Medicines & Healthcare products
Regulatory Agency

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

27 July 2023

Dear

FOI 23/479

Thank you for your email dated 20 June 2023, where you asked:

> *How many Yellow Card reports of adverse events of special interest has the MHRA followed up?*

Firstly, please accept my apologies for the delay in responding to your request. I can confirm that the MHRA does hold some of the information that you have requested. However, we have also determined that the information is exempt under Section 12 of the Freedom of Information 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, this information is not easily extractable. The MHRA have received over 26,000 Yellow Card reports of adverse events of special interest for the COVID-19 vaccines. An individual would need to manually open each Yellow Card report to check whether a request for further information was sent, and subsequently 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.

Completing the process outlined for each Yellow Card report 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.

To assist with taking forward a refined request, we can advise that the Information Commissioner has recently issued a decision notice which concerned very similar information, and this considers the retrieval of adverse event follow-up information in some detail. This is available on the Information Commissioner’s website at the following link:

https://ico.org.uk/media/action-weve-taken/decision-notices/2023/4025975/ic-235833-s6h9.pdf

As the decision notice explains, we are currently in direct discussion with the requester in that case with a view to determining and agreeing what information they are most interested in, and which could be provided within the 24 limit of FOI:

> *33. MHRA explained that it is currently handling a number of requests from the complainant and, rather than simply advising them to narrow the scope of their request, it would like to engage with them directly in order to understand the information which is of most interest to them. It also wishes to take the opportunity to outline the types of information which are retrievable within the appropriate limit, and to offer advice regarding the scheduling of any subsequent refined requests in order to avoid aggregation and further refusals based on the appropriate limit.*

We can see there is a strong cross-over between the subject of your requests for Yellow Card follow-up information and those referred to in the Information Commissioner's decision notice, and we believe that the outcome of our engagement with the requester in that case – both in terms of the types of information which may be retrievable within the appropriate limit, and the scheduling of requests for similar information to avoid aggregation and further refusals under Section 12 – could be very relevant for your own requests for this type of information. Our FOI Manager Lou Lander is working on this; if you would like to discuss this further with her, you may contact her here: lou.lander@mhra.gov.uk.

Unfortunately, we have been unable to fulfil your request on this occasion, 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