Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

www.gov.uk/mhra

24th August 2023

Dear [redacted]

FOI 23/557

Thank you of your email dated 29th July 2023, where you requested the following regarding Yellow Card reports where a COVID-19 vaccine was the suspect vaccine:

1) How many of the AstraZeneca COVID-19 vaccine reports have been verified as vaccine injuries or adverse reactions?
2) How many of the Pfizer COVID-19 vaccine reports have been verified as vaccine injuries or adverse reactions?
3) How many of the Moderna COVID-19 vaccine reports have been verified as vaccine injuries or adverse reactions?
4) How many of the unspecified COVID-19 vaccine reports have been verified as vaccine injuries or adverse reactions?

In response to questions 1 – 4 the MHRA does not hold the requested information of whether an event is verified as being a vaccine injury or adverse reaction. A reported adverse reaction included in a Yellow Card report may not necessarily be due to a medicine or vaccine. While the MHRA carefully assesses Yellow Card reports to facilitate assessment of the link between a medicine or vaccine and the reported adverse event, we do not assign causality (i.e., whether the patient's reaction was caused by the medicinal product) at the level of individual reports. MHRA considers data from Yellow Card reports, along with relevant information from other sources in their overall assessment of whether there may be a causal link between a medicinal product and an adverse event. Should a new link between a medicine and a safety concern be confirmed, the MHRA will take regulatory action, such as updating product information to include a warning for patients and healthcare professionals.

We are able to provide you with the number of reports we have received through the Yellow Card scheme for COVID-19 vaccinations. You may be aware that in December 2022, COVID-19 vaccine interactive reporting profiles were made available on our website. These COVID-19 vaccine reports are interactive and provide a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for medicines and COVID-19 vaccines. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies.
When considering the attached 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 medicine or vaccine, 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.

A list of the recognised adverse effects of the COVID-19 vaccines is provided in the information for healthcare professionals and the recipient information.

You may also be aware that the MHRA published the Summary of Yellow Card reporting for COVID-19 vaccines which detailed the number and types of all UK suspected adverse reactions received via the scheme as well as providing information on any emerging safety issues at the time of publication. Since the cessation of this publication, robust safety monitoring and surveillance of any COVID-19 vaccines used in the UK has continued along with timely communication on any updated safety advice when needed.

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

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