Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

31st May 2023

www.gov.uk/mhra

Dear [redacted]

FOI 23/370

Thank you for your email dated 25 May 2023, where you requested disclosure of the following information under the Freedom of Information (FOI) act:

For all fatal Yellow Card reports relating to the COVID-19 Vaccine AstraZeneca:

a) How many reports from reporters working in primary, secondary or tertiary care have the MHRA followed up to request further information?
b) How many of those follow ups for further information have not been unanswered?

I can confirm that the MHRA holds the information that you have requested. However, we have also determined that the information is exempt under Section 12 of the Freedom of Information (FOI) Act and we cannot process your request any further. Section 12 of the Act allows public authorities to 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.

Although we hold information on whether a Yellow Card report has been followed up and whether a response has been received, this information is not easily extractable. The MHRA has received 668 Yellow Card reports associated with COVID-19 vaccine AstraZeneca that reported a fatal outcome, which were reported by a healthcare professional. An individual would need to locate these 668 reports, before manually opening each Yellow Card report to check whether a request for further information was sent and whether a response was received. Checking a single Yellow Card report for evidence of follow up, and a subsequent response, would take a minimum of 120 seconds and in some instances longer. In addition to this, due to the volume of reports that fall in the scope of this request, the data included within the response would require review by more than one colleague to ensure the information provided was accurate. Following manually checking each report, multiple colleagues would then have to input into the draft response. Completing the process outlined above would mean an individual would spend over 24 hours locating, retrieving, and extracting the information for your request, therefore exceeding the time limit defined under the FOI act.

Medicines & Healthcare products
Regulatory Agency

To provide some background, 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 for any information that would benefit in our assessment and encourage all reporters to send relevant updates on their reports. Additionally, we follow-up all reports with a fatal outcome to enquire whether a post-mortem was conducted and to request a copy of the report.

Unfortunately, we have been unable to fulfil 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,

FOI Team,
Safety and Surveillance

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