



Medicines & Healthcare products
Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00930**

17 September 2026

Dear [REDACTED]

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

I am making a request under the Freedom of Information Act 2000 regarding suspected adverse drug reaction reports submitted to the MHRA Yellow Card Scheme for Pfizer-BioNTech COVID-19 vaccine batches FA1027 and FF3319.

For each batch separately, please provide the following information held by the MHRA:

- 1. The total number of UK Yellow Card reports associated with the batch.*
- 2. The total number of reported reactions/events associated with the following MedDRA preferred terms, or the closest equivalent terms used within the MHRA database:*

- * Aortic dissection*
- * Artery dissection*
- * Aortitis*
- * Periaortitis*
- * Arteritis*
- * Vasculitis*
- * Aortic aneurysm*
- * Iliac artery aneurysm*
- * Iliac artery dissection*
- * Aortic thrombosis*
- * Arterial thrombosis*
- * Thrombosis*
- * Tachycardia*
- * Sinus tachycardia*
- * Palpitations*
- * Exercise intolerance*
- * Dyspnoea on exertion*

- 1. For each of the above reaction terms, where held, please provide:*

- * number of individual Yellow Card reports;*
- * number classified as serious;*
- * number resulting in hospitalisation;*
- * number resulting in death;*

* *patient age and sex in aggregated form where disclosure permits.*

1. *Please provide the dates, or at least month and year, on which reports involving aortic dissection, artery dissection, aortitis, periaortitis, arteritis or vasculitis were received for either batch.*

2. *Please state how many doses from batches FA1027 and FF3319 were distributed and/or administered in the United Kingdom, if this information is held. If exact administration figures are not held, please provide the closest available denominator, such as doses supplied or released.*

3. *Please provide any safety signal assessment, pharmacovigilance review, internal analysis or aggregate assessment specifically relating to either FA1027 or FF3319, insofar as this can be supplied within the appropriate FOI cost limit.*

I am not requesting individual patient-identifiable information, copies of individual Yellow Card forms or personal medical information.

If some of the requested terminology does not correspond precisely with the MedDRA coding used by MHRA, please use the closest applicable Preferred Term and state which terminology was used.

If any element of this request would exceed the statutory cost limit, please provide the information that can be supplied within the limit and advise me how the remaining request could be narrowed.

Where practical, I would prefer the numerical information in CSV or spreadsheet format, although a table within the response is also acceptable.

MHRA Response

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

We can confirm that the number of UK spontaneous suspected adverse reaction (ADR) reports for the Pfizer-BioNTech COVID-19 vaccine for the specified batches up to and including 14/09/2026 are as follows:

Batch FA1027: 2702 reports

Batch FF3319: 2457 reports

Please note that not all terms you specified are available as Preferred Terms (PTs) in the current Medical Dictionary for Regulatory Activities (MedDRA) (version 29.0). For such terms, the closest MedDRA PT was searched within the MHRA database, as specified below in bold text:

- *Periaortitis* – **Aortitis**.
- *Iliac artery aneurysm* – **Peripheral artery aneurysm**.
- *Exercise intolerance* – **Exercise tolerance decreased**.
- *Dyspnoea on exertion* – **Dyspnoea exertional**.

Please find the remaining data you requested attached for batch **FA1027** in **Annex 1**, and batch **FF3319** in **Annex 2**.

Please note that for both batches, if reports were not returned in our search for particular terms of interest, these have not been included in the tables provided. We have not received

any reports with a fatal outcome concerning the MedDRA PTs requested for these batch numbers. For batch FA1027, we have not received any reports for the PTs you requested date information for.

On a Yellow Card report, batch number is an optional field and is also in free text format. Therefore, this information may not always be provided or when this information is provided, entries will vary between reports depending on how the reporter has entered this information. This does mean that manual review is required and whilst we do strive for consistency and accuracy in the information we provide, this cannot always be certain due to the way the information is collected on a Yellow Card report form.

For the purpose of this Fol request, we have searched the batch number field for different variations. The full lists of batch number variations searched on our database for this Fol request are attached as **Annex 3**.

For reference, a Yellow Card report is considered serious according to two criteria; firstly, a reported reaction can be considered serious according to our medical dictionary. Secondly, a reported reaction can be considered serious if the original reporter selects one of the six serious criteria available. These seriousness criteria are the reported reaction (1) resulting in death, (2) being considered life threatening, (3) resulting in hospitalisation, (4) being considered disabling or incapacitating, (5) involving a congenital anomaly or birth defect, or (6) being considered medically significant for another reason.

It is important to note that the aggregated number of serious reports within the tables provided includes hospitalisation reports.

It is also important to be aware that not all batches of the COVID-19 vaccines are the same size, and some batches may have had more wastage than other batches or be distributed more widely outside of the UK. Therefore, we would not expect the number of ADR reports for all batches to be the same as they have been administered to different numbers of patients. Furthermore, different batches would have been used at different stages of the vaccination campaign, and in different patient groups, which could also impact reporting rates. For example, reporting rates were typically higher at the beginning of the vaccination campaign as individuals received their first dose and the likelihood of experiencing a reaction, as well as the propensity to report it, differs across patients of different ages.

When considering spontaneous data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. Each year, millions of doses of vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after administration of a vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.
- 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine or vaccine, and may be stimulated by promotion and publicity about a drug or vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

- The MHRA continuously monitors the safety of medicines and vaccines through a variety of pharmacovigilance processes, including the Yellow Card scheme. As part of our signal detection processes, all adverse reaction reports received by the Yellow Card scheme are assessed, and cumulative information is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.
- As spontaneous data do not necessarily refer to proven side effects, you should refer to the product information of the vaccine which can be found here: [ARCHIVE: Information for Healthcare Professionals on COVID-19 Vaccine Pfizer/BioNTech \(Regulation 174\) - GOV.UK](#) for details on the possible side effects of the vaccine.

Unfortunately, we do not hold information about the number of doses from batches FA1027 and FF3319 that were distributed and/or administered in the United Kingdom. We would encourage you to contact the UK Health Security Agency (UKHSA) to request this information: [UK Health Security Agency - GOV.UK](#).

Regarding your final question, we do not hold any signal assessments, pharmacovigilance reviews, internal analyses or aggregate assessments specific to batches FA1027 or FF3319.

We hope this information is helpful. 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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