Medicines & Healthcare products Regulatory Agency

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[redacted]
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09 February 2024

Dear [redacted],

FOI 24/099

Thank you for your Freedom of Information (FOI) request dated 30th January 2024, in which you asked the following:

Within the MHRA's response to Dr Tess Lawrie, Director of Evidence-based Medicine Consultancy Ltd and EbMC Squared CiC, from Dr June Raine, dated 22 July 2021 (MHRA reference CEO 18916), the MHRA states the following:

"With regards to your points on under-reporting in pharmacovigilance data, the reporting rate for ADRs is variable and can depend on a multitude of factors. These estimates should not be used as indicators of the reporting rate for COVID-19 vaccines, for which there is high public awareness of the Yellow Card scheme and the reporting of suspected reactions."

Where the MHRA claims 'there is high public awareness of the Yellow Card scheme and the reporting of suspected reactions' please provide the evidence held by the MHRA at the time of the letter (up to 22 July 2021) in support of this claim.

This same claim from the MHRA implies that the high level of adverse events reported in the period between 4 January 2021 and 26 May 2021, as highlighted by Dr Lawrie, are in some way attributable to your claim of 'high public awareness of the Yellow Card scheme and the reporting of suspected reactions,' therefore I kindly request that you provide the evidence held by the MHRA at the time of the letter (up to 22 July 2021) in support of this.

The MHRA do not hold a specific document for disclosure that could be provided in response to this request. The statement made by the MHRA concerning high public awareness of the Yellow Card scheme and the reporting of suspected reactions was inferred from the number of Yellow Cards received reporting suspected side effects to the COVID-19 vaccines. Information on the number of Yellow cards reported and the reporting rates associated with the COVID-19 vaccines was made publicly available throughout the pandemic in our Coronavirus vaccine - summary of Yellow Card reporting - GOV.UK (www.gov.uk).

Yellow Card reporting rates for the COVID-19 vaccinations are higher than for other medicines or vaccines as throughout the pandemic, the MHRA worked to ensure that people knew how to report suspected side effects to the Yellow Card scheme. In addition to social media campaigns, we issued a Drug Safety Update, a press release, and embedded information about Yellow Card reporting into healthcare professionals training materials. The general public were also encouraged to report any suspected side effects to the COVID-19 vaccines to the MHRA on the televised press briefings. Information on reporting side effects to the MHRA was carried in all of the vaccine product information received by the general public upon vaccination, as well as in the Public Health England (now UK Health Security Agency) materials received when individuals were first invited for vaccination.

We 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
Medicines and Healthcare products Regulatory Agency