Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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www.gov.uk/mhra

21st September 2023

Dear [redacted]

RE: FOI 23/634

Thank you for your recent FOI request from 25h September 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 Pfizer monovalent and bivalent Covid-19 vaccine (for which, as of 25 August 2023, you had 930 reports), how many have you followed up with healthcare colleagues to request further information?

We confirm that we hold the information you've requested, and we are providing this below.

As you will know 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, and encourage all reporters to send relevant updates on their reports.

The MHRA has received 971 Yellow Card reports for COVID-19 Pfizer BioNtech monovalent and bivalent vaccines with a fatal outcome up to and including 2nd August 2023. At the current time, we have sent correspondence to request further information to aid our assessment for 946 reports. A total of 529 of these requests have been sent to healthcare professionals and 459 with relatives or carers of the patient. Some reports may have been followed up with a relative or carer *and* a healthcare professional where that information has been provided; hence the sum of reports which have been followed up for further information will not equal the unique number of reports. Additionally, some reports were deemed not to require further information to aid our assessment activities.

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.

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.

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