components used for storing the vaccine.

29. As stated in a previous inquiry [16] , it is the Ombudsman's view that there are strong reasons to consider that there is an overriding public interest in disclosure of information relating to the safety and efficacy of medicines, that is, information contained in Modules 4 and 5 of applications for marketing authorisations, such as clinical study reports. This is because such information is aimed at demonstrating the safety and efficacy of a medicine and therefore has clear implications for the health of persons using the medicine. It is important that such information, and EMA's conclusions relating thereto, can be re-checked by outside experts. The public interest in disclosure aimed at enhancing public health will therefore normally defeat any claim of commercial sensitivity in relation to such information.

30. The same is not normally true for information relating to the **manufacturing process of a medicine** , such as the information in the documents at issue.

31. First, the information in the requested documents does not demonstrate if a medicine is safe and effective.

32. Second, the specific manufacturing information is commercially valuable.

33. All that said, if a member of the public were to put forward concrete reasons, aimed at protecting public health, to justify obtaining access to this information, it would need to be examined if, exceptionally, there was a public interest in disclosure that could be deemed more important than the interest in protecting the commercial interests of the manufacturer concerned.

34. The Ombudsman further notes that, as regards the vaccine at issue, EMA has proactively published extensive (non-confidential) information not only on the safety and efficacy [17] but also on the quality [18] of the vaccine. EMA has also provided the complainant with additional information addressing his specific concerns about certain excipient components, which shows that it has indeed taken these concerns into account when assessing the application for a marketing authorisation for the vaccine.

35. The Ombudsman however does recognise there is a legitimate political debate about equitable access to such vital vaccines during such a global pandemic. She notes the European Parliament has called for a temporary patent waiver in this area [19] . Such a political debate, while crucial, is however one that she as an independent Ombudsman cannot enter.

36. As regards the consultation of the manufacturer concerned by EMA, the Ombudsman notes that the public access rules require EMA to consult with the author of a document if, after carrying out its own individual assessment of the content of the documents, it has doubts as regards whether to disclose the document. [20] EMA thus acted in line with its legal obligations when it consulted the manufacturer.

37. EMA's initial assessment led it to conclude that certain information was merely of a presentational nature.

38. The manufacturer insisted that this information does give some insights into the manufacturing process of the vaccine, in particular if the reader has in-depth knowledge of the area. Whilst the public would gain little from the disclosure of this information, it is likely to be useful to competitors of the manufacturer.

39. EMA considered these views and arrived at the conclusion that no partial access was possible.

40. The Ombudsman's inquiry team has reviewed the text which EMA initially considered might be disclosed. The redacted text is mainly tables with the substantive content removed. The Ombudsman thus concludes that the view of EMA was reasonable. It would indeed be possible for a well-informed competitor to draw relevant conclusions regarding the manufacturing process from the text in question. For example, it would be able to estimate how many steps there were in a given process.

41. As regards the application of the Helsinki Declaration, EMA has stated that the documents at issue do not contain information about studies on humans (clinical trials). This is true - the documents at issue do not contain information about studies on humans. Rather, the documents contain a detailed "road-map" showing how to manufacture the vaccine at issue.

42. In light of all this, the Ombudsman considers that EMA was justified in applying the exemption for the protection of commercial interests to the documents in their entirety.
Conclusion
Based on the inquiry, the Ombudsman closes this case with the following conclusion:

There was no maladministration by the European Medicines Agency in refusing public access to the documents at issue.

The complainant and EMA will be informed of this decision **.**

Emily O'Reilly European Ombudsman

Strasbourg, 10/11/2021

[1] See:
https://www.ema.europa.eu/en/news/ema-recommends-first-covid-19-vaccine-authorisation-eu
(Comirnaty) and
https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-moderna-authorisation-eu
(COVID-19 vaccine (Moderna)).

[2] For more information, see:
https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/obtaining-eu-marketing-authorisa
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[3] The request is available at: https://fragdenstaat.de/anfrage/impfstoffe/ .

[4] In accordance with Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32001R1049 .

[5] The CTD is a structured document that forms part of an application for a marketing authorisation and consists of five Modules. Module 3 concerns the quality of the product concerned.

[6] In accordance with Article 4(2), first indent of Regulation 1049/2001.

[7] See
https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-

[8] An excipient is a component of a medicine other than the active substance, added in the formulation for a specific purpose. For example, they can function as carriers or protectants of an active substance (such as a vaccine).

[9] See:
https://www.ema.europa.eu/en/documents/other/heads-medicines-agencies/european-medicines-agency-gui
(This guidance provides under point 3.1: *"A general principle regarding quality and manufacturing information is that detailed information is commercially confidential but general information should be disclosed."*

[10] See EMA's assessment report ('EPAR') of 11 March 2021:

https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna
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[11] WMA Declaration of Helsinki - Ethical Principles for Medical Research involving Human Subjects:
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involvi
.

[12] Available at: https://clinicaldata.ema.europa.eu/web/cdp/home

[13] See overview of EMA's exceptional transparency measures for COVID-19 medicines:
https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-
.

[14] Judgment of the General Court of 25 September 2018, *Amicus Therapeutics v EMA* :

https://curia.europa.eu/juris/document/document.jsf?text=&docid=206064&pageIndex=0&doclang=EN&mode
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[15] See:
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html .

[16] See decision on the partial refusal of the EMA to give public access to studies related to the approval of a medicinal product (case OI/3/2014/FOR):
https://www.ombudsman.europa.eu/en/decision/en/68107 .

[17] See, for example, footnote 12.

[18] See, for example, chapter '2.2 Quality aspects' of the EPAR (footnote 10).

[19] See:
https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-calls-for-temporary-cov

[20] In accordance with Article 4(4) of Regulation 1049/2001.