Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

29 January 2024

Dear [redacted]

FOI 23/1015

Thank you for your FOI request dated 29 December 2023, where you requested:

- The total amount of COVID-19 vaccine adverse reactions and deaths reported to Yellow Card for Scotland from Dec 8th 2020 - present 2023?
- What percentage of reactions are classified as serious and non-serious and the top 10 most common reported adverse reactions.

As you will know we have issued an updated response to your previous FOI request (FOI 23/764) due to an error in the data provided. The below information provides a response to your above request only.

The MHRA has received 35,653 spontaneous suspected Adverse Drug Reaction (ADR) reports following COVID-19 vaccination from Scotland between 8 December 2020 and 31 December 2023 (inclusive), 216 of which were included a fatal outcome. The 35,653 ADRs contained 114,923 adverse reactions. Please note that a single Yellow Card report may contain multiple suspect reactions, therefore the number of ADRs will not equal the total number of unique reports. The 10 most reported ADRs are 'Headache', 'Fatigue', 'Pyrexia', 'Nausea', 'Chills', 'Myalgia', 'Pain in extremity', Dizziness', 'Arthralgia' and 'Pain'.

Yellow Card reports are classified as either non-serious or serious (including fatal). 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 according to 6 criteria[1]. Based on this, 59% of the reports were considered serious and 41% were considered non-serious.

[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.

It is important to note that conclusions on the safety and risks of the vaccines cannot be made on this data alone. Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the vaccine has caused the reaction. It may be difficult to tell the difference between something that has occurred naturally and an adverse reaction. Sometimes reactions can be part of the condition being treated rather than being caused by the vaccine and many suspected ADRs reported on a Yellow Card do not have any relation to the vaccine or medicine and it is often coincidental that symptoms occurred around the same time as administration.

Please note that the information supplied in this response relies on the reporter providing a Scottish postcode in the original Yellow Card. If the postcode is incorrectly provided, or if the reporter has provided an email address in place of a postal address, the Yellow Card will not be included in this data. As the data has been extracted using available postal addresses only, it may not reflect the true number of ADR reports following COVID-19 vaccinations reported from Scotland. It is important to note that the number of reports received for Scotland does not directly equate to the number of people who may have experienced adverse reactions and therefore cannot be used to determine the incidence of reactions. ADR reporting rates are influenced by many aspects, including the extent of use.

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,
Safety and Surveillance Group