Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00929**

15 October 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 20 August. You wrote:

I refer to MHRA response FOI 23/211 dated 23 March 2023 concerning the imbalance in important protocol deviations in the pivotal Pfizer/BioNTech BNT162b2 clinical trial.

That response stated that no formal investigation of the imbalance was undertaken but that the imbalance was noted during assessment but was not pursued because the proportions were considered low. 1.4% in the BNT162b2 group and 0.3% in the placebo group.

Please provide the following recorded information only:

1 Copies of any contemporaneous MHRA assessment records, reviewer comments, assessment reports, notes, emails, meeting records or other documents recording or discussing the imbalance in important protocol deviations between the BNT162b2 and placebo groups.

2 Copies of any recorded analysis or consideration of whether that imbalance could have affected:
a) the primary efficacy analysis
b) the comparability of the randomised groups
c) exclusion of participants from the evaluable efficacy population
d) blinding or allocation integrity
e) the reliability of the reported vaccine-efficacy estimate.

3 Copies of any recorded risk assessment, regulatory reasoning, criteria or other documentation supporting the decision that the imbalance did not require formal investigation or further pursuit.

4 Please provide any recorded sensitivity analysis, alternative analysis or other calculation undertaken by or supplied to MHRA examining whether exclusion or inclusion of participants affected by these protocol deviations altered the efficacy findings.

5 FOI23/211 stated that Pfizer subsequently provided an explanation that

the imbalance largely reflected investigational-product handling requirements including ultra-low temperature storage, dilution and temperature excursions.

Please provide:

a) the date on which MHRA requested that information from Pfizer
b) a copy of MHRA's request
c) a copy of Pfizer's response
d) any MHRA assessment, correspondence, notes or other recorded information considering whether Pfizer's explanation was independently verified or regarded as sufficient.

6 Please provide any recorded information showing whether MHRA examined the individual categories of protocol deviation before concluding that the overall imbalance was not significant enough to warrant investigation rather than relying solely on the overall percentages of 1.4% and 0.3%.

For avoidance of doubt, I am not requesting the participant-level protocol-deviation lists already disclosed in connection with FOI 23/211 and I do not seek the creation of new analysis or explanations. I am seeking only recorded information already held concerning MHRA's regulatory consideration of this known imbalance and its decision not to investigate it formally.

Where no recorded information falling within any particular part of this request is held, please state this explicitly.

MHRA Response

We can neither confirm nor deny we hold information falling within the description specified in your request under section 12(2) of the Freedom of Information Act, as to do so would exceed the cost limit.

This is because we estimate the cost of checking if we hold the requested information or not would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(2) of the FoI Act the Agency is not therefore obliged to comply with your request and we will not be processing it further. The reason being to search the number of separate elements mentioned in your request would require upwards of 24 hours. We have counted ~10 document types mentioned in your request including; emails, notes, and meeting records which are time-consuming to locate. We would also recommend avoiding terms such as ‘Other documents’ even with supporting context, this term would confer a wide search avenue.

Advice and assistance

Under Section 16 of the FoI Act we should help you narrow your request so that it may fall beneath the cost limit.

We have located the correspondence in relation to FOI 23/211, and this meets the following parts of your FoI request:

- Q.1. multiple forms of information requested, therefore, documents held may only address Q.1 in part/s)
- Q.2. as above.
- Q.3. as above.
- Q.5. in full
- Q.6. In full

We would suggest refining your request to the correspondence related to 23/211 and any relevant excerpts directly referred to in that correspondence. This will be the most direct route to obtaining the main/key information which you are seeking.

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 Contact Information 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/