EMA/473966/2023
Stakeholders and Communication

Dear Requester,

Subject: **Vaxzevria (COVID 19 Vaccine (ChAdOx1 S [recombinant])) - Release letter to the requester**

Thank you for your request for access to documents, in which you apply for copies of the following documents concerning the above-mentioned product, in particular:

- PSURs (including appendices) and their corresponding Assessment Reports.

Your request has been handled in accordance with Article 7 of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (the Regulation)[1] and Section 3 of the Annex to the "*European Medicines Agency policy on access to documents - POLICY/0043*"[2] (the Agency Policy). Moreover, it has been assessed pursuant to Article 4 of the Regulation and Section 4.1.1 of the Agency policy and Section 1 of the Annex to the same policy.

As it concerns a number of documents, and the Agency has to assess 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. **If at any point you consider that the documents you received in the previous batches satisfy your request and that you therefore no longer wish to receive the remainder of the documents originally requested, we would appreciate it if you could inform the coordinator accordingly.**

This batch includes the following document concerning Vaxzevria:

- pbrer-29-jun-2022-to-28-dec-2022-eu Appendix 1-2.

Based on the above assessment, the Agency considers that access to the requested document in this batch should be granted.

However, the document has 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(s) would undermine the privacy and integrity of any individual.

You may submit a confirmatory application (hereafter referred to as "appeal") in writing against this decision to the European Medicines Agency, within 15 working days of the release of the document. Should you wish to do so, you are kindly invited to provide reasons against this decision to redact

[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.

parts of the document at this stage, which you believe should be taken into account by the Agency in adopting a final decision.

Once your appeal has been received, you will be informed of the outcome within 15 working days (extendable in exceptional circumstances), either granting you access to redacted parts of the document or confirming refusal of access. In the latter case, you will also be informed of any further appeal routes open to you to consider.

The appeal should be submitted using the online request form, available on the European Medicines Agency website, under the following location: https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency.

Please use the ASK Procedure Number mentioned in the subject line in any correspondence related to this request.

Please find attached the document concerned. 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.

If you have any queries on the enclosed, please do not hesitate to contact the Access to Documents Service at AskEMAATD@ema.europa.eu.

Yours sincerely,

pp. Poulimenou Despina

Digitally signed by Poulimenou Despina
Date: 2023.10.31 15:19:37 +01'00'

Head of Access to Documents Service
Documents Access and Publication Department