FOI 23/066

9th March 2023

Dear

Thank you for your further information request dated 20 January where you asked the following:

1) How does the MHRA, in absence of any data, approve for emergency or otherwise, a medicine or vaccine without information, science or data to inform on potential dangers or interactions with other medicines or vaccines? Furthermore, where are the studies about the dangers of such vaccine interactions on people whose immune system is already compromised?

2) It is clear, there is now evidence that shows there is a large increase in myocarditis and pericarditis with increased uptake of these vaccines, yet, the risk is still classed as <1/10000. What is the actual % increased risk and the potential for death caused by continued uptake these boosters / vaccines?

3) How does the MHRA measure the vaccine efficacy? and what are the time periods which this is measured; and why are these limited time periods chosen?, furthermore, if a patient becomes ill with same symptoms of the disease the vaccine is designed to protect against, where is that recorded in these documents and why does this, seemingly, not impact the vaccine efficacy value?

4) Where are the studies of the impacts on fertility with these vaccines for adult, and potential risks to children's ability to have a healthy reproductive system?

5) More importantly, there is a lack of concentration on a targeting approach for the use of these vaccines. Moreover, where are the studies which show that healthy children and adults need(ed) these vaccines in the first place to fight off this virus a. Is advising on the correct use of vaccines not part of the MHRA remit?

We will address each of your questions in turn:

Firstly, all the COVID-19 vaccines used in the UK vaccination programme were approved following a rigorous review by the MHRA and the Government's independent advisory body, the Commission on Human Medicines (CHM), of their safety, quality and effectiveness. The MHRA concluded that the COVID-19 vaccines were safe and effective and that the benefits outweigh any risk.

Where a medicine will be co-administered with another medicine this is assessed pre-authorisation. For example, when new vaccines are added to the UK childhood immunisation schedule, they are routinely investigated in combination with the existing vaccines that will be co-administered. A specific example is clinical studies in infants demonstrated that the immune responses of the co-administered routine vaccines were unaffected by concomitant administration of Bexsero (meningitis B vaccine), based on non-inferior antibody response rates to the routine vaccines given alone. Further information can be found in the Public Assessment Report for Bexsero: https://www.ema.europa.eu/en/documents/assessment-report/bexsero-epar-public-assessment-report_en.pdf

If no data on co-administration are available, no recommendation on co-administration is made by the MHRA in the product information.

However, the authorities that regulate vaccination administration and vaccine campaigns can recommend co-administration if they consider that there is a need and a rationale for it.

Advice on co-administration of COVID-19 vaccines with other vaccines is given in chapter 14a of the Green book which has the latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK. As outlined, in the Green book, initially data on co-administration of COVID-19 vaccine with other vaccines was limited but more information has become available since then (please see Chapter-14a of the Green book for further details. The Green book also provides advice on the use of COVID-19 vaccines in individuals with immunosuppression.

Medicines are not routinely tested on immunocompromised individuals unless the medicine is used to treat these patients. In the case of COVID-19 vaccines, 'Use in immunocompromised individuals' is included as missing information in the Risk Management Plans (RMPs) for these vaccines and all the companies have proposed suitable studies to evaluate the use of their COVID-19 vaccine in immunocompromised individuals. The findings of these studies will be evaluated alongside any other relevant data.

Secondly, no medicine or vaccine is completely risk-free and, hence the MHRA continually monitors the safety of the COVID 19 vaccines through a comprehensive COVID-19 Vaccine Surveillance Strategy. This monitoring strategy is proactive and based on a wide range of information sources, with a dedicated team of scientists continually reviewing information to look for safety issues or any unexpected, rare events.

The Yellow Card scheme is one of these sources of information and is the UK system for collecting suspected side effects to medicines and vaccines from healthcare professionals and patients. We publish a summary of Yellow Card reporting for the COVID-19 vaccines which summarises information received via the Yellow Card scheme. This report now focuses on the COVID-19 vaccines administered from the beginning of the Autumn 2022 booster campaign. Please see our existing record for a summary of information received via the Yellow Card scheme on COVID-19 vaccine primary and booster vaccination campaigns up to the end of August 2022 as well as safety investigations carried out by the MHRA on these products. These published summaries include information on reports of myocarditis and pericarditis received in association with COVID-19 vaccines deployed in the UK including reporting rates per million doses for myocarditis and pericarditis and the number of reports received with a fatal outcome in the UK for COVID-19 vaccine primary and booster doses.

Thirdly, vaccine efficacy is usually measured in randomised controlled clinical trials. It is calculated by comparing the proportion of trial subjects that developed symptomatic COVID-19 in the vaccine arm with the proportion that developed symptomatic COVID-19 in the placebo arm. The calculation is made after a certain number of COVID-19 cases have occurred in the trial as a whole. This number is decided at the start of the trial. This means that a time period is not chosen.

More details on the measurement of vaccine efficacy are found in Public Assessment Reports (PARs) that can be found online at: https://products.mhra.gov.uk/

Of note, the clinical data for all the authorised vaccines have been published by the EMA. A link to their clinical repository is provided below:

https://clinicaldata.ema.europa.eu/web/cdp/home

Data are available on the impact of the vaccination campaign in reducing infections, illness and mortality in the UK, as monitored by the UK Health Security Agency.

Fourthly, there is no evidence to suggest that COVID-19 vaccines will affect fertility and a person's ability to have children. A recently published systematic review and meta-analyses of published studies on the impact of COVID-19 vaccines on fertility did not find any proven association between COVID-19 vaccines and fertility impairment in either men or women.

Finally, the MHRA does not hold the information requested in your final question. The body responsible for advising the UK Government on the COVID-19 vaccine roll out is the Joint Committee on Vaccination and Immunisation (JCVI). JCVI advice is independent of MHRA.

We hope this information is helpful.

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

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