Medicines & Healthcare products Regulatory Agency

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

[redacted]

16 January 2024

Dear [redacted]

FOI 23/997

Thank you for your request dated 13 December 2023 where you asked for the following information under the FOIA:

Please would you send me all correspondence sent or received in March and April 2021, between MHRA and AstraZeneca staff discussing the use of the terms TTS (Thrombosis with Thrombocytopenia) and VITT (Vaccine Induced Thrombosis and Thrombocytopenia, akaVaccine-induced immune Thrombocytopenia and Thrombosis)

If this request takes you beyond the cost threshold, please would you search all emails sent between MHRA staff and AstraZeneca staff during these months for the word "term" OR 'label' AND TTS OR VITT.

Please note, this is similar to an earlier request I made, which I have now withdrawn. This should be considered a new request.

As your request mentions, this is similar to one you previously submitted; that request was logged as FOI 23/836 and a formal refusal notice for that request was issued to you on 29 November 2023. When you indicated to us in further correspondence that you now wished to 'withdraw' that request, we advised on 21 December 2023 that FOI 23/836 had already been closed on 29 November 2023.

Your request of 16 December 2023 repeats the wording of the previous request, and it has been made within the same 60 consecutive working day period as your previous request and the requests referred to below. We therefore consider that the same provisions of the FOIA apply in this case, and we will explain this below.

The MHRA may hold information in relation to your request. However, on this occasion we are refusing the request as Section 12(4)(d) applies. To explain, we're aware that you and at least one of your colleagues at the Telegraph have submitted a number of requests

concerning COVID-19 vaccine safety within a short period of time. While we appreciate the interest in this topic, the FOIA does allow for the aggregation of requests in circumstances where it appears that one or more requesters are working together and making a number of requests for related information. There are provisions within section 12(4)(d) and the Fees Regulations 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 consecutive working days and the requesters appear to be 'acting in concert':

Freedom of Information Act 2000 12
Exemption where cost of compliance exceeds appropriate limit. (4)The Minister 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.

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.

In this case, FOI requests from Telegraph staff for related information have already been refused as the amount of information sought exceeds the appropriate limit in section 12, and the time needed for your own request can be aggregated with the time that was needed for those.

We can provide some advice and assistance. As we have recently handled a number of FOI requests from the Telegraph concerning COVID-19 vaccine safety, rather than simply advising you to narrow the scope of your request, 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