Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

28th December 2023

Dear [redacted]

RE: FOI 23/935

Thank you for your email dated 30th November 2023, where you requested disclosure of the following data about Yellow Card reports and the AstraZeneca vaccine under the Freedom of Information (FOI) act:

> *Between 1 January 2021 and 28 March 2021, please can you tell me:*
>
> *1) How many Yellow Card reports did the MHRA receive of suspected adverse reactions to the Oxford/AstraZeneca vaccine in which the patient died shortly after vaccination?*
> *2) How many of these reports has the MHRA followed up with healthcare colleagues to request further information?*
> *3) Of these follow up requests, how many have gone unanswered?*

The MHRA publishes reports of suspected adverse reactions received through the Yellow Card scheme on our website including COVID-19 vaccine reports. The COVID-19 vaccine reports are interactive, meaning users can filter the data displays for information they are interested in, including whether the report included a fatal outcome. Please note, a list of the recognised adverse effects of the COVID-19 vaccines is provided in the information for healthcare professionals and the recipient information here.

For the specific dates you are interested in, the MHRA have received 461 UK spontaneous suspected adverse reaction reports with COVID-19 vaccine AstraZeneca between 1 January 2021 and 28 March 2021. Please be aware that this includes all reports regardless of the time between vaccination and fatal outcome. Reports received via the Yellow Card scheme can be reported at any time after a suspected side effect has occurred. Additionally, the time frame from when the patient received the vaccine to experiencing a suspected side effect is not always provided by the reporter. We review all reports of death regardless of the time to onset from receiving a medicine or vaccine. This figure may meet your request however if you would like information specifically where the patient has died *shortly after vaccination,* please define what time frame you would like us to consider here, and we will take forward as a new request. Please note we may have to review reports individually to calculate this information, which may engage section 12 considerations depending on the time that would be needed for manual review.

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Further to points 2 and 3 of your request, we intend to publish information relating to the number of reports with a fatal outcome for COVID-19 vaccines where the MHRA has contacted the reporter for further information; including the number of these where responses have been received in return. As we plan to publish this information, we consider that your request is covered by Section 22 of the Freedom of Information Act (information intended for future publication) and the information you have asked for is therefore exempt from disclosure. Section 22 is a qualified exemption which means we have considered whether there is a greater public interest in releasing the information requested or withholding it. We recognise there is strong interest in seeing this data and accept it should not be withheld. This information is intended to be published by the end of February 2023.

To provide some additional background, you may know that we acknowledge receipt of each report, and our team of safety experts follow up for additional information as necessary, based on the completeness, severity and clinical details provided in the report. We actively follow up Yellow Cards of special interest including those with a fatal outcome for any information that would benefit in our assessment and encourage all reporters to send relevant updates on their reports.

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,
Vigilance and Risk Management of Medicines Division