Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
www.gov.uk/mhra

11th April 2023

Dear [redacted]

RE: FOI 23/146

Please accept my apologies for the delay with this response, further to your email dated 13th February 2023, where you asked for the following:

- Updated figures for adverse events for Isle of Man postcodes for all Covid-19 brand vaccines to date, and updated DAP attachments for each vaccine to the current date.
- The ages of those who reported the adverse events.
- Information on the number of vaccinations (1st, 2nd or booster, etc) of the people reporting, and the time after that the adverse event occurred.
- Specify which batch number per brand was most reported with an adverse event.
- Provide the dates Isle of Man Yellow card information was sent to or requested by the Isle of Man government, any medical services including nobles, manxcare, DHSC and state which department.

I can confirm up to and including 08 March 2023 the MHRA have received 1,052 direct UK spontaneous Yellow Card reports associated with a Covid-19 vaccine where the reporter provided a postcode registered within the Isle of Man (IM1 to IM9). As we mentioned before, 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.

Table 1 below provides a breakdown of the number of reports that the MHRA have received for each of the Covid-19 vaccines. You will note that the sum of reports in the table does not equal the total number of individual reports as one report may include more than one vaccine brand.

Table 1: Total number of suspected ADR reports from the Isle of Man up to and including 8th March 2023.

Covid-19 Vaccine	Total number of reports

Covid-19 Vaccine AstraZeneca	629
Covid-19 Vaccine Moderna	100
Covid-19 Pfizer/BioNTech Vaccine	307
Covid-19 Vaccine Brand unspecified	^
Covid-19 Bivalent Pfizer	7
Covid-19 Bivalent Moderna	11

Tables 2 to 7 are attached as a separate document. Table 2 provides the number of reports for COVID-19 vaccines by patient age groups and tables 3-7 list the reactions received for all the Covid-19 vaccines. Please note due to a change in policy on how we display data for COVID-19 vaccines, where there are less than 5 reports, the numbers have been replaced with a ^ in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters. This is the same for data published in COVID-19 vaccine reports. As outlined in our privacy policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law, and as such is exempted under Section 40 and 41 of the FOIA. Given this change, providing you with reaction terms at the level provided previously (PT level) meant that all but a few rows of reactions were censored. Therefore, we have provided data for reactions terms that are broader (HLT level) to try to be more helpful meaning less data is censored for your review. To clarify HLTs contain a group of similar related PT terms which are grouped together. If you would still like data at the lower-level reaction term we can provide this but as said above, the majority will unfortunately be censored due to their being less than 5 reports for the reactions listed.

For information about the number of vaccines administered please refer to our colleagues at the Department of Health and Social Care. You can request information at dhsc.publicenquiries@dhsc.gov.uk. Or you may find the information you need via this link: Vaccinations in England | Coronavirus in the UK (data.gov.uk)

Table 8 provides a breakdown of the most frequently reported batch number per vaccine brand. It is important to note that it is not mandatory to provide batch numbers when submitting a Yellow Card report, and therefore this may not be a true reflection of the number of Yellow Card reports submitted for the respective batches.

Table 8: Most frequently reported batch number for COVID-19 vaccines received from the Isle of Man up to and including 08 March 2023.

Brand of Covid-19 Vaccine	Batch number
Covid-19 Vaccine AstraZeneca	41202002
Covid-19 Vaccine Moderna	3003651
Covid-19 Pfizer/BioNTech Vaccine	ER1741
Covid-19 Bivalent Pfizer	FJ5782
Covid-19 Bivalent Moderna	200020A

Furthermore, different batches would have been used at different stages of the vaccination campaign, and in different patient groups, which could also impact reporting rates. For example, reporting rates were typically higher at the beginning of the vaccination campaign as individuals received their first dose and the likelihood of experiencing a reaction, as well as the propensity to report it, differs across patients of different ages. Please be assured that the MHRA reviews Yellow Card data regularly and

we would communicate any concerns raised with the public and healthcare professionals. If you would like further information on batch usage, please contact the UK Health Security Agency (UKHSA) who hold this information.

When considering the spontaneous data provided in this response, it is important to keep in mind the following points:

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the drug or vaccine. 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. 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 or vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. For these reasons the above data should not be used as a basis for determining incidence of side effects. During assessment we take into account of the variable levels of reporting as part of our monitoring procedures.

For your final request regarding the dates of which information has been requested by the Isle of Man government, we received 3 FOI requests for data from the IoM government. Two requests were from the Department for Enterprise and the third from the chief pharmacist; all requests were received in 2021.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

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Regulating Medicines and Medical Devices

Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF