Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00825**

25 August 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 27 July. You wrote:

I am writing to request information under the Freedom of Information Act 2000 regarding the AstraZeneca COVID-19 vaccine, specifically batch number PV46662.

This request is intended as an update to the information previously provided in FOI 22/713, which contained data up to 25 May 2022. I would be grateful if you could provide the same information using the most recent data available at the date this request is processed.

Specifically, I request the following:

1. *Total Adverse Reaction Reports*

* *The total number of UK Yellow Card reports received for AstraZeneca COVID-19 vaccine batch PV46662 from the beginning of reporting to the most recent date available.*

2. *Breakdown of Adverse Reactions*

* *An updated Vaccine Analysis Print (VAP) or equivalent document showing all reported suspected adverse reactions associated with batch PV46662.*
* *Any accompanying guidance notes required to interpret the data.*

3. *Patient Ethnicity*

* *An updated breakdown of adverse reaction reports by reported patient ethnicity, in the same format as provided in FOI 22/713.*

4. *Comparison with Other AstraZeneca Vaccine Batches*

* *Please provide any analysis held by the MHRA comparing batch PV46662 with other AstraZeneca COVID-19 vaccine batches, including:*

* *The total number of Yellow Card reports received for each batch (or the batches with the highest numbers of reports, if providing every batch would exceed the appropriate cost limit).*

* *Any analysis comparing reporting rates between batches where the number of doses administered is known.*
* *Whether batch PV46662 has been identified as having a higher, lower or expected rate of suspected adverse reaction reports compared with other AstraZeneca vaccine batches.*
* *Details of any internal reviews, investigations, signal assessments or pharmacovigilance analyses undertaken specifically in relation to batch PV46662.*
* *Whether PV46662 has ever been the subject of any batch-specific safety signal, investigation or enhanced monitoring, and if so, please provide details and the outcome of that assessment.*

5. *Ocular (Eye-Related) Adverse Reactions*

* *Please provide details of all reported ocular or ophthalmic adverse reactions associated with batch PV46662, including:*

* *The reported ocular adverse reaction terms (using MedDRA preferred terms where available).*
* *The number of reports for each ocular adverse reaction.*
* *The number of serious and non-serious reports for each ocular adverse reaction, where recorded.*
* *Any MHRA signal assessments, reviews or conclusions specifically relating to ocular adverse reactions associated with this batch.*

6. *Fatal Outcomes*

* *The number of Yellow Card reports associated with batch PV46662 that reported a fatal outcome, noting that a reported fatality does not imply causation.*

7. *Serious Adverse Reactions*

* *The number of reports classified as serious, together with a breakdown of the seriousness criteria where available (e.g. hospitalisation, life-threatening event, disability, congenital anomaly, medically significant event or death).*

8. *Batch Distribution Information*

* *If held by the MHRA, please provide:*

* *The total number of doses from batch PV46662 supplied or administered within the UK.*
* *If this information is not held by the MHRA, I would be grateful if you could confirm this and advise whether it is held by the UK Health Security Agency (UKHSA) or another public authority.*

9. *Regulatory Assessment*

* *Please confirm whether the MHRA's current assessment remains that no batch-specific safety concerns have been identified for PV46662, or whether this assessment has changed since the response provided under FOI 22/713.*
* *If the assessment has changed, please provide details of the evidence supporting that change.*

Where information is exempt from disclosure, I would be grateful if you could cite the specific exemption(s) relied upon and release any remaining information that is not

exempt.

Where possible, I request that the information be provided electronically in PDF or spreadsheet format.

If any part of this request is likely to exceed the appropriate cost limit under the Freedom of Information Act, please advise me how the request may be refined so that the information can be provided.

MHRA Response

We confirm that we hold the information you have requested.

The MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance approaches 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 reviewed at regular intervals.

Total Adverse Reaction Reports and Breakdown of Adverse Reactions:

Firstly, it should be noted that reporters have the option to include batch number within a free text field, however this is not mandatory. Please note that the accuracy of the data relies on the batch number correctly being provided by the reporter on the Yellow Card and that the data will not contain entries where there may be typographical errors in the original report. For this FOI request, we have searched the batch number field for the relevant vaccine using multiple variations of batch number, either with spaces between letters and numbers, dashes between letters and numbers as well as variations between numbers and letters. Specifically, the search criteria included the variations below:

- The letter U and the letter V
- The letter W and the letter V
- Spaces between the letters and numbers
- Dashes between the letters and numbers

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 form.

