Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

7 November 2023

Dear [redacted]

FOI 23/751

Thank you for your email of 9 October 2023, where asked the following question under the Freedom of Information Act:

I would like to know if the MHRA has reviewed Pfizer's pregnancy and lactation cumulative review document which specifies a wide range of adverse events reported for breast-feeding infants exposed to the Pfizer-BioNTech Covid-19 vaccine/COMIRNATY via their vaccinated mothers and foetal harm due to trans-placental exposure.

[…]

Based on this report how can the MHRA be recommending that COMIRNATY is safe in pregnant and lactating women? Why is the UK HSA promoting its use in this cohort?

You have not provided a link to the document to which you refer, therefore the MHRA is not able to say whether or not we have reviewed this document. It is noted that you refer to this as a document submitted to the US Food and Drug Administration which describes adverse events reported for pregnant and breastfeeding women. We can provide some information explaining how the MHRA has closely and continually monitored the safety of the COVID-19 vaccines during pregnancy and breastfeeding since the initial roll out of the COVID-19 vaccination programme. The vaccine manufacturers are also required to submit information

to the MHRA on the safety of their products in these cohorts, including adverse reaction reports and updates from ongoing studies involving pregnant women.

In the UK, the Yellow Card scheme is a mechanism by which anybody can voluntarily report any suspected adverse reactions or side effects to the vaccine. It is very important to note that a Yellow Card report does not necessarily mean the vaccine caused that reaction or event. We ask for any suspicions to be reported, even if the reporter isn't sure if it was caused by the vaccine. Reports to the scheme are known as suspected adverse drug reactions (ADRs). Many suspected ADRs reported on a Yellow Card do not have any relation to the vaccine or medicine. The reports are continually reviewed to detect possible new side effects that may require regulatory action, and to differentiate these from things that would have happened regardless of the vaccine or medicine being administered, for instance due to underlying or undiagnosed illness.

It is important to note that pregnant women may be at an increased risk of becoming severely ill with COVID-19, particularly if they get infected in the third trimester or if they also have underlying medical problems, compared to non-pregnant women. The MHRA's ongoing review of the safety of COVID-19 vaccines in pregnancy included review of suspected adverse reaction reports and also published information. Overall the number of Yellow Card reports for pregnant women are low in relation to the number of pregnant women who have received COVID-19 vaccines. Pregnant women have reported similar suspected reactions to the vaccines as people who are not pregnant. Reports of miscarