Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
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7 June 2023

Dear [redacted]

FOI 23/167

Thank you for your emails of 7 March and 24 April 2023, where you requested the following:

1) Details of the prompt actions taken by the MHRA following the Danish health authority suspending the Astra Zeneca vaccine's use for all age groups on 11 March 2021 (pending a detailed analysis) beyond the advice given by Dame June Raine on 18 March 2021. For example, the Danish Ministry sent a letter to every person who had received AZ in the previous 14 days, telling them what symptoms to look out for and when to contact their doctor

2) How many doses of the AstraZeneca vaccine were given to patients, between the period of 11 March 2021 to 7 May 2021.

3) Any internal minutes where the Danish development or cerebral venous sinus thrombosis was discussed, including but not limited to your regular COVID-19 Vaccine Signal Meetings. Clarified on 24 April to refer to the period between 1 March 2021 to end of May 2021.

4) Why the Danish health authority's safety concern was not on the agenda of the next MHRA board meeting, held on 16 March 2021.

Apologies for the delay in responding to you. We can confirm that the MHRA holds some of the information requested, and some of the information is available in the public domain. The MHRA does not hold information on the number of doses of the AstraZeneca vaccine were given to patients, between the period of 11 March 2021 to 7 May 2021. The MHRA also does not hold the information requested in question 4, however as can be seen in the minute from the MHRA Board meeting on 16 March, Dr June Raine referred to the ongoing review of blood clots with COVID-19 vaccines.

In response to request number 1, as stated in the MHRA announcement on 18 March 2021 the MHRA had undertaken a thorough review of all available data concerning blood clots occurring with thrombocytopenia and was contintuing to review data concerning blood clots in cerebral veins. At the time of the 18 March statement, the advice from the Commission on Human Medicines was that the available evidence did not support a link between the AstraZeneca COVID-19 vaccine and no

regulatory action was recommended at that time, while further review was ongoing. The MHRA's position was aligned with that of the European Medicines Agency (EMA). The MHRA also provided regular updates to the COVID-19 Subcommittee of the Joint Committee on Vaccination and Immunisation on the safety review to support policy decisions on COVID-19 vaccination.

The findings of the further review into cerebral venous sinus thrombosis were announced on 7 April 2021. As stated, following this review, which included agreement of a case definition for the syndrome and involved expert advice from haematologists and the CHM, a link between the events and AstraZeneca COVID-19 vaccine was considered possible. Therefore regulatory action was taken in the form of updates to the product information for this vaccine, to include warnings about the extremely rare risk of blood clots with thrombocytopenia and the symptoms to be aware of. Communications were issued to healthcare professionals and the MHRA worked with the UK Health Security Agency to include information in the leaflets on COVID-19 vaccination. The MHRA also updated the weekly Coronavirus summary of Yellow Card reporting to reflect the latest assessment and regulatory position.

Regarding request number 3, a search for any mention of the Danish Health Authority suspension of COVID-19 vaccine AstraZeneca or CVST in any internal MHRA minutes would involve the use of a Discovery Search Tool. Based on experience in using this tool to perform Agency-wide searches for documents, the time taken to set up and refine the search criteria then extract and review the results to identify relevant records would take in excess of 24 hours. Therefore the request is exempt under Section 12 of the Freedom of information Act. 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 advise refinement of this request to concern specific MHRA meetings discussing vaccine safety.

I hope this information is helpful. 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,

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
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SK9 5AF