EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr. [redacted]
Frag den Staat
Germany
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EMA/325497/2021
Stakeholders and Communication

Dear Mr. [redacted],

Subject: **Comirnaty (COVID-19 mRNA vaccine (nucleoside-modified)) and COVID-19 Vaccine Moderna (COVID-19 mRNA Vaccine (nucleoside-modified)) - ASK-82701 (Batch 1)- 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.

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

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 **first batch** includes the following document:

- 3.2.S.2.3 control-of-materials-raw.

However, the document has been redacted as follows:

In accordance with Article 4(2) 1st indent of the Regulation, commercially confidential information, such as the identity of the materials including the raw materials and consumables used in the

[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.

manufacturing of the active substance, quantitative information concerning the raw materials and specifications of materials and consumables used in the manufacturing process of the active substance, as well as detailed information on quantitative acceptance criteria established for raw materials was redacted in order to avoid that the disclosure of the document would undermine the protection of commercial interests of a natural or legal person.

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.

The document 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 this document is made available to you in order to provide you with access in accordance with the Regulation and the Agency policy.

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 document 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.

Please note that the content of this document, including the redacted parts, does not directly address any of your concerns and requests for clarification expressed in the six questions asked as part of your confirmatory application. We will reply to the questions that you posed in the confirmatory application shortly by a separate communication.

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 as mentioned above 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)