Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Stephen Feldman
[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

27th July 2021

Dear Mr Feldman,

FOI 21/752

Thank you for your email on 1st July requesting how the MHRA determine that the rate and nature of Yellow Card reporting for COVID-19 vaccines is not unusual.

Statistical and scientific analyses are completed to determine if the reports received are unexpected. The data published by the MHRA shows that the safety of the COVID-19 vaccines is as expected based on the robust clinical trial data that supported the authorisations of Pfizer/BioNTech COVID-19 vaccine, COVID-19 vaccine AstraZeneca and COVID-19 vaccine Moderna. It is known from the clinical trials that the more common side effects for the vaccines can occur at a rate of more than one in 10 doses (for example, local reactions or symptoms resembling transient flu-like symptoms). Therefore, Yellow Card reporting is lower than the reporting rate of possible side effects from the clinical trials, although we generally do not expect all suspected side effects to be reported on Yellow Cards.

Prior to starting the COVID-19 vaccination programme, information from previous UK vaccination programmes was used to help the MHRA estimate the anticipated volume of Yellow Card reports. However, the incident numbers, including fatal reports from previous vaccination campaigns, are not being used as a comparative measure for the data in the summary report. The number and nature of the reports are dependent on various factors, including the number of doses administered and the use of concurrent treatments (for instance, to manage fevers), and there is no previous vaccination programme with similar parameters to the COVID-19 vaccination rollout. For the COVID-19 vaccines, the nature of reported suspected side effects is broadly similar across age groups, although, as seen in the clinical trials and as is usually seen with other vaccines, they may be reported more frequently in younger adults.

Furthermore, it is acknowledged by the MHRA that the overall reporting rate for the COVID-19 vaccines has been higher than the Yellow Card reporting rate seen for other medicines and vaccines. One of the reasons this is not viewed as unusual is due to this programme being on a larger scale than previous immunisation campaigns, as most people in the UK are being invited to receive two doses of a COVID-19 vaccine. There is also an increased public awareness of the Yellow Card scheme. The MHRA has made substantial efforts to engage healthcare professionals and members of the public with the Yellow Card scheme during the pandemic. We have completed

social media campaigns; issued a Drug Safety Update and a press release informing healthcare professionals and members of the public that reporting to the new site will enable the MHRA to rapidly identify new and emerging side effects. The general public have also been encouraged to report any suspected side effects to the vaccine to the MHRA via a Yellow Card on televised press briefings. It was essential for us to do this since the Yellow Card scheme relies on voluntary reporting of suspected side effects or medical device incidents.

An additional reason the figures are not seen as unusual is due to the suspected side effects being reported. Most of the reported reactions are mild to moderate in severity and usually resolve within a few days of vaccination. The common suspected reactions reported tend to be listed as possible side effects in the COVID-19 vaccine's product information or seen in the clinical trial data. It is also important to note that a report of a suspected reaction to the Yellow Card scheme does not necessarily mean that the vaccine caused it, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illnesses unrelated to vaccination can also be factors in reports. Therefore, it is important not to compare the reported adverse reactions from the COVID-19 vaccines with other vaccines.

Overall, the MHRA considers multiple factors in addition to the volume of reports submitted; there is no exact threshold for the number of reports received that would change the total and nature of reports from expected to unusual.

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 this response's date and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division