Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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[redacted]

24 October 2023

Dear [redacted]

FOI 23/703

Thank you for your email of 25 September 2023, where you requested the following under the Freedom of Information Act:

> *I request disclosure of all emails and all other internal communications, anonymised but not otherwise redacted, relating to or making any reference to the study by Fraiman, J., et al., entitled 'Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults' published in the journal Vaccine. The pre-print was published in June 2022 so please start your search from this month to the current time.*

On review of your request, we have considered it to be exempt under Section 12 of the Freedom of information Act. 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.

We understand that you sought advice from our FOI Manager about whether this request could be submitted alongside your previous request FOI 23/634, as you were concerned about the time that might be needed for the retrieval of the two requests, and you were advised that while an estimate couldn't be given, it was recommended that in general it was best to submit only one request at a time.

We acknowledge that you have followed this advice and did not proceed with the new request until FOI 23/634 was completed. However, the two requests have both been submitted within the same 60 day period, being made on 25 August 2023 and 25 September 2023, and we consider that the time needed to locate and retrieve information for the new request should be aggregated with the time spent in retrieving information for your previous request FOI 23/634. This is section 12(4)(d) of the FOI Act, which with section 5 of the 'Fees Regulations 2004' says that where 2 or more requests are received by a public authority within any period of 60 consecutive working days from one person, and which relate to any extent for the same or similar information, then the estimated cost of complying with these requests may be aggregated. The ICO's guidance says that "A public authority needs to consider each case on its own facts but requests are likely to relate to the same

or similar information where, for example, the requestor has expressly linked the requests, or where there is an overarching theme or common thread running between the requests in terms of the nature of the information that has been requested." As with the previous request, 23/634, this request continues the overarching theme of serious adverse events following COVID-19 vaccination.

We should explain that the retrieval of the information requested in FOI 23/634 itself exceeded the 24 hour appropriate limit in section 12 of the FOI Act by a number of hours. As you are aware from your previous correspondence with us for that request and others, the time needed for manual review and extraction of follow-up information for each relevant Yellow Card report is a minimum of two minutes and sometimes longer; in correspondence following the response to FOI 23/634, we confirmed that 837 of the relevant Yellow Card reports in that case received a follow up. While it was realised during the retrieval of the information that completing the exercise would exceed the appropriate limit by several hours, we considered that it would be most helpful to provide a full response on that occasion rather than issue a refusal; this was particularly because a great deal of time had been spent providing advice and assistance to you with a view to helping you make a request for information you were interested in.

However, the time then needed to locate and retrieve information for a further request relating to the subject of Covid-19 adverse events would further exceed the appropriate limit, and as the requests do fall within the same 60 day consecutive working day period, we are applying section 12(4)(d) to refuse this request.

We conducted an exercise to identify initial search terms and some preliminary searches through our IT team for the information you have requested; these preliminary searches identified over 1000 emails of potential relevance. At this point we cannot say if all of these are relevant; to do this, these would then need to be exported from the archive and uploaded to a file share for access and further review to identify whether they fall within your request. Similarly, further review would still be required to determine if additional searches would be needed for common or variable terms that may be used; for example, a search combining the lead author's name and "study", or a search for links which may have been included which do not contain the title of the paper. These activities all fall under those specified in section 12 for locating retrieving and extracting information that meets the request.

As the appropriate limit has been reached and exceeded, our advice and assistance here focuses on setting out when the 60 consecutive working day period from the time of FOI 23/634 will end, and when and how a new request for information on Covid-19 adverse events might be submitted to avoid further aggregation. This would be 20 November 2023.

However, rather than simply re-submit the request in its present form, we would also advise consideration of the following points. In order to identify all information that may be relevant for this request as it's worded at the moment, we would need to conduct searches of MHRA mailboxes for the time period specified in your request, June 2022 to the date of your request, 25 September 2023. All such searches may produce large numbers of results, as variable search terms need to be used; in order to capture all relevant information, irrelevant results may also be captured by the initial searches, and further manual review is always required to identify the specific information relevant to the request. If the search terms are too limited, or combination of key words is not tried, then relevant results may be missed. Any searches which generate in excess of a thousand emails requiring this manual review risks engaging section 12. The present wording of your request is also very broad; it asks for "*all emails and all other internal communications, anonymised but not*

otherwise redacted, relating to or making any reference to the study"; this means that any email that mentions the study in any way will be relevant to the request, so not only would any relevant emails relating to the work of the Safety and Surveillance Group fall within the scope of the request, but also any other more general correspondence that mentions the study in any way, for example, correspondence, requests and enquiries from members of the public. We would therefore ask you to consider, if you wish to continue in future with a request for information about the study, whether there is a way to make your request more focused on the particular type of information you are interested in, rather than casting a wide net for any or all references.

As noted above, to avoid further aggregation, a further request for similar information should be submitted after 20 November 2023.

Yours sincerely,

FOI Team,

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