

FOI 23/010

3<sup>rd</sup> February 2023

Dear

Thank you of your email dated 7th January 2023, where you requested:

1. The total number of individuals making Yellow Card reports regarding COVID-19 vaccines
2. How many of those individuals making reports has the MHRA contacted requesting further information?

I can confirm that the MHRA does hold some of the information that you have requested. However, we have also determined that the information is exempt under Section 12 of the Freedom of Information Act and we cannot process your request any further. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving, and extracting the information.

Yellow Cards can be submitted electronically via our Yellow Card website or app, physically on a Yellow Card, or via our phonenumber. When submitting these reports, reporters can choose what personal identifying information to provide. This can include their name, address, phone number, or email address. Reporters do not have to provide each of these details, and as such, there is no one variable that can be used to calculate the number of reporters. In order to complete your first request, we would need to extract the reporter details for every Yellow Card associated with a COVID-19 vaccine and manually validate this list for duplicate reporters. We consider the review of all reporters who have submitted a Yellow Card report associated with a COVID-19 vaccine will take longer than 24 working hours to complete.

With regard to your second request, although we hold information on whether a Yellow Card report has been followed up, this information is not easily extractable. The MHRA has received over 470,000 Yellow Card reports associated with a COVID-19 vaccines. An individual would need to manually open each Yellow Card report to check whether a request for further information was sent. Checking a single Yellow Card report for evidence of follow up would take a minimum of 45 seconds and in some instances longer. This would equate to an individual spending over 5875 hours for this aspect of your request.

We acknowledge receipt of each 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.

Unfortunately, we have been unable to fulfil your request, you do 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