FOI 23/011

10th February 2023

Dear

Please accept our apologies for the delay in responding to your request. Thank you of your emails dated 7th January 2023, where you requested Yellow Card data for COVID-19 vaccines relating to information contained in the Summary of Yellow Card reporting, information on causation with respect to Yellow Card reports and COVID-19 vaccines, and information relating to the analysis and epidemiological studies described in the COVID-19 vaccine monitoring strategy.

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.

Please note that for some of your request concerning Yellow Card data, this information can be found in COVID-19 vaccine reports on our Yellow Card website. These reports were launched in December 2022 and enables us to provide improvements in format, accessibility and data protection whilst allowing access to more data than has been published previously.

It is difficult to suggest specific refinements to your requests given the volume of questions included in the 3 emails. However please note that your request relating to the summary of Yellow Card reporting whereby the ask involves tracking each published version of the report and extracting information at each of those points in time would fall under Section 12 as a standalone request. Additionally, we do not hold a document that you have requested regarding any MHRA assessment of why COVID-19 vaccines have been dismissed as causing adverse reactions. We consider that in order to fulfil your request including the explanation of MHRA processes, tracking and sourcing documents, and extraction of relevant data along with calculations pertaining to the data, will take longer than 24 working hours to complete.

We suggest you refine your request significantly, however please note that any refinement of your request is also subject to section 12. We hope you have found the information regarding the exemption useful and we look forward to receiving a refined request in due course.

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