Medicines & Healthcare products Regulatory Agency

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E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

19 April 2024

MHRA reference: FOI 24/278

Dear [redacted]

Thank you for your information request, which we received on 20 March 2024. Following receipt of our response to FOI 24/203, in relation to this information:

"If you are referring to assessments made by the MHRA, it is important to be aware that while Yellow Card reports with a fatal outcome are reviewed by MHRA assessors to determine which additional information will be requested from the reporter, in the assessment of a safety issue, Yellow Card reports are evaluated cumulatively, alongside other information and evidence. Causality is not assigned to individual reports, nor is an assessment recorded for individual reports. All the information is assessed on a continual basis to see whether a new side effect is identified, or the safety profile has changed. In addition, we also apply statistical techniques which can tell us if we are seeing disproportionately more cases than we would expect to see based on what is known about background rates of illness in the absence of vaccination. If it is considered that a medicine may be causing the side effect, we will look at the risk of the side effects in relation to its benefits to consider whether regulatory action is needed."

you asked:

Can you please supply me with all documents that contain the statistical analyses (proportionality analyses) that you refer to in FOI 24/203, carried out my [sic] MHRA?

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

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We confirm that we hold the information you have asked for; however, we consider that the information is exempt from disclosure because Section 12 of the FOIA applies.

Section 12 allows public authorities to refuse requests where the cost of dealing with them would exceed the “appropriate limit” in the FOIA; for central government departments this is set at £600. This represents the estimated cost of one person spending 24 working hours to determine if the requested information is held, and then to locate, retrieve and extract it. We will explain how compliance with your request would exceed the appropriate limit and why section 12 applies in this case.

The statistical techniques we refer to in the response to FOI 24/203 are explained in a Commission on Human Medicines Expert Working Group report on COVID-19 vaccine safety surveillance published here, in particular, the ‘observed vs expected’ analysis. These analyses were performed numerous times for various topics since the deployment of the COVID-19 vaccines.

We note that the Freedom of Information Act grants access to information rather than ‘documents’, and this means that your request captures all information on the topics you have specified, whether it forms a specific report on the subject or is held as it forms one part of a much broader document including additional information. This means that your request has an extremely broad scope; it requires us not simply to identify key information on the specified subject, but rather to fully comply with the wording of request, the relevant information must include every piece of information held by the public authority that falls within scope.

To retrieve information for all parts of your request, we would need to review a range of broader documents in order to retrieve and extract the relevant information within them (fatal reports), for example all our assessment reports concerning 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.

When section 12 of the FOIA applies, we also provide advice to assist you in making a new, narrowed request for a smaller amount of information. In this case, we advise that you could narrow your request by asking about a specific safety topic and timeframe.

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If you view the summaries on the links below and scroll down the page, you will be able to see the safety topics:

https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting--2

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk.

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

FOI Team
Safety & Surveillance
Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF