Medicines & Healthcare products Regulatory Agency

[redacted]

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MHRA Website

Our Ref: **FOI2026/00356**

28 April 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 30 March. You wrote:

> *Please could you tell me the total number of adverse drug reactions (ADRs) reported to you through the Yellow Card scheme in the 2025 calendar year?*
> *In relation to the figures for 2025 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 and (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

We confirm that we hold the information you have requested and provide it below.

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.

We can confirm between 01/01/2025 up to and including 31/12/2025 the MHRA has received 132,478 UK spontaneous suspected adverse drug reports (ADR) via the Yellow Card scheme.

As part of our signal detection processes all fatal adverse drug reaction reports received by the Yellow Card scheme are assessed and cumulative fatal information reviewed at regular intervals. 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 may have caused the event, or whether the event and fatal outcome were likely to be purely coincidental and due to underlying illness.

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 one of which is hospitalisation or prolonged inpatient hospitalisation.

In regard to point (i), of the 132,478 UK spontaneous suspected ADR reports received in 2025, 1,678 were associated with a fatal outcome.

Further to point (ii), 10,596 suspected ADR reports included the 'hospitalisation or prolonged inpatient hospitalisation' flag.

In response to point (iii), of the 1,678 reports with a fatal outcome, 217 reports also inlcuded the 'hospitalisation or prolonged inpatient hospitalisation' flag.

In order to address the final part of your request, please refer to Table 1 below which provides UK spontaneous suspected ADR reports received in 2025 that include a fatal outcome for the 10 most frequently reported suspect drugs.

Table 1: The number of UK spontaneous suspected ADR reports inlcuding a fatal outcome received between 01/01/2025 and 31/12/2025 for the 10 most frequently reported suspect drugs.

Suspect drug	Number of reports
CLOZAPINE	283
PREGABALIN	89
ADALIMUMAB	75
TIRZEPATIDE	74
PARACETAMOL	56
CODEINE	41
PREDNISOLONE	39
TRAMADOL	39
SERTRALINE	38
APIXABAN	29

Please note that 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

[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.

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 awareness and publicity about a drug.

- As spontaneous data do not necessarily refer to proven side effects, you should refer to the product information for the medicine which can be found here: MHRA Products | Home for details on the possible side effects.

We 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

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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