



Medicines & Healthcare products
Regulatory Agency

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Our Ref: **FOI2026/00205**

13 October 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 25 February. We apologise for a significant delay in our response; this was due to an oversight on our end when processing requests. You wrote:

I write under the Freedom of Information Act 2000 in relation to the Pfizer/BioNTech COVID-19 vaccine batch FH4751.

The published case series print indicates 60 reports coded as "Dyspnoea" (shortness of breath) for this batch.

I am seeking a breakdown of the underlying clinical causes or diagnoses associated with those dyspnoea reports.

For the reports in which dyspnoea was recorded, please provide:

- 1. A breakdown of the stated or subsequently identified clinical diagnoses or medical conditions associated with the breathlessness (for example pulmonary embolism, myocarditis, cardiac arrhythmia, anaphylaxis, pneumonia, interstitial lung disease, hypersensitivity pneumonitis, heart failure, anxiety-related hyperventilation, or any other identified cause).*
- 2. Where no specific diagnosis was identified, please confirm how many dyspnoea reports were recorded without an underlying cause being specified.*
- 3. Please confirm whether the MHRA reviewed the dyspnoea reports for batch FH4751 to determine whether a common clinical mechanism or safety signal was present, and if so, provide the conclusion of that review.*

I am not requesting identifiable personal data, but a substantive breakdown of the underlying clinical causes recorded in association with the dyspnoea reports.

MHRA Response

We confirm that we hold some of the information you have requested.

We can confirm that, up to and including 28 September 2026, the MHRA has received a total of 61 UK spontaneous suspected adverse drug reaction reports concerning dyspnoea in association with the Pfizer/BioNTech COVID-19 vaccine, batch FH4751.

Please see the attached line listing, which provides the reported suspected adverse reaction terms for each of the 61 reports identified.

It is important to note at the outset that these are reports of suspected adverse reactions. A reported reaction does not necessarily mean that it was caused by the vaccine, only that the reporter had a suspicion that it may have been. The Yellow Card data do not confirm clinical diagnoses or underlying causes, and reported symptoms may be related to underlying or concurrent medical conditions or may be coincidental.

Please note that the Yellow Card database is dynamic, and reports may be added, updated or amended over time. The figure provided in this response reflects the reports retrieved using the search parameters applied for this request, up to and including 28 September 2026. As a result, this total may differ from figures produced at an earlier date or using different search criteria.

Please see the attached line listing, which provides the reported suspected adverse reaction terms for each of the 61 reports identified. These reported terms should not be interpreted as confirmed clinical diagnoses or confirmed causes of dyspnoea.

Reporters have the option to include a batch number within a free-text field on a Yellow Card report; however, this is not mandatory. As this information is collected in a free-text field, entries may vary between reports depending on how the reporter enters the batch number.

As such, to extract the data in this response, the batch number field was normalised prior to searching for FH4751. The normalisation accounted for differences in capitalisation, removed spaces and dashes, and accounted for potential substitution of visually similar letters and numbers relevant to this batch. Specifically, the search accounted for:

- upper- and lower-case entries;
- the number 5 and the letter S;
- the number 1 and the letter I;
- the number 1 and the letter L;
- spaces within the batch number; and
- dashes within the batch number.

The MHRA does not hold confirmed clinical diagnoses or confirmed underlying causes for each of the dyspnoea reports. The information held is based on suspected adverse reaction reports submitted through the Yellow Card Scheme. Therefore, the MHRA does not hold a confirmed count of reports where dyspnoea was recorded without an underlying cause being specified.

The MHRA has not conducted a review of dyspnoea reports for batch FH4751.

It is also important to note that the number of reports received via the Yellow Card Scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different medicinal products. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular vaccine, and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced vaccines during the first one to two years on the market and then falls over time.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: <https://products.mhra.gov.uk/> for details on the possible side effects.

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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