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

17th May 2024

Dear [redacted]

FOI 2024/00088

Thank you for your email dated 3rd May 2024, where you asked for information on the following:

> "*How many people suffered a Serious Adverse Event From having the Novavax SARS-CoV-2rs with Matrix M1 Adjuvant.*"

Since the launch of the COVID-19 immunisation campaign, the MHRA has been proactively monitoring the safety of all COVID-19 vaccines approved in the UK. This is a requirement for all authorised medicines and vaccines in the UK, and put in place a strategy to do this specifically for COVID-19 vaccines following the initial roll out. Through this strategy, we were able to rapidly detect, confirm, and quantify any new risks and weigh these against the expected benefits. We then take any necessary action to minimise risks to individuals. Details of the strategy can be found in the following link: COVID-19: vaccine surveillance strategy - GOV.UK (www.gov.uk).

As you may be aware, the MHRA has been publishing Vaccine Analysis Prints (VAPs) and a summary of Yellow Card reporting concerning COVID-19 vaccines. The Novavax Vaccine Analysis Print can be found here. These VAPs contain data on all spontaneous suspected adverse reactions reported in association with a COVID-19 vaccine via the Yellow Card scheme. With this, you can view the VAP for the COVID-19 Novavax vaccine and find out the number of serious adverse drug reaction reports the MHRA has received. The Yellow Card scheme collects and monitors information on suspected safety concerns involving healthcare products, like medicines or medical devices and takes action to ensure their safe use in clinical practice.

When reviewing the VAPs, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. Each year, millions of doses of routine vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. 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.

The MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

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

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
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

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