EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Frag den Staat

Germany

EMA/541145/2021
Stakeholders and Communication

Dear Requester,

Subject: **Comirnaty (COVID-19 mRNA vaccine (nucleoside-modified)) and Spikevax (COVID-19 mRNA Vaccine (nucleoside-modified) - ASK-82701 (Batch 4) - Release letter to the requester - Confirmatory application (appeal)**

We refer to your confirmatory application (hereafter referred to as "appeal") of 21st April 2021 appealing against the refusal of the European Medicines Agency (the Agency) to grant access to the documents concerning Comirnaty (COVID-19 mRNA vaccine (nucleoside-modified)) and COVID-19 Vaccine Moderna (COVID-19 mRNA Vaccine (nucleoside-modified)) as per our letter of 15th March 2021 with reference number EMA/82015/2021.

Your appeal has been handled in accordance with Article 8(1) of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (the Regulation)[1], and Section 4 of the Annex to the "*European Medicines Agency policy on access to documents - POLICY/0043*" (the Agency policy)[2]. Moreover, it has been assessed pursuant to Article 4 of the Regulation, Section 4.1.1 of the Agency policy and Section 1 of the Annex to the same policy.

As it concerns a large number of documents, and the Agency has to examine each document individually to ensure that no private or public interests are being compromised, we are not in a position to fulfil your request immediately. Therefore, the Agency endeavours to provide you with sets of documents at certain intervals. This decision is in line with the principle set out in our policy which states the Agency will apply the principle of proportionality in order to avoid the core business tasks of the Agency and its performance being jeopardised by the administrative workload related to activities conducted by the Agency in accordance with the Regulation.

The **fourth batch** includes the following documents of Appendix 3.2.A.2 of Comirnaty (COVID-19 mRNA vaccine (nucleoside-modified)):

- adventitious-agents-puurs
- adventitious-agents-2
- adventitious-agents-3
- adventitious-agents-4

Having assessed your appeal, the Agency considers that access to the documents requested should be granted.

1 OJ L 145, 31.5.2001, p. 43–48
2 EMA/729522/2016 "*European Medicines Agency policy on access to documents - POLICY/0043*" of 4 October 2018, available at https://www.ema.europa.eu/documents/other/policy/0043-european-medicines-agency-policy-access-documents_en.pdf.

However, the documents have been redacted as follows:

In accordance with Article 4(1) (b) of the Regulation and the European Union legislation regarding the protection of personal data, all protected personal data was redacted in order to avoid that the disclosure of the document would undermine the privacy and integrity of any individual;

In accordance with Article 4(2) 1st indent of the Regulation, details related to raw materials and information related to the raw material vendor(s) were redacted in order to avoid that the disclosure of the document would undermine the protection of commercial interests of the marketing authorisation holder.

The EMA policy on access to documents (related to medicinal products for human and veterinary use)[3] defines commercially 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". EMA has ascertained that the details related to Comirnaty raw materials and the identity of Comirnaty raw material vendor(s) are not in the public domain or publicly available.

A release by EMA of details related to the choice of raw materials and to the identity of raw material vendor(s) would enable a competitor to optimize their own manufacturing processes and raw material supplier network in the competitive and innovative market for RNA vaccines. This knowledge would help competitors to avoid costs and delays associated with having to develop their own processes. By avoiding delays, this would enable shorter development times allowing faster emergence of competitor vaccines, and thus a faster erosion of the marketing authorisation holder's market share.

Please note that the above position is aligned with the provisions of the "HMA/EMA guidance document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation application: Release of information after the granting of a marketing authorisation".[4] In particular, section 3.1 explains that, as a general principle, detailed quality information is commercially confidential.

The Agency has also conducted an assessment of your request with a view to identifying the presence of an overriding public interest in disclosing the elements of information that have been redacted. It has not been possible, however, to ascertain the presence of such an interest that could override the protection of the interest identified under Article 4(2), 1st indent of the Regulation.

In this regard, should you wish to avail yourself of the remedies available under Union law against this decision, please be informed that you can bring a complaint before the European Ombudsman, pursuant to Article 228 of the Treaty on the Functioning of the European Union (TFEU). You can also institute legal proceedings before the General Court of the European Union in accordance with Article 263 of the TFEU.

All the documents concerned will be sent to you via Eudralink no sooner than 10 working days after the legal consultation stage with the third party has been finalised. Please note that these documents are made available to you in order to provide you with access in accordance with the Regulation and the Agency policy.

[3] EMA/729522/2016 "European Medicines Agency policy on access to documents - POLICY/0043" of 4 October 2018, available at https://www.ema.europa.eu/documents/other/policy/0043-european-medicines-agency-policy-access-documents_en.pdf.

[4] In this respect, see: the HMA/EMA guidance document on the identification of CCI and personal data within the structure of the MAA – release of information after the granting of a MA, pages 4, 5 and 36. Available at: https://www.ema.europa.eu/en/documents/other/heads-medicines-agencies/european-medicines-agency-guidance-document-identification-commercially-confidential-information_en.pdf.

In that regard, please visit the Agency's public website to know more about the applicable copyright and limited reproduction notices.

Please note that, according to Article 16 of the Regulation, the release of the requested documents in accordance with this Regulation is without prejudice to any existing rules on copyright which may limit a third party's right to reproduce or exploit released documents. The European Medicines Agency shall assume no liability for any unlawful or unauthorised use, disclosure or reproduction of these documents.

If you have any queries on the enclosed, please do not hesitate to contact the Access to Documents Service, by submitting an online request form or by sending your request to AskEMAATD@ema.europa.eu. Please use the ASK Procedure Number mentioned in the subject line in any correspondence related to this request.

In case this letter becomes publicly available, please redact personal data such as the first name and surname of the sender, e-mail address as well as any other personal data, as relevant. The Agency considers this information to be protected personal data in the meaning of Article 3(1) of Regulation (EU) No 2018/1725 and Article 4(1) of the General Data Protection Regulation EU 2016/679. Personal data is information that permits to identify a natural person.

Yours sincerely,

Head of Documents Access and Publication Department
(Signature on file)

Head of Legal Department
(Signature on file)