Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00371**

01 May 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 5 April 2026. You wrote:

> *"Please send me the clinical study report of Pfizer Study A0501104 including all appendices."*

MHRA Response

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

We confirm that we hold the information you have requested. However, we consider that some of the information you have asked is commercially sensitive, and is therefore, exempt from disclosure under Section 40(2) (S40 – Personal information) and Sections 43(2) (S43 – Commercial interests) of the FOIA.

In response to your request, we are providing the following document:

- **Clinical Study Report of Pfizer Study A0501104.**
- **Appendix 16.1.1. – Final Protocol and Protocol Amendments**
- **Appendix 16.1.7. – Description of Randomization**
- **Appendix 16.1.9. – Statistical Analysis Plan**
- **Appendix 16.2.7. – Adverse Events**

Please note that some redactions have been applied to these documents under the Section 40(2) (S40 – Personal information), Section 41(1) (S41 – Information provided in confidence) and Section 43(2) (S43 – Commercial interests) of the FOIA.

We will explain these exemptions below.

Section 40:
(2) Information is exempt information if it contains elements of personal data, the disclosure of which would be unfair in that it would breach the first principle of the Data Protection Act which says that information must be processed fairly and lawfully.

Section 41:
(1) Information is exempt information if — (a) it was obtained by the public authority from any other person (including another public authority), and, (b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.

Section 43:
(2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

Section 43 is a qualified exemption and requires that we consider the public interest.

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in withholding the information outweighs the public interest in releasing the information held. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in withholding. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of releasing the information
To release all information available in these documents would be of benefit in general to show transparency in MHRA's day-to-day work for the public to see how MHRA considered the clinical study report (including the appendices) specific to the medicinal products and found it to be acceptable for use.

Considerations in favour of withholding the information
Information included in the clinical study report (such as consent forms, list of investigators, referenced publications, analytical reports, laboratory data) is commercially sensitive information that has been provided to MHRA in confidence. The marketing authorisation holder has spent time and resources in developing their product in order to meet the regulatory guidelines. This information can be used by rival companies in developing their own products, thus overcoming regulatory hurdles at the expense of the marketing authorisation holder.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

This concludes our response to your request.

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.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/