Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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5th July 2023

Dear [redacted]

RE: FOI 23/379

Apologies for the delay in responding and thank you for your recent FOI request from 26h May 2023, where you requested disclosure of the following information under the Freedom of Information (FOI) act:

For all fatal Yellow Card reports relating to the COVID-19 Moderna vaccine:

i) How many of these Yellow Card reports has the MHRA followed up with healthcare colleagues to request further information?
ii) Of these follow up requests, how many have gone unanswered?

To provide some background, we acknowledge receipt of each report, and our team of safety experts follow up for additional information as necessary, based on the completeness, severity and clinical details provided in the report. We actively follow up Yellow Cards of special interest including those with a fatal outcome for any information that would benefit in our assessment such as a post-mortem report and encourage all reporters to send relevant updates on their reports. Users are also now able to proactively update their Yellow Card reports through their accounts themselves.

The MHRA has received 121 Yellow Card reports for the COVID-19 Moderna vaccine with a fatal outcome. I can confirm we have requested further information specifically with a healthcare professional for 65 of these reports, 42 of which have been unanswered. Whilst many of the requests for further information have not been responded to, this does not reflect our ability to complete our safety monitoring activities. One of our main roles is to continually monitor the safety of medicines and vaccines during use, and as you may know we have in place a proactive strategy to do this for COVID-19 vaccines. Through this strategy we supplement our routine safety monitoring, with epidemiology studies, including data analysis on national vaccine usage, anonymised GP-based electronic healthcare records, and other healthcare data to proactively monitor safety. These combined safety data enable the MHRA to detect side effects or safety issues associated with COVID-19 vaccines.

Patient safety is our highest priority and the MHRA takes all reports with a fatal outcome very seriously, with each report being assessed, together with additional sources of evidence, by a team of

safety experts. We also monitor deaths rates over time and the information is thoroughly analysed for patterns or evidence which might suggest a causal link between the vaccination and the death.

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

- A reported reaction does not necessarily mean it has been caused by the vaccine or medicine, only that the reporter had a suspicion it may have. 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 or compare the safety profile of different vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

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