Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI 2026.00852**

01 September 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 03 August 2026. You wrote:

> *I would be grateful if you could provide information regarding the following aspects of the Yellow Card Scheme:*
> *1. Funding for the regional Yellow Card Centres*
> *The annual funding or commissioning amount allocated to each of the six regional Yellow Card Centres, preferably for the most recent financial years. I would also appreciate clarification on whether this funding is provided through a grant, service contract or another commissioning arrangement.*
> *2. Number of dedicated Yellow Card assessors at the MHRA*
> *The number of full-time equivalent MHRA staff specifically involved in reviewing and managing Yellow Card reports. Where possible, could this be divided by functions such as report validation, clinical assessment, follow-up and signal detection?*
> *3. Number of reports received through each reporting route*
> *The annual number of reports submitted through:*
> *· the Yellow Card website;*
> *· the mobile application;*
> *· paper forms;*
> *· electronic health record or clinical IT systems;*
> *· other routes, such as telephone or email-assisted reporting*
> *4. Number of unique suspected adverse reaction cases*
> *The annual number of unique suspected adverse reaction cases remaining after duplicate reports from patients, healthcare professionals and pharmaceutical companies have been identified and combined. A brief explanation of how duplicate reports are identified would also be helpful.*
> *5. Reporting by healthcare professionals*
> *The measures used to encourage healthcare professionals to report suspected adverse reactions and to reduce under-reporting. In particular, I would be grateful for clarification on whether reporting is regarded as a legal requirement, a professional obligation or a recommendation, and whether compliance or under-reporting is formally monitored.*
>
> *Where this information is already publicly available, links to the relevant reports or datasets would be greatly appreciated.*

MHRA Response

We can confirm that the Agency holds this information.

In response to your first point, I can confirm that the MHRA commissions a network of six regional Yellow Card Centres to locally promote and educate healthcare professionals, patients and their organisations about the importance of Yellow Card reporting to support wider vigilance activity across the UK. This financial year, each centre received approximately £23k under formal service contract arrangements for Yellow Card promotion work. This contribution represents only a proportion of the actual cost incurred by each centre in delivering these services, which support both the MHRA and the wider health system.

In terms of your second point, I can confirm that there are two primary teams responsible for the management of Yellow Card (YC) reports and signal detection activities. Within the Patient Safety Monitoring (PSM) team, there are 36 assessors who process Yellow Card reports within our case management system. Their responsibilities include conducting follow-up activities where required and undertaking signal detection for established medicines. Within the Benefit-Risk Evaluation (BRE) team, there are 106 assessors who assess Yellow Card reports and perform signal detection activities for Black Triangle medicines (newly authorised medicines and vaccines) as well as for medical devices.

The activities outlined above represent only part of an assessor's role within the MHRA. Assessors are responsible for a wide range of additional functions, including responding to enquiries, providing data to stakeholders, managing Freedom of Information (FOI) requests, supporting responses to press and parliamentary questions, processing safety variations to product information, reviewing Risk Management Plans, and preparing papers for discussions at committee meetings.

To address your third point please see table 1 below which provides the number of UK spontaneous YC reports received in 2025 via each reporting route, as well as the number of reports received from industry. These reports were identified by pulling out the reporting routes from each case. They were grouped to show reports submitted through the Yellow Card website, the mobile application, paper forms, electronic health records or clinical IT systems and other routes, such as telephone or email.

Table 1: Number of UK spontaneous YC received in 2025 from each reporting route and the number of reports from industry

Reporting route	Number of reports
YC website	85366
YC APP	759
Paper	1977
Clinical systems	12205
Other	186
Industry	31616

In response to your fourth point, the case management system incorporates automated duplicate detection functionality, which identifies reports that may relate to the same case. These potential duplicates are reviewed by the relevant team to verify whether they represent true duplicates. Where appropriate, the reports are merged to ensure a single unique case record is maintained. Consequently, the numbers provided above are accurate where

enough information has been provided in each case to accurately identify and merge duplicate cases.

When considering 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 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.

In response to your final point, the MHRA encourages healthcare professionals to report spontaneous suspected adverse drug reactions, medical device incidents and other healthcare product safety concerns through the Yellow Card scheme. This is supported through guidance, education and training, safety communications, stakeholder engagement, awareness campaigns, regional Yellow Card Centres and improvements to reporting routes.

Reporting to the Yellow Card scheme is not generally a statutory legal requirement for individual healthcare professionals. The MHRA does not have jurisdiction over healthcare professionals' roles and responsibilities; however, Yellow Card reporting is supported and encouraged through relevant professional codes of conduct and the expectations of professional regulators. It is therefore regarded as an important professional responsibility and contribution to patient and public safety.

The MHRA does not routinely monitor compliance by individual healthcare professionals or formally measure under-reporting at an individual level. Under-reporting is a recognised limitation of spontaneous reporting systems worldwide, which the MHRA seeks to mitigate through continued awareness raising, education, engagement, and improvements to reporting routes. Spontaneous reports remain an important source of information for vigilance and are carefully considered alongside a range of other safety data and information to support the MHRA's wider vigilance work. While under-reporting is inherent to spontaneous reporting systems, it does not detract from their value in helping to identify potential safety signals and inform further assessment where appropriate to protect public health through effective regulation.

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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