Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

6 December 2023

Dear [redacted]

FOI 23/774

Thank you for your email of 16 October 2023 where you requested the following:

'The following post-authorization records in the possession of MHRA concerning the Vaxzevria [formerly AstraZeneca] COVID-19 vaccine1 and/ or COVID-19 vaccine ChAdOx1 S [recombinant]:

1) Cumulative Analysis of Post-Authorization Adverse Event Reports

2) Periodic Safety Update Reports (PSURs).'

Thank you for your patience while we considered the public interest test. We hold some of the information requested as outlined below.

Periodic safety update reports (PSURs) are pharmacovigilance documents submitted by Marketing Authorisation Holders (MAHs) at defined time points during the post-authorisation phase. The main objective of a PSUR is to present a comprehensive, concise and critical analysis of the risk-benefit balance of the medicinal product taking into account new or emerging information in the context of cumulative information on risks and benefits. For further information about PSURs, please see the Guideline on good pharmacovigilance practices (GVP): Module VII – Periodic safety update report available at: Good pharmacovigilance practices | European Medicines Agency (europa.eu)

The MHRA does not hold a document that contains a single cumulative analysis conducted by the MHRA of post-authorisation suspected adverse reaction reports received in association with COVID-19 vaccine AstraZeneca. However, you may be interested in the MHRA's Coronavirus vaccine summary of Yellow Card reporting which summarises information received by the UK's spontaneous suspected adverse drug reaction reporting system, the Yellow Card scheme, as well as any safety investigations carried out by the MHRA under the COVID-19 Vaccine Surveillance Strategy for COVID-19 vaccines deployed in the UK including COVID-19 vaccine AstraZeneca. Interactive COVID-19 vaccine reports are also available that contain a complete listing of all

suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for individual COVID-19 vaccines.

Cumulative analyses of post-authorisation safety data for COVID-19 vaccine AstraZeneca conducted by the MAH are contained within the PSURs for Vaxzevria. We can confirm that the MHRA holds copies of the following PSURs for this vaccine:

- **PSUR 1** 29 December 2020 to 28 June 2021
- **PSUR 2** 29 June 2021 to 28 December 2021
- **PSUR 3** 29 December 2021 to 28 June 2022
- **PSUR 4** 29 June 2022 to 28 December 2022

PSUR 1 and **PSUR 2** are provided with this response. Information that has been redacted is exempt under Section 40 (Personal Information). Section 40 provides that personal information may be exempt from release where to do so would contravene data protection principles.

PSUR 3 and **PSUR 4** are exempt from release under Section 22 (Information intended for future publication) as the information you have requested is due to be published by the European Medicines Agency (EMA) shortly (*please see https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health-emergency-international-concern-2020-23/transparency-exceptional-measures-covid-19-medicines*). Section 22 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. However, we consider that the public interest will be better served by not releasing the information as this will be made available by the EMA in the near future.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the agency who has not previously been involved in your request. If you wish to pursue that option, please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
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