

Freedom of Information Team Department of Health and Social Care 39 Victoria Street London SW1H 0EU

www.gov.uk/dhsc

Ms Lois Bayliss By email to: <u>LoisBayliss@broadyorkshirelaw.co.uk</u>

10 July 2023

Dear Mr Bayliss,

Freedom of Information Request Reference FOI-1459731

Thank you for your request dated 19 June to the Department of Health and Social Care (DHSC), a copy of which can be found in the accompanying annex.

Your request has been handled under the Freedom of Information Act 2000 (FOIA).

DHSC holds some of the information requested. The Department's response was provided to the coroner in June 2023. DHSC is not responsible for the publication of Regulation 28 reports. It is within the coroner's discretion to make Regulation 28 reports, and their respective responses, available to the public.

Outside of the Act and at our discretion, you can find more information about the publication of Regulation 28 reports in the following link.

https://www.judiciary.uk/wp-content/uploads/2021/11/PFD-publication-policy-9-11-21.pdf

If you are not satisfied with the handling of your request, you have the right to appeal by asking for an internal review. This should be sent to <u>freedomofinformation@dhsc.gov.uk</u> or to the address at the top of this letter and be submitted within two months of the date of this letter.

Please remember to quote the reference number above in any future communication.

If you are not content with the outcome of your internal review, you may complain directly to the Information Commissioner's Office (ICO). Generally, the ICO cannot make a decision unless you have already appealed our original response and received our internal review decision. You should raise your concerns with the ICO within three months of your last meaningful contact with us.

Guidance on contacting the ICO can be found at <u>https://ico.org.uk/global/contact-us</u> and information about making a complaint can be found at <u>https://ico.org.uk/make-a-complaint</u>.

Yours sincerely,

Freedom of Information Team freedomofinformation@dhsc.gov.uk Annex

DCMS Data Protection Team

By email:

stephen.barclay.mp@parliament.uk

Lois Yvonne Bayliss 219 Handsworth Road Sheffield S13 9BH E – loisbayliss@broadyorkshirelaw.co.uk

19th June 2023

Dear Sirs

FREEDOM OF INFORMATION ACT 2000 REQUEST

Dear Mr Barclay (Secretary of State for Health)

On the 13th October 2022 Nadia Persaud area coroner for East London issued a Regulation 28 REPORT TO PREVENT FUTURE DEATHS (1) in relation to the death of Oli Akram Hoque.

In section 5 the coroner stated the following;

CORONER'S CONCERNS

During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you. The MATTERS OF CONCERN are as follows: The Inquest heard evidence from a senior medical assessor from the Medicines and Healthcare Regulatory Agency (MHRA). The Inquest heard that from the 25th February 2021 the MHRA investigated the potential signal of immune thrombocytopenia. This identified three cases of cerebral venous sinus thrombosis which could possibly be associated with the Astra Zeneca Covid 19 vaccine. The MHRA could not fully consider these cases as they did not receive all of the necessary clinical information. The Inquest heard that the MHRA do not have the power to compel relevant clinical information, to assist them with safety investigations. In light of the clear public interest in ensuring that the MHRA are unable to compel the timely production of relevant clinical data.

The action required was expressed in section 6 of the Regulation 28 as follows, with a response requested by the 8th December 2022.

ACTION SHOULD BE TAKEN

In my opinion action should be taken to prevent future deaths and I believe you [AND/OR your organisation] have the power to take such action.

Having reviewed the Chief Coroners published data base on Regulation 28 responses, see link;

You searched for - Courts and Tribunals Judiciary

I have been unable to find any response for this particular Regulation 28 and therefore would you ask that you answer the following.

- 1. Why to date has no response been provided to this Regulation 28.
- 2. If there has been a delay in relation to you being able to provide the requested response:
 - What is the reason for this delay.
 - > By what date do you anticipate being in a position to respond.
 - Given the fact that the coroner has raised the risk of further harm/ deaths resulting from the inability of the MHRA to undertake robust reviews due to not having access to the required clinical information - do you consider that the delay in providing a response as to what action is to be taken to mitigate this identified risk is acceptable.
 - In the event that a response has been provided and a decision made not to make the response publicly available can you please explain why this decision was made and provide the evidence to support this decision.

I thank you in anticipation of your response,

Regards

Lois Bayliss