FOI 23/117

9th March 2023

Dear

Thank you for your email dated 9th February 2023, where you asked:

For all Yellow Card reports relating to covid-19 vaccines,

a) how many have you followed up with colleagues in primary, secondary or tertiary care to request further information?

b) how many of these follow ups have gone unanswered from primary, secondary or tertiary care?

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.

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 alone, not including manually reviewing to determine if the request for information had been answered.

To provide some background, 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, we follow-up all reports with a fatal outcome 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, 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,

Vigilance and Risk Management of Medicines Division