

EMA/244285/2021 Stakeholders and Communication

Dear Requester,

Subject: Vaxzevria COVID-19 Vaccine AstraZeneca ASK-81593 Letter to the requester; document(s) not held by the Agency

Thank you for your request for access to documents received on 6 April 2021, for which the procedure was initiated on 8 April 2021, in which you apply for a copy of the following documents concerning Vaxzevria, in particular:

• Correspondence with authorities of the Federal Republic of Germany regarding the restriction of vaccinations of under-60-year-olds with the AstraZeneca vaccine.

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 regrets to inform you that the documents you requested are not held by the Agency. We are therefore not in a position to provide you with access to these documents.

After conducting an extensive search in the documents held by the Agency, we concluded that there was no correspondence sent or received by the EMA with the Federal Republic of Germany regarding the restriction of vaccinations of under-60-year-olds with the AstraZeneca vaccine.

As provided for in Article 2(3) of the Regulation, the right of access, as defined in that Regulation, applies only to existing documents that are held by the Agency.

In light of the above, the Agency is not in position to satisfy your request.

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). Alternatively, you can institute legal proceedings before the General Court of the European Union in accordance with Article 263 of the TFEU.

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

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.



¹ OJ L 145, 31.5.2001, P. 43-48

The on-line request form is available at EMA's website: https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency

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 Document Access and Publication Service Stakeholders and Communication Division (Signature on file) Legal Administrator Legal Department (Signature on file)