

## **FOI 23/104 - Revised request regarding follow up of Yellow Card reports**

02 March 2023

Thank you for your email dated 4 February 2023 in which you requested how many of the first 1400 Yellow Card reports relating to COVID-19 vaccinations were followed up, whereby the MHRA contacted the person making the report requesting further information.

As explained previously, we acknowledge receipt of each Yellow Card 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 for any information that would benefit in our assessment and encourage all reporters to send relevant updates on their reports. Additionally, all fatal reports are followed up to enquire whether a post-mortem was conducted and to request a copy of the report. Not all Yellow Card reports require follow up by the MHRA. For example, if the reporter provides a comprehensive account of the clinical details upon first submission or if the reporter does not provide permission for the MHRA to contact them again.

Of the first 1400 UK spontaneous Yellow Card reports submitted to the MHRA by healthcare professionals or patients and their representatives, 176 were followed up for further information by the MHRA. Please note, as mentioned above, we actively encourage all reporters to send relevant updates on their reports and this number does not include reports in which the reporter has spontaneously sent the MHRA relevant updates on their report.

To provide further context, 823 of the first 1400 Yellow Cards submitted to the MHRA reported symptoms that have been defined as non-serious within our medical dictionary.

Furthermore, of the first 1400 Yellow Card reports submitted relating to the COVID-19 vaccines, 8 reported a fatal outcome. Each of these 8 reports was followed up for further information from the reporter within a timely manner to allow further assessment by the MHRA.

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 Group

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The Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

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