Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

27 July 2023

Dear

FOI 23/360

Thank you for your email dated 22nd May 2023, where you asked:

> *For all fatal Yellow Card reports relating to the Pfizer monovalent and bivalent Covid-19 vaccine (for which, as of 22 May 2023, you had 903 reports),*
>
> > *a) how many have you followed up with colleagues in primary, secondary or tertiary care to request further information?*
> > *b) how many follow ups have gone unanswered from colleagues in primary, secondary or tertiary care?*

Firstly, please accept my apologies for the delay in responding to your request. 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. An individual would need to manually open each Yellow Card report to check whether a request for further information was sent, and subsequently whether a response was received. Checking a single Yellow Card report for evidence of follow up, and a subsequent response, would take a minimum of 2 minutes and in some instances longer. Completing the process outlined above would mean an individual would spend over 24 hours locating, retrieving, and extracting the information for your request, therefore exceeding the time limit defined under the FOI act.

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

The Agency has provided an explanation of the retrieval for Yellow Card report data to the ICO for their investigation of FOI 23/117, and the ICO's decision notice is now published[1]so I will not repeat this explanation here. I can confirm that this request above needs the same process for reviewing Yellow Card reports.

Our FOI Manager has advised that she has been in contact with you about your requests and is now looking at what information can be retrieved within 24 hours to help provide advice and assistance about making a narrowed request; she is contacting you separately about this.

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,
Safety and Surveillance

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

[1] https://ico.org.uk/media/action-weve-taken/decision-notices/2023/4025975/ic-235833-s6h9.pdf