Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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www.gov.uk/mhra

21 June 2023

Dear [redacted]

FOI 23/353

Please accept our apologies for the delay in responding to you. Thank you for submitting an FOI request dated 18th May 2023, where you requested the following information:

"A summary of the number of yellow cards submitted to the MHRA, following a suspected adverse reaction to all of the COVID-19 vaccines, for Scotland, from 2020 until present day in May 2023.

Please provide:
a) Number of cards submitted
b) Number of adverse reactions reported
c) Number of serious adverse reactions reported
d) Number of fatal events reported from 2020 to May 2023

If possible, please provide the information by each vaccine brand.
Please also provide the data by age group."

All of the data provided within this response relates to UK spontaneous suspected Adverse Drug Reaction (ADR) reports received directly (not via pharmaceutical companies) by the MHRA between 01 January 2020 and 31 May 2023, inclusive. Please note that the accuracy of the data relies on the postcode being provided by the reporter. Where reporters have only provided an email address and not a postal address these reports will not be included in the numbers provided.

Please see attached an Annex including data as per your request:

- Table 1 contains the total number of direct UK spontaneous adverse drug reaction (ADR) reports received from Scotland for COVID-19 vaccines including those with a fatal outcome, the total number of reactions within the reports, and the total number of reactions which were serious in nature as per our Medical Dictionary for Regulatory Activities (MedDRA).

- Table 2 contains a breakdown of the total number of direct UK spontaneous ADR reports received from Scotland where the suspect drug was a COVID-19 vaccine by patient age group and vaccine reported.

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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, the extent of use of a particular vaccine, and may be stimulated by promotion and publicity about a 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 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 Group