Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

11 August 2023

Dear [redacted]

FOI 23/296

Thank you for your email of 21 April 2023, where you requested disclosure of all data, studies and analyses carried out by the MHRA to examine causes of deaths from the following events as a consequence of the AstraZeneca Covid 19 Vaccination:

1. Brain Stem Infarction
2. Acute Intracerebral Haemorrhage
3. Vaccine Induced Thrombosis and Thrombocytopenia

and the "reports being given to the government from the MHRA", to which the Senior Coroner [redacted] referred to in a Daily Mail article on 19 April 2023.

Firstly, we apologise for the delay in responding. However, we cannot respond to your request in its present wording as there are several parts where it is not clear what recorded information you are asking for. Under section 1(3) of the FOIA, we need to ask for your clarification of certain points, and we will indicate these below.

Firstly, we should explain that the MHRA conducts safety analyses which include adverse events with a fatal outcome. You have requested disclosure of studies and analyses carried out by the MHRA to *examine causes of deaths* from brain stem infarction, acute intracerebral haemorrhage and vaccine-induced thrombsosis and thrombocytopenia.

However, this is not part of the MHRA's role. The MHRA evaluates a range of safety data to assess the likelihood of an overall association between a medicinal product and an adverse event, regardless of whether the event has a fatal outcome or not. As part of these assessments, reports with a fatal outcome would be carefully evaluated in relation to determination of the public health impact of the safety concern. It is not the MHRA's role to assign cause of death in relation to suspected adverse events following any medicinal product. This is the case for both individual reports and aggregated data.

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We would first ask if you could clarify if your request does intend to refer specifically to 'all data, studies and analyses carried out by the MHRA to examine cause of death' as this is not information that the MHRA would hold.

We would also like to seek clarification regarding the request for "*reports being given to the government from the MHRA*". It is not clear from your request what reports the Senior Coroner [redacted] is referring to and we cannot identify what information you are asking for without further description from you. We would be grateful if you could provide further details of these in order to progress your request.

We hope that the explanation we have provided above of the role of the MHRA and the work we undertake will help you to clarify your request.

We should also advise that in its present wording, if you do wish to continue with a new request using the terms "*all data, studies and analyses*" in relation to the above three events, this would be a very broad request, as it could be considered to include any and all Yellow Card data concerning these events as well as other assessments and analyses. Requests which ask for 'all information on' and 'all data held for' can be so broad in scope that they may cover more information than we can retrieve within the 24-hour 'appropriate limit' in FOIA.

If you think it might be helpful to discuss your requests further, you are welcome to contact our FOI Manager Lou.Lander@mhra.gov.uk who will be able to give further advice about framing a new request.

We hope this explanation is useful, and we apologise that we did not contact you with these details sooner.

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

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