Medicines & Healthcare products
Regulatory Agency

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Denise Facey
[redacted]

02 May 2024

MHRA reference: FOI2024/00060

Dear [redacted]

Thank you for your information request, which we received on 25 April. You asked for:

> *ORIGINAL REQUEST: I have recently received from the NHS a letter in which it stated the following:*
> *regulatory update by the MHRA in August 2023 which states large vessel vasculitis is not caused by the COVID-19 vaccine AstraZeneca (9:13) (6:19-21)*
> *I cannot find this report and wondered if you could send me this please and any updates to this since August 2023.*
>
> *CLARIFICATION: This information was sent to me by the VDPS vaccine damage payment service. The information I sent you is exactly the information that was sent to me.*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

Thank you for providing a response to our request for clarification. From the additional information you have provided, we have identified that that the report you refer to is the '*Summary of MHRA's regulatory position for specified events reported with COVID-19 Vaccine Pfizer/BioNTech, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna*'.

This report was requested by the NHS Business Services Authority to provide an update on the current regulatory position regarding COVID-19 vaccination and

vasculitis. It is important to note that the statement about the MHRA report in your original request is not a direct quote from the MHRA's regulatory position document.

We confirm that we hold the information you have asked for, and we are disclosing this information in full. Please find the information in the attached disclosure document.

We can confirm that there have not been updates to the report dated August 2023.

We hope this information is useful for you.

This concludes our response to your request.

If you have a query about this response, please contact us at

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Safety and Surveillance Group
Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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