Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

18th March 2021

Dear [redacted]

Our Ref: FOI 21/187

Thank you for your email dated 16th February 2021, where you asked:

"1. For ADR events of all of the products currently being administered in the U.K Government's vaccination programme could you please group the total of all ADR figures into sex and age groups. I have been unable to find this information on your specific web page and I am assuming therefore that it has not been made public.

2. I would like a tally number of all weekly yellow card reports received by the MHRA from January 1st 2018 through to 12/2/2021 showing the total number of yellow card reports the MHRA has received for each week.

3. I would like full copies of all yellow card reports received by the MHRA that mention either the Pfizer product or the Astrazeneca product covering the dates 8/12/20 -12/2/21. This will include the full detailed written reports of each yellow card submitted and not just the number received.

4. I would like complete, unredacted copies of all contracts signed between Pfizer and the MHRA and Astrazeneca and the MHRA. In particular I would like full, unredacted clauses and contracts signed in relation to these companies being granted full legal indemnity to any claims by the MHRA and U.K Government on the 8/12/20. (If you do not hold these then please advise as to which government agency does)"

I can confirm that the MHRA collects reports of suspected adverse reactions to medicines and vaccines via the Yellow Card Scheme. Section 12 of the FOI Act specifies that a public authority may 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. We consider that extracting the adverse reactions data that you have requested will take longer than 24 working hours to complete.

We would be able to provide you with Drug Analysis Prints (DAPs) which include the number of reports of all suspected adverse reactions to a particular medicine or vaccine if you were to narrow your request by, for example, limiting your request to specific vaccines on the schedule.

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Additionally, adverse reaction data for COVID 19 vaccines has been published by the MHRA and is available to view at the following link to our webpage:

https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

We intend to publish all suspected reactions reported in association with available COVID-19 vaccines in an interactive format as iDAPs, along with our ADR summary that is published each week. The use of iDAPs will enable users to view the data by categories of their choice such as age, sex and seriousness of reports. User will also be able to download the data tables in CSV format. We would be happy to provide you with a link to this when it is published.

Please note, patient and reporter information is exempt from release under Section 40 of the FOI Act which protects personal data, the disclosure of which would breach one or more of the data protection principles. Therefore, copies of Yellow Card reports cannot be released.

As your request has been refused under Section 12 of the FOI Act, we cannot answer any part of it however we will be happy to provide a response to any refined request you send in the future.

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