Medicines & Healthcare products Regulatory Agency

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[redacted]
By email: [redacted]

12 January 2024

FOI **23/985**

Dear[redacted]

Thank you for your Freedom of Information request dated 07 December 2023. I apologise for the delay in responding to your request.

Your Request **and Our Response**

Please find below answers to the questions you have raised below.

1.Why an already vulnerable group with a non-medical condition is being linked to a medical decision? Why are children with ASD more at risk? What is the justification of this ?

The MHRA does not hold this information. The decision to include people with neuro-disabilities in the clinically vulnerable group was made by JCVI and we advise that you contact them on this. and can be contacted via e-mail: JCVI@dh.gsi.gov.uk. The handbook can be found following this link:

COVID-19: the green book, chapter 14a - GOV.UK (www.gov.uk)

2.Please can you also provide me and share with me the evidence based research you use to demonstrate ;

a. The COVID-19 vaccinations 'proven safety record' and where this vaccine has specifically been tested in 10 year old children and any adverse short, medium and long term side effects monitored

b. Evidence based research where testing has taken place in the 2 control groups, non vaccinated children who have had COVID-19 and vaccinated children who have had COVID-19 and the contraction and recurrence of COVID-19 in both of these groups.

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I can confirm that the MHRA does not hold a report of the COVID-19 vaccines' 'proven safety record'. The MHRA's position on the safety of the COVID-19 vaccines is underpinned by the totality of evidence for the respective vaccines from clinical trials to the cumulative safety data from the post-marketing period. This comprises a range of data and assessments which we have determined is exempt under Section 12 of the Freedom of Information Act. 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. In this case one person would have to undertake searches of multiple repositories for documents containing 'Covid 19 vaccine safety' and that the use of this tool would take MHRA over the costs limits for central government. You are advised to consider narrowing the scope of your request to a particular safety topic.

However, you may find this information helpful, which is taken from the EMA Comirnaty webpage:

A study in children aged 5 to 11 showed that the immune response to Comirnaty given at a lower dose (10 micrograms) was comparable to that seen with the higher dose (30 micrograms) in 16- to 25-year-olds (as measured by the level of antibodies against SARS-CoV-2). Of the 1,305 children receiving the vaccine, three developed COVID-19 compared with 16 out of the 663 children who received placebo. This means that, in this study, the vaccine was 90.7% effective at preventing symptomatic COVID-19 (although the true rate could be between 67.7% and 98.3%).

For further information, the requester should see the Public Assessment Reports (PARs) published by the European Medicines Agency (EMA) and MHRA. Links to these are provided below:

https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

https://products.mhra.gov.uk/search/?search=Comirnaty&page=1&doc=Par&rerouteType=0

https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

3a.Evidence and data that COVID-19 spreads more easily in Winter

I can confirm that MRHA does not hold this information.

3b. The evidence-based research demonstrating that multiple COVID-19 vaccinations in children and any short, medium or long term adverse effects and secondly that this prevents them from contracting COVID-19 with evidence based research again in the relevant control groups (children of this age group who are vaccinated and unvaccinated).

For Q3b, there is the following information for Comirnaty taken from the EMA website that you may find useful:

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Additional data showed that subsequent doses, including boosters, lead to a rise in levels antibodies against SARs CoV 2. Available data also indicate that vaccines adapted specifically to target circulating strains of the virus are expected to elicit a strong immune response against these strains. You can find this study here: Comirnaty | European Medicines Agency (europa.eu)

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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

Yours sincerely,

FOI Team
MHRA Customer Service Experience Centre