Medicines & Healthcare products Regulatory Agency

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

[redacted]

29th November 2023

Dear [redacted]

FOI 23/846

Thank you for your request dated 01 November 2023 where you asked for the following information under the FOIA:

- *what proportion of the 1,415 reports you followed up on and whether, in each case, medical notes were examined?*

If the request breaches the cost limit:

- *limit my request to 4th January 2021 to 31st May 2021.*
- *If it is possible, please B) provide the date the report was made and the date the medical records were requested. If B takes me over the cost limit, please ignore that part of the request.*

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 for additional information and whether a response has been received, thus meaning the additional information reviewed, this information is not easily extracted. The MHRA has received 1417 UK spontaneous suspected adverse reaction reports for COVID-19 AstraZeneca vaccine which include a fatal outcome. 1276 of those reports were received directly via the Yellow Card scheme. Reports received directly to the scheme are from members of the public or healthcare professionals, and it is the MHRA's duty to follow-up these reports where necessary. We also receive reports of adverse reactions indirectly via

pharmaceutical companies. For these reports, pharmaceutical companies have a legal obligation to follow-up for further information where necessary with the original reporter.

An individual would need to locate the 1276 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 2 minutes and in some instances longer based on a sampling exercise. Therefore, the time taken would be 42 hours and 30mins for your request at a minimum. You have subsequently suggested that we limit your request to reports received within a particular period if section 12 applies. Between 04 January 2021 and 31 May 2021, the MHRA received 829 UK spontaneous suspected adverse reaction reports directly for COVID-19 AstraZeneca vaccine which include a fatal outcome. Based on the minimum 2-minute calculation above, this suggested refinement would still breach the 24-hour FOI time limit at 27 hours and 36 minutes. Please note that we have provided some general advice about section 12 below.

We can provide advice and assistance about refining a new request so that the information can be retrieved within the appropriate limit. We should first advise that low level dates may be subject to section 40 and 41 of the FOIA. 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. Low level dates alongside current available data published on our website may lead to patient or reporter identification.

We would therefore suggest focusing any refined request on higher level data. If you wish to focus on follow-up information for the COVID-19 AstraZeneca vaccine, we would be able to retrieve the total number of reports with a fatal outcome that were followed up for additional information.

However, we note that you have at least one other request ongoing at the moment and so should make you aware that the time needed for that may be taken into account under section 12(4)(d) if further requests are also submitted. In general, we would recommend allowing one request to conclude prior to submitting a further request. We also wanted to make you aware that if it appears one or more requesters are working together and making a number of requests for related information, there are provisions within section 12(4)(d) which allow for the aggregation of requests for the same or similar information, from one or more requesters, if these are made within a period of 60 working days and the requesters appear to be acting in concert.

Additionally, we would like to engage with you and your colleagues in order to understand the information which would be of greatest importance to you. We will then be able to outline the types of information which are retrievable within the appropriate limit. We can also offer advice regarding the scheduling of any subsequent refined requests in order to avoid aggregation and further refusals based on the appropriate limit.

We would also advise on a broader point about section 12 of the FOIA, as this may assist in helping you to frame your requests. We should explain that when section 12 applies, it applies to the whole request. This will include any further suggestions for narrowing included within the request itself. There is no requirement in the FOIA for a public authority to work up to the cost limit, or to retrieve information up to the cost limit if it is estimated that the request

will exceed the appropriate limit; if section 12 applies, the ICO recommends that the whole request should be refused. These points are explained in the ICO's guidance on section 12:

https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/section-12-requests-where-the-cost-of-compliance-exceeds-the-appropriate-limit/#:~:text=Section%2012%20%281%29%20allows%20you%20to%20refuse%20to,staff%20time%20in%20searching%20for%20the%20requested%20information.

I hope that the explanation provided is helpful, but 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