



Medicines & Healthcare products Regulatory Agency

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

Our Ref: **FOI2025/00117**

6 March 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 6 February. You wrote:

I am currently exploring datasets that provide information on adverse drug events for research purposes.

I would like to inquire whether it is possible to access anonymised individual case safety reports from the Yellow Card scheme and whether these data can be linked to Hospital Episode Statistics or other NHS datasets for further analysis.

Additionally, I would appreciate any guidance on the application process and requirements for accessing these data.

MHRA Response

We confirm that we hold the information you have requested.

Yellow Card data requests fall into the following categories:

Category 1a – Anonymised aggregated adverse drug reaction (ADR) data in the format of interactive Drug Analysis Prints (iDAPs). Drug Analysis Prints contain complete listings of all suspected adverse drug reactions or side effects, which have been reported to the MHRA via the Yellow Card Scheme. These are freely available from our website at [What is being reported | Making medicines and medical devices safer](#).

Category 1b – A list of data fields which exclude any information that can identify the patient and reporter and therefore can be released without the need for PEAG consideration. The data fields that can be provided are listed below. Details of your request should be sent to Pharmacovigilanceservice@mhra.gov.uk

Category 1b data case details listed below are releasable under the Freedom of Information Act (FOIA) without consideration by the PEAG.

- Patient age categories (ten year age bands)
- Patient sex
- Suspect drug(s)
- Dose of suspect drug(s)
- Route of administration

- Suspected adverse drug reaction(s)
- Year of receipt

Category II – If you require more than the Ib data fields then your request will be classed as a category II request. Applicants should complete this form and then send to type2yellowcarddata@mhra.gov.uk.

Further guidance on Access to Yellow Card Data is attached. This guidance document provides further detail on the categorisation of data requests and should be read in full before submitting an application for type II yellow card data. The application form for type II yellow card data is also attached.

Cases are anonymised and therefore any data provided cannot be linked to Hospital Episode Statistics or other NHS datasets for analysis.

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
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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 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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