



Medicines & Healthcare products  
Regulatory Agency

MHRA Central Freedom of  
Information Team  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU

[foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk)

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

Our Ref: **FOI2025/00090**

**Date**

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 2<sup>nd</sup> February 2025.

You wrote:

*Under the Freedom of Information Act will you please let me have following information urgently.*

- 1. The total number of adverse drug reactions and fatalities recorded under the Yellow Card Scheme for RIVAROXABAN*
- 2 The total number of adverse drug reactions and fatalities recorded under the Yellow Card Scheme for FUROSEMIDE*
- 3 The total number of adverse drug reactions and fatalities recorded under the Yellow Card Scheme for ZOLENDROLIC ACID*
- 4. The total number of adverse drug reactions and fatalities recorded under the Yellow Card Scheme for CO-TRIMOXAZOL*

## **MHRA Response**

We confirm that we hold the information you have requested.

Please find tables below providing information on spontaneous UK reports received for Rivaroxaban (Table 1), Furosemide (Table 2), Zoledronic Acid (Table 3) and Co-Trimoxazole (Table 4), up to and including 24.02.2025.

**Table 1: All UK spontaneous suspected adverse drug reaction (ADR) reports, including number reporting a fatal outcome, for rivaroxaban. Data up to and including 24.02.2025.**

Report Type	Total number of reports
Number of UK spontaneous suspected ADR reports	7692
Number of UK spontaneous suspected ADR reports with a fatal outcome	475

**Table 2: All UK spontaneous suspected adverse drug reaction (ADR) reports, including number reporting a fatal outcome, for furosemide\*. Data up to and including 24.02.2025.**

Report Type	Total number of reports
Number of UK spontaneous suspected ADR reports	3076
Number of UK spontaneous suspected ADR reports with a fatal outcome	139

***\*Includes reports where a multi-drug formulation containing furosemide was reported as a suspect drug.***

**Table 3: All UK spontaneous suspected adverse drug reaction (ADR) reports, including number reporting a fatal outcome, for zoledronic acid. Data up to and including 24.02.2025.**

Report Type	Total number of reports
Number of UK spontaneous suspected ADR reports	1953
Number of UK spontaneous suspected ADR reports with a fatal outcome	108

**Table 4: All UK spontaneous suspected adverse drug reaction (ADR) reports, including number reporting a fatal outcome, for co-trimoxazole (trimethoprim and sulfamethoxazole reported as a combination formulation). Data up to and including 24.02.2025.**

Report Type	Total number of reports
Number of UK spontaneous suspected ADR reports	5480
Number of UK spontaneous suspected ADR reports with a fatal outcome	221

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

- A reported reaction does not necessarily mean it has been caused by the medicine, 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 medicines. Reporting rates are influenced by the seriousness of the reaction, their ease of recognition, the extent of use and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines, medicines during the first one to two years on the market and then falls over time.

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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### **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](mailto: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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