Further to your request, up to and including 2nd of August 2026, we can confirm that the MHRA has received a total of 3,191 UK spontaneous suspected adverse reaction reports to the Yellow Card Scheme for the COVID-19 AstraZeneca vaccine associated with the batch number PV46662. Please also find attached a Vaccine Analysis Print (VAP) for the COVID-19 AstraZeneca vaccine with the batch number PV46662. The VAP provides a breakdown of the reported adverse reactions. A VAP guidance sheet is also enclosed which provides you with further information on how to interpret the print.

Patient Ethnicity:

In reference to your third question, table 1 below provides a breakdown of the number of UK spontaneous suspected adverse reaction reports received for the COVID-19 AstraZeneca vaccine with the batch number PV46662 up to and including 2nd of August 2026 broken down by reported patient ethnicity. It is also important to note, that whilst we encourage reporters to provide as much information as possible about the patient, patient ethnicity is not a mandatory field, and therefore, may not always be reported.

Table 1: UK Spontaneous suspected adverse reaction reports received broken down by patient ethnicity for the COVID-19 vaccine AstraZeneca with the batch number PV46662 up to and including 2nd of August 2026

Patient Ethnicity	Case Count
African	15
Any other Asian background	17
Any other Black background	*
Any other ethnic background	6
Any other mixed background	18
Any other White background	138
Bangladeshi	*
British	2,206
Caribbean	12
Chinese	10
Indian	47
Irish	45
Not known/not stated	12
Pakistani	9
White & Asian	12
White & Black African	*
White & Black Caribbean	11
Not reported	623

*Please note that where the total number of reports is <5, the total has been removed to protect patient confidentiality.

Comparison with Other AstraZeneca Vaccine Batches:

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. Please be assured that the MHRA reviews Yellow Card data regularly and we would communicate any concerns raised with the public and healthcare professionals.

Ocular (Eye-Related) Adverse Reactions:

Regarding your request for the reported ocular adverse reaction terms and the number of reports for each ocular adverse reaction, please refer to the VAP attached to this response. I can confirm that up to and including 2nd of August 2026, the MHRA has received 89 serious reports and 31 non-serious reports for ocular adverse reactions associated with the COVID-19 AstraZeneca vaccine with the batch number PV46662.

Fatal Outcomes:

Please also refer to the VAP attached for the number of Yellow Card reports associated with batch number PV46662 that reported a fatal outcome up to and including 2nd of August 2026.

Serious Adverse Reactions:

Further to your request, the MHRA has received 1,965 serious Yellow Card reports up to and including 2nd of August 2026 with the COVID-19 AstraZeneca vaccine with the batch number PV46662. Please see table 2 for the breakdown of seriousness criteria where available. 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, whether the original reporter considers the report to be serious whereby they can select based on the 6 serious criteria[1] available.

Table 2: A breakdown of the number of reports received for the AstraZeneca COVID-19 Vaccine for batch number PV46662 up to and including 2nd of August 2026

Breakdown of seriousness criteria	Case Count
Fatal	33
Life Threatening	67
Hospitalisation	154
Disability	259
Congenital Anomaly	2
Other Medically Important Condition	1,728

Please note, cases can have more than one seriousness term so the number reflected in the case count column will be higher than the total number of serious Yellow Card reports we have received.

Batch Distribution Information:

If you would like further information on batch usage, please contact the UK Health Security Agency (UKHSA) who hold this information.

Regulatory Assessment:

The MHRA also continually reviews reports associated with vaccine batches and investigates any potential quality or safety concerns where appropriate. The presence of Yellow Card reports associated with a particular batch does not, by itself, demonstrate that the batch was defective or that reported medical events were caused by the vaccine.

Regarding your concerns about AstraZeneca COVID-19 vaccine batch PV46662, our ongoing safety monitoring of the COVID-19 vaccines has not identified any batch specific safety concerns, and no regulatory action has been taken for individual batches of these vaccines, including batch PV46662.

When considering the spontaneous ADR data detailed above, 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. The fact that symptoms or events occur after use 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 the vaccines. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

[1] The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant.

- It is also important to note that Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls over time.

As this data does not necessarily refer to proven side effects, you should refer to the product information (Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL)) for details on the possible side effects of each COVID-19 vaccine, which can be found on the MHRA Products website here.

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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