Medicines & Healthcare products
Regulatory Agency

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[redacted]

9 November 2023

FOI 23/764

Dear [redacted]

Thank you for your FOI request dated 12th October 2023, where you requested:

"Can you tell me the total amount of COVID-19 vaccine adverse reactions and deaths reported to Yellow Card for Scotland from Dec 8th, 2020-present 2023? Please identify what percentage of reactions are classified as serious and non-serious".

Since 8th December 2020 up to and including 29th October 2023, 46,552 spontaneous suspected Yellow Card reports have been submitted to us from Scotland with a COVID-19 vaccine, within these cases 154,413 adverse reactions have been reported. Multiple reactions may be included in each report, for example an individual may report arm pain, redness, and tiredness as three separate reactions within their single report.

Further to the above, 302 of these spontaneous suspected Yellow Card reports included a fatal outcome. The MHRA takes all reports, including those with a fatal outcome very seriously. All reports with a fatal outcome are reviewed alongside all available evidence including an assessment of post-mortem details if available, to consider whether the vaccine (or medicine) may have caused the event, or whether the event and fatal outcome were likely to be purely coincidental and due to underlying illness.

You also asked for the percentages of these reports that were classified as serious versus non-serious. 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, 75% of the reports were considered serious and 25% 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.

For COVID-19 vaccines, the overwhelming majority of reports of suspected reactions received relate to injection-site reactions (sore arm for example) and generalised symptoms such as 'flu-like' illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally, these happen shortly after the vaccination and are not associated with more serious or lasting illness.

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. As is the case with fatalities as mentioned above, 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

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
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