Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Mr Graham Crawley
request-761407-4fb6e7a9@whatdotheyknow.com

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

28th June 2021

Dear Mr Crawley,

FOI 21/601

Thank you for contacting the MHRA regarding the reports we have received concerning the Oxford University/AstraZeneca and Pfizer/BioNTech COVID-19 vaccines.

Under the Freedom of Information (FOI) act, you have requested to be provided with the following:

"Please provide the following information for the AstraZeneca ChAdOx1-S and Pfizer/BioNTech BNT162b2 vaccines:
What adverse reactions, including deaths, have been reported so far in 2021 for each vaccine by or on behalf of vaccinees who were taking Adalimumab or other TNF inhibitors at the time of vaccination"

Unfortunately, we are unable to provide details of concomitant medications for individual cases. Because of the way this information is captured within our database, this would require manual extraction of the information from each individual case.

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 be reassured that any information provided regarding a patient's drug history, concomitant medication or concurrent condition is considered during the routine assessment of all cases that we receive.

The MHRA is not aware of any robust evidence which suggests that individuals taking any of the medications, or classes of medications mentioned, are at increased risk of any particular adverse reactions, nor whether these individuals are at increased risk of more severe adverse reactions than those who do not take these medications.

As a precaution, we encourage patients who are taking other medications to discuss any concerns with their doctor or pharmacist, who will be in the best position to advise them.

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The MHRA is committed to transparency and as you may be aware, we are publishing a weekly summary of Yellow Card reporting which can be found on this link: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting. In this publication, you will find information on the reports that we have received for each of the approved COVID-19 vaccines.

It is important to note that Yellow Card reports are not proof of a side effect occurring due to a vaccine but a suspicion by the reporter that the medicine or vaccine may have caused the side effect. Each year, millions of doses of routine vaccines are given in the UK alone, and when any vaccine is administered to very large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms or events occur after use of a vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the vaccine. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

Dr June Raine, MHRA Chief Executive, said:

“Over 44 million doses of vaccines against COVID-19 have now been administered in the UK, saving thousands of lives through the biggest vaccination programme that has ever taken place in this country.”

“It is still vitally important that people come forward for their vaccination when invited to do so.”

“We ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report it to the Coronavirus Yellow Card website.”

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,

Vigilance and Risk Management of Medicines Division

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, 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

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