



Medicines & Healthcare products
Regulatory Agency

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Our Ref: **FOI2026/00450**

20 May 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 23 April. You wrote:

1. Further to FOI 2025/00636, please provide the following information per year for Isle of Man postcode yellowcard reports for Covid vaccines covering from 01 January 2021 to current date:

A. Total number of reports where the primary reporter qualification was Healthcare Professional (HCP).

B. Of those HCP reports, how many were classified as "serious" under MHRA seriousness criteria.

C. Of those HCP reports, how many recorded a fatal outcome.

(If small numbers require suppression, please provide totals across all years combined rather than yearly breakdown.)

2. A. Please confirm whether previous Isle of Man totals provided in response to FOI 2025/00636 include reports submitted by Marketing Authorisation Holders (industry).

B. If not, please provide the total number of industry-submitted COVID-19 vaccine reports associated with Isle of Man postcode as one figure.

3. A. Please confirm whether any Isle of Man COVID-19 vaccine recipients were included in the MHRA's enhanced or active monitoring programmes (including the Yellow Card follow-up surveys or similar schemes).

B. If so, how many were contacted since 2021?

MHRA Response

We confirm that we hold the information you have requested.

Further to your request, I can confirm the Yellow Card scheme has received a total of 1,103 UK spontaneous suspected ADR reports associated with all COVID-19 vaccines, where the reporter postcode was registered within the Isle of Man (IM1 to IM9), from the 1st January 2021 to the 19th May 2026. As we mentioned in our previous responses, addresses and post codes are not mandatory fields for completing an ADR report. Therefore, this information may not be a complete representation of all reports from this area as reports where the postcode

is incorrectly provided, or where the reporter has only provided their email address, will not be included in this output.

Of the 1,103 spontaneous suspected adverse reaction reports received for COVID-19 vaccines from the Isle of Man, 6 were submitted by Healthcare Professionals (HCP). Of these 6 reports, 3 were classified as "serious" under the MHRA seriousness criteria. 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 criteria¹ available. Of these 3 reports, none were reported with a fatal outcome.

Further to point 2, I can confirm that this FOI as well as FOI 2025/00636 does not include reports submitted by Marketing Authorisation Holders (industry). These figures include only reports submitted directly via the Yellow Card scheme, either by healthcare professionals or patients. Reports from pharmaceutical companies are not included as they do not capture the original reporter's postcode, as such it wouldn't be possible to identify reports specifically from the Isle of Man.

Further to point 3, we have reviewed registrations from our Yellow Card Vaccine Monitor active surveillance and can confirm we have a single registration from the Isle of Man. Since 1st January 2021, 5 requests for additional information were sent to this reporter in line with the routine follow-up conducted for Yellow Card Vaccine Monitor. Further information about our COVID-19 surveillance strategy, including the Yellow Card Vaccine Monitor, is available online <https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance>

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,

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.

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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 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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check with service team to see if anything has come out