Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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21st August 2023

Dear [redacted]

FOI 23/520

Thank you for your follow up Freedom of Information (FOI) request dated 18th July 2023 where you asked for the number of Yellow Card reports for the following scenarios:

- The total number of all ADR reactions
- The total number of all ADR reports
- The total number all ADR reactions for subcutaneous products only
- The total number all ADR reports for subcutaneous products only

Please accept my apologies for the delayed response and thank you for your patience. I can confirm as of 27th June 2023, the MHRA have received a total of 1,650,643 UK spontaneous suspected Yellow Card reports associated with a total of 4,108,164 suspected reactions. In terms of those reporting subcutaneous route of administration, as of 27th June 2023 we have received a total of 54,943 UK spontaneous Yellow Card reports associated with 129,981 reactions. As previously mentioned, the numbers of reports have been provided based on the reported route of administration. Therefore, please note that the accuracy of the data relies on the route of administration being provided by the reporter. Where reporters have not specified the route of administration as subcutaneous, reports will not be included in the numbers provided. The data has not been provided based on authorised method of administration listed in product information.

When considering the spontaneous ADR data provided, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the suspect drug or vaccine, only that the reporter had a suspicion it may have been. When any medicine is given to patients, some recipients will inevitably experience illness following its use. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. 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, and may be stimulated by promotion and

publicity. 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 enclosed data should not be used as a basis for determining incidence of side effects.

I hope the information provided is helpful.

Yours sincerely,

FOI Team,
Safety and Surveillance