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

31 October 2023

Dear [redacted]

FOI 23/729

Thank you for your email of 03 October 2023, where you requested the following:

"..the detailed review MHRA carried out into suspected cases of blood clots following Covid vaccination, referred to in the below government statement - https://www.gov.uk/government/publications/covid-19-vaccination-blood-clotting-information-for-healthcare-professionals/information-for-healthcare-professionals-on-blood-clotting-following-covid-19-vaccination"

The guidance to which you refer was issued by the UK Health Security Agency and refers to information on reports of blood clots with lowered platelets (thrombocytopenia) occurring in people following receipt of the AstraZeneca COVID-19 vaccine up to 11 August 2021.

The UKHSA guidance refers to review of suspected cases of these events by the MHRA. The MHRA is responsible for authorising and regulating medicinal and blood products in the UK. Part of this role involves the ongoing review of the safety of medicinal products authorised in the UK, including the COVID-19 vaccines used in the UK vaccination campaign. You can read more about how the MHRA monitored the safety of the vaccines here.

The review of blood clots occurring with thrombocytopenia referred to a series of assessments undertaken 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

[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)

vaccine, incidence rates based on UK data, information from other countries and the marketing authorisation holder.

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. Therefore there is not a single document which represents the MHRA's 'detailed review' of suspected reports of blood clots following the AstraZeneca COVID-19 vaccine. For your information, a summary of the CHM discussions on this topic can be found here.

The information listed here which comprised the review process 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 Section 12 of the FOI Act (24 hours). You are advised to refine your request by clearly defining the scope of the information you are seeking, for example by reviewing the links provided in this reply to MHRA statements on this safety topic requesting information considered by the CHM at a specific meeting in relation to the advice on a possible link between the AstraZeneca COVID-19 vaccine and blood clots with thrombocytopenia. 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. We would also like to make you aware that some of the information which comprised the review may be subject to other exemptions under the FOI Act.

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.

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The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

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Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU