



Medicines & Healthcare products Regulatory Agency

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

Our Ref: **FOI 2025/00343**

6th May 2025

[REDACTED]
[REDACTED]

Dear [REDACTED],

Thank you for your Freedom of Information (FOI) request dated 3rd April requesting the following:

“Please could you tell me the total number of adverse drug reactions (ADRs) reported to you through the Yellow Card scheme in the 2024 calendar year?

In relation to the figures for 2024 could you also provide

- (i) the number of UK suspected ADR reports received with a fatal outcome,*
- (ii) number of ADR reports received which resulted in prolonged hospitalisation*
- (iii) the number of reports received which resulted in prolonged hospitalisation AND had a fatal outcome?*

In relation to the fatal outcomes could you please provide a table showing the ten drugs that were most frequently recorded as having caused such a reaction along with the number of times each one was recorded as having a fatal outcome.”

MHRA Response

The Yellow Card scheme is run by the Medicines and Healthcare products Regulatory Agency (MHRA), which safeguards medicines, vaccines, medical devices, blood products and e-cigarettes quality and efficacy in the United Kingdom. Through the Yellow Card scheme, the MHRA collects and monitors information on suspected safety concerns involving healthcare products, like side effects caused by a medicine, or adverse incidents involving medical devices.

I can confirm between 01/01/2024 up to and including 31/12/2024 the MHRA has received 102,690 UK spontaneous suspected adverse drug reports via the Yellow



Medicines & Healthcare products Regulatory Agency

Card scheme. Table 1 below shows the number of reports that indicate a fatal outcome as well as the number considered serious due to the selection of hospitalisation or prolonged inpatient hospitalisation from the 6 serious categories¹ available. It's Important to be aware when interpreting Yellow Card data, that the hospitalisation flag is not a mandatory field and is therefore not always populated by the reporter.

Table 1: The number of UK spontaneous suspected ADR reports received between 01/01/2024 and 31/12/2024 associated with hospitalisations and fatal outcomes.

Fatal outcome	Hospitalised	Hospitalised with a fatal outcome
1,727	9,652	255

As with any serious suspected ADR, reports with a fatal outcome are fully evaluated by the MHRA, including an assessment of post-mortem details if available, to consider whether the medicine (or vaccine) may have caused the event, or whether the event and fatal outcome were likely to be purely coincidental and due to underlying illness. We hold weekly signal meetings in which drug/vaccine-reaction combinations which meet defined criteria are assessed by a group of scientists, physicians and pharmacists to determine if risk-minimisation measures need to be implemented. This includes potentially unrecognised drug interactions. Any emerging evidence relating to possible risks associated with medicines and vaccines, would be carefully reviewed and, if appropriate, regulatory action would be taken if any serious risks were confirmed.

In order to address your final request please refer to table 2 below which is a breakdown of the top 10 drugs which are associated with fatal outcome reports received in this period.

Table 2: A breakdown of the top 10 drugs associated with fatal outcome reports received between 01/01/2024 and 31/12/2024.

Product Name	Number of reports
Clozapine	263
Covid-19 vaccine AstraZeneca	79
Lanreotide	61

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.



Medicines & Healthcare products Regulatory Agency

Darbepoetin Alfa	55
Prednisolone	44
Adalimumab	43
Tozinameran	37
Methotrexate	30
Pregabalin	30
Paracetamol	27

Yellow Card data for clozapine is subject to reporting bias which results in an unusually high number of reports compared to other medicines. This is because people treated with clozapine in the UK are required to undergo weekly, 2-weekly or monthly blood monitoring and are monitored more closely in clinical practice than patients receiving most other medicines. This in turn increases the likelihood that adverse reactions, as well as co-incidental medical events, are detected and reported to us.

When considering this 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 medicine or vaccine, only that the reporter had a suspicion it may have been. The fact that symptoms occur after use of a vaccine or medicine, 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 or compare the safety profile of different products. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccine during the first one to two years on the market and then falls over time.

I hope the information provided 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



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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](https://ico.org.uk/for-the-public/foi/) or telephone 0303 123 1113.

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