Medicines & Healthcare products
Regulatory Agency

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[redacted]

15 March 2024

Dear [redacted]

FOI 24/167

Thank you for your email dated 18 February 2024 in response to the clarification sent you on 14 February 2024 pertaining to your Freedom of Information request.

Your original FOI 24/062 requested, *'the anonymised data that it holds, and which has been disclosed to AstraZeneca, Pfizer and Moderna regarding doses, dates and deaths relating to Covid 19 vaccines'*.

You were requested to provide some clarification on the information you wish to receive and subsequently responded to request, *'communications with enclosures sent to Astra Zeneca, Pfizer and Moderna that you refer to'.*

The response provided to you for this clarified request under FOI 24/097 again asked for further information and clarification around the request made, specifically if you wanted any email communications with attachments that was sent from an MHRA email address to AstraZeneca, Pfizer or Moderna concerning the COVID-19 vaccines. It also included suggestions for a refined request under section 16 of the FOIA. You since responded to this with the following,

In my original email I requested
'the anonymised data that it holds, and which has been disclosed to AstraZeneca, Pfizer and Moderna regarding doses, dates and deaths relating to Covid 19 vaccines', and for your refinement dated 29 January 2024 which requested disclosure of 'communications with enclosures sent to Astra Zeneca, Pfizer and Moderna that you refer to'.

How are the documents sent to the pharmaceutical companies referred to? Was it a one off or on a continual basis?

If a one off, the correspondence, whether email or letter with enclosures. If on a continual basis, then the last set of correspondence.

Unfortunately, based on your request it is still unclear what information you wish to receive and whether we can fulfil your request based on the information we hold. Therefore, below is some explanation to provide some background that will help you understand what we may be able to provide under the FOIA.

Reviewing the wording of your request suggests this may relate to a recent parliamentary debate and a separate FOI request that was made to a different public authority, the UKHSA, regarding 'data on dosage, dates and deaths for COVID-19 vaccines'. If this is the data you are specifically interested in, we would suggest that you may wish to reach out to the UKHSA with a request. They can be contacted here:

InformationRights@UKHSA.gov.uk

In terms of data that the MHRA hold, you may know that we receive reports of adverse drug reactions (ADR) via the Yellow Card scheme from members of the public and healthcare professionals. Pharmaceutical companies also have a legal obligation to send reports to us.

ADR reports may hold information on the date a vaccine was administered, or they may include a fatal outcome. However, we would only hold this information if a patient had experienced a suspected adverse reaction, and a report was submitted to the MHRA.

The MHRA does not hold information on the number of patients that have a COVID-19 vaccine listed as a cause of death on their death certificate, as this falls outside of our remit. The MHRA do not determine causality of individual reports, and this includes reports of fatalities. You may wish to contact the Office for National Statistics (ONS) here FOI.Team@ons.gov.uk as they may hold this information.

Additionally, whilst we consider vaccine uptake as part of our analysis of the safety of vaccines, information on the number of individuals administered a vaccine is not held by the MHRA. This information is held by the UK Health Security Agency (UKHSA).

UK ADR reports (excluding those from Northern Ireland) are subject to Part 11 and Schedule 12A of the Human Medicines Regulations 2012, which requires MHRA to share all Yellow Card reports about suspected adverse reactions to medicines with the World Health Organisation's Uppsala Monitoring Centre and pharmaceutical companies who hold a license for the medicines or vaccine that has been included in a report. The transmission of reports takes place daily for all reports processed through our internal database on the same day. Reporter details are not disclosed in the reports that are transmitted.

If you wish to request this data, we should advise that, whilst we hold ADR reports, the provision of copies of reports is exempt from release under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI Act. Supplying you with this information could lead to patient or reporter identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in

relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme.

We should also advise that if you wished to make a request for all ADR reports, this would require such significant retrieval and review that it would be considered a 'disproportionate' burden and the request refused; we have recently received a decision notice from the Information Commissioner about a request which asked for copies of all reports relating to fatalities, which found that this request was correctly refused.

We can advise that if you are interested in *anonymised* adverse reaction data for COVID-19 vaccines, which is drawn from the ADR reports, then this is already publicly available. All reports received via the Yellow Card scheme and from pharmaceutical companies for COVID-19 vaccines, are published on our website via COVID-19 vaccine reports. These are summary graphs and tables that are interactive, allowing users to filter the data to view information that is of most interest to them.

In accordance with Section 16 of the FOI, concerning the provision of advice and assistance to those requesting information under FOI, you are advised to narrow the scope of your request and, once you have had the opportunity to consider our explanation of the information held by the MHRA, to provide further clarification on the exact information you wish to receive. As stated in FOI 24/097, for example, you could narrow a request to focus on one vaccine and a specific type of information, subset of data or safety topic. We hope this information has been helpful and that the publicly available data or the suggestion of referral to other government Agencies is useful in relation to your request.

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,

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