Medicines & Healthcare products Regulatory Agency

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

[redacted]

29 January 2024

Dear [redacted]

FOI 24/064

Thank you for your Freedom of Information request dated 21 January 2024 in which you requested from the MHRA information on *'Covid vaccine dosage, dates and deaths. This has been released to Pfizer, Moderna plus others.'*

The MHRA continually monitors safety during widespread use of a vaccine. For the COVID-19 vaccines specifically, we developed a proactive strategy to do this. Part of our monitoring role includes reviewing reports of suspected side effects. Any member of the public or health professional can submit suspected side effects through the Yellow Card scheme.

As outlined in our Privacy Policy, UK reports received via the Yellow Card scheme (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 potential side effects to medicines with the World Health Organisation's Uppsala Monitoring Centre and pharmaceutical companies that hold a licence for that medicine or vaccine. As such, any Adverse Drug Reaction (ADR) reports received via the Yellow Card scheme concerning the Pfizer, Moderna or other COVID-19 vaccines would have been sent to the respective pharmaceutical company.

Information surrounding what has been reported for the COVID-19 vaccines is publicly available on our website. Here you can find a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for all COVID-19 vaccines. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. As such, some of the anonymised data we have shared with Pfizer, Moderna or other pharmaceutical companies is already publicly available on our website.

The MHRA do hold other information that has been disclosed to Pfizer, Moderna and other pharmaceutical companies regarding doses, dates and deaths relating to COVID-19 vaccines. This information is held in several different repositories within MHRA which would require separate searches to identify documents of potential interest, followed by review of retrieved documents to determine whether they contain relevant information.

Based on the breadth of information requested, identification of all information that may be relevant to your request would involve the use of a Discovery Search Tool. Based on experience in using this tool to perform Agency-wide searches for documents, the time taken to set up and refine the search criteria, then extract and review the results to identify relevant records, would take in excess of 24 hours. Therefore, this information is exempt from disclosure under Section 12 of the Freedom of Information (FOI) act.

Section 12 of the FOI Act specifies that a public authority may refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

In accordance with Section 16 of the FOI Act, concerning the provision of advice and assistance to those requesting information under FOI, you are advised to narrow the scope of your request. For example, to one vaccine and a specific type of information, subset of data or safety topic. However, please note that other exemptions may affect release of the requested data. For example, due to data protection laws, we are unable to provide details that may identify a particular patient or reporter. As such, information such as date of death is exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI Act.

In order to refine your request, we suggest you review the publicly available information on our website referenced earlier in this response and submit a new request taking into account the advice given above. New requests should be sent to MHRACustomerServices@mhra.gov.uk.

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
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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
Wilmslow
Cheshire
SK9 5AF