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

4 October 2023

Dear [redacted]

FOI 23/661

Thank you for your email of 7 September 2023, where you requested disclosure of all the reports, data, analyses or advice provided by the MHRA to any government departments about the specific case referred to in an article published by the Mail Online on 19 April 2023

We can confirm that we do not hold the information requested.

To explain why this is, 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. Reports or analysis concerning possible safety issues, particularly those provided to government departments or other external bodies are conducted based on the totality of relevant information and not generally for individual cases; this means that they consider and present the data and results from a wider range of cases, not one specifically.

Therefore, for this request, the MHRA does not hold any reports, data, analyses or advice which were provided to any government department on the specific case your request refers to. This is because no reports were provided to any government departments *on this specific case*.

In relation to the events mentioned in the article, the MHRA undertook an in-depth review of blood clots occurring with thrombocytopenia from the end of February 2021 up to 6 April 2021 (though the safety issue was subject to ongoing review after the regulatory action of updates to the product information and MHRA communications[1]). This review was made up of numerous assessment reports and presentations, both of which contain a range of data from various sources, including but not restricted to Yellow Card reports, and assessments of this information against a case definition for thrombosis with thrombocytopenia syndrome, information on the number of people in the UK who had received this vaccine, incidence rates based on UK data, information from other countries and the marketing authorisation holder.

[1] UK regulator confirms that people should continue to receive the COVID-19 vaccine AstraZeneca - GOV.UK (www.gov.uk)
MHRA issues new advice, concluding a possible link between COVID-19 Vaccine AstraZeneca and extremely rare, unlikely to occur blood clots - GOV.UK (www.gov.uk)

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The assessments were provided to the Commission on Human Medicines and its Expert Working Group on COVID-19 Vaccine Benefit Risk on multiple occasions during the above time period in the context of seeking advice, for example on proposed regulatory actions.

The MHRA was an invited observer to the JCVI COVID-19 subcommittee and was often, but not always requested to present updates on the safety data for the COVID-19 vaccines. The minutes of the JCVI COVID-19 subcommittee can be found here.

The information listed here (exception being the JCVI minutes) is held by the MHRA and you may wish to consider this to see if you wish to ask for something particular of interest within this. We should advise that a request for all of the above may exceed the appropriate time limit stated in the FOI Act. Therefore you are advised to consider restricting any request to particular documents on a specific safety issue; we would also recommend including a specific and limited time period of interest in any request. If you wish to understand more about the dates of particular meetings to help with framing the wording of a request, please let us know and we will assist further.

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