



Medicines & Healthcare products  
Regulatory Agency

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Our Ref: **FOI2026/00068**

10 March 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 22 January. You wrote:

*I would like to submit a freedom of information request regarding the drug analysis print for immunoglobulin normal. There is aggregated data on drug analysis prints, however I am looking for more granular data.*

*Specifically, I please request a breakdown of the type and frequency of all different adverse events reported within skin and subcutaneous tissue for all subcutaneous immunoglobulin brands, broken down by brand, in the UK since 1st January 2015 to the most current date available reported via the yellow card system and pharmaceutical industry.*

*Route of administration to include: - 'intravenous bolus; subcutaneous' - 'other; subcutaneous' - 'subcutaneous'. The output should include - all sexes - age groups - reporter types - severity.*

## MHRA Response

We confirm that we hold the information you have requested.

It may be helpful to firstly provide some background information to allow interpretation of this data. The Yellow Card scheme is the UK system for collecting and monitoring information on suspected adverse drug reactions (ADRs). The scheme is run by the MHRA and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. There is also a legal obligation for pharmaceutical companies to report serious ADR reports to their drugs. All reports, including from patients, are reviewed through a signal detection process to identify previously unrecognised concerns about medicines and consider if further action is necessary.

The MHRA uses the Medical Dictionary for Regulatory Activities ([MedDRA](#)) which is an international standardised medical terminology used to classify information related to adverse effects into our database. This search was conducted using the Medical Dictionary for Regulatory Activities Preferred Terms (PT) captured in these reports, which are based on information provided by the original reporter.

Further to your request, I can confirm the Yellow Card scheme has received a total of 99 UK spontaneous suspected ADR reports associated with immunoglobulin normal where the route was specified as subcutaneous, with suspected reactions in the skin and subcutaneous tissue disorders MedDRA System Organ Class (SOC), between the dates of 01/01/2015 - 28/02/2026.

Please find attached Excel document which contains tables displaying the above reports broken down by brand, seriousness, MedDRA PT reaction breakdown, patient sex, aggregated age group, and reporter type. Please note that each report may list more than one suspect drug; therefore, the total number of reports received cannot be accurately derived from the figures presented in the tables.

Please note the accuracy of this data relies on the route of administration being correctly provided by the reporter in the original Yellow Card. Therefore, this information may not be a complete representation of all reports for subcutaneous immunoglobulin, as reports where the route of administration was not provided will not be included in this output.

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 medicine or medicinal product, only that the reporter had a suspicion it may have. The fact that symptoms or events occur after use of a product, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the product. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.
- 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.

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](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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