Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

[redacted]

28 March 2024

FOI 24/216

Dear [redacted]

Thank you for your information request, dated 29 February 2024 and following our response to FOI 24/001 where you asked in relation to the 'One Million Study' conducted by the Drug Safety Research Unit (DSRU):

"Do you have any records on why the '1 million' sample undertaking was reduced to about 6000, and who approved this (especially given the high rate of reaction - 50% of all responses - indicated in the smaller report? I would be grateful (under FOIA) if you could provide the internal correspondence which MHRA has relating to this."

As previously stated, the report you are asking about was not produced by the MHRA, and the DSRU is not a part of the MHRA. On contacting the DSRU, they advised us that the 'One Million Study' was not conducted; instead, it was modified and conducted under the title '*Post-authorisation active surveillance of the Safety of COVID-19 Vaccine AstraZeneca (AZD-1222) in the UK'*.

In these circumstances, to determine whether we hold any relevant information we would need to conduct an IT search across all correspondence and documents. The information you have requested is therefore exempt under Section 12 of the FOIA. 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 note that this request is the latest in a series of related requests for similar COVID-19 vaccine safety monitoring information made within a period of sixty consecutive working days. Under section 12(4) of the FOIA we may aggregate the time needed to conduct searches for your present request with the time estimate for retrieving information for previous requests within the same 60-day period; we particularly draw your attention to FOI 24/003 here, where the time needed for that request alone exceeded the 24-hour appropriate limit in section 12.

Section 12(4)(a) and (b) of the FOI Act states that:

Freedom of Information Act 2000
12 Exemption where cost of compliance exceeds appropriate limit.
(4)The [F1Minister for the Cabinet Office] may by regulations provide that, in such circumstances as may be prescribed, where two or more requests for information are made to a public authority—(a)by one person, or
(b)by different persons who appear to the public authority to be acting in concert or in pursuance of a campaign, the estimated cost of complying with any of the requests is to be taken to be the estimated total cost of complying with all of them.

This section of the FOI operates in conjunction with section 5 of the 'Fees Regulations' -

The Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004
Estimating the cost of complying with a request – aggregation of related requests
5.—(1) In circumstances in which this regulation applies, where two or more requests for information to which section 1(1) of the 2000 Act would, apart from the appropriate limit, to any extent apply, are made to a public authority—
(a)by one person, or
(b)by different persons who appear to the public authority to be acting in concert or in pursuance of a campaign,
the estimated cost of complying with any of the requests is to be taken to be the total costs which may be taken into account by the authority, under regulation 4, of complying with all of them.
(2) This regulation applies in circumstances in which–
(a)the two or more requests referred to in paragraph (1) relate, to any extent, to the same or similar information, and
(b)those requests are received by the public authority within any period of sixty consecutive working days.

To assist with narrowing, we would suggest that you focus on safety monitoring information which may be held by the MHRA, or focus on a safety topic of interest – you may find this useful https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting: if you scroll down the page you will see the safety topics discussed.

However, as noted above, we are aware that you have submitted numerous enquiries to the MHRA within a 60-day period, with each request immediately following a response being issued to you. We would therefore draw your attention to the Information Commissioner's guidance on making effective requests for information. We include links here:

https://ico.org.uk/for-the-public/official-information/how-to-write-an-effective-request-for-information/

https://ico.org.uk/for-the-public/official-information/preparing-and-submitting-your-information-request/

The ICO's 'Top Tips' and guidance on 'Protecting public money' are available here:

https://ico.org.uk/for-the-public/official-information/

While we would consider a new request from you, we advise that you may wish to consider the above guidance prior to submitting further requests within the same 60 consecutive working day period. Requests which ask for correspondence will require more extensive searches to be conducted than those needed for a focused request, and so may engage section 12; so we would recommend that if you wish to pursue a new request once the 60 day period has passed, a more specific request for information on one safety topic may be more easily retrievable.

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