Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00352**

19 May 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 28 March. You wrote:

> *My request relates to Pfizer's 'Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine' (ref C4591021). Interim Report 5 reported significantly higher incidence of some serious heart-related conditions among the vaccinated cohort.*
>
> *1. In relation to Interim Report 5:*
> *a) when did MHRA decide to remove the Section 22 Exemption?*
> *b) when, by whom and where was Interim Report 5 published?*
> *c) please can I have a copy of MHRA's assessment of it*
>
> *2. In relation to the Final Report:*
> *a) does MHRA hold a copy of the Final Report?*
> *b) if so, when did MHRA receive it?*
> *c) please can you send me a copy*
> *d) please can I have a copy of MHRA's assessment of it*

MHRA Response

We can confirm that the Agency holds some of this information. However, the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

However, to be helpful you can find the information you seek at: Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine | HMA-EMA Catalogues of real-world data sources and studies

MHRA understands the document to have been uploaded/published through the ENCePP/EMA PASS registry process associated with the study sponsor and/or EU pharmacovigilance framework.

For clarification, the report itself is not an MHRA authored document. To the extent that FOIA exemptions were engaged, the considerations included anticipated publication via the relevant pharmacovigilance/PASS publication mechanisms rather than publication by MHRA

itself. On these grounds we acknowledge in previous responses we incorrectly relied on S22(1) when the correct exemption at the time was S22A, this would not have changed the information disclosed at the time as it is still a publication-based exemption.

The MHRA did not produce a formal assessment of the above report.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113

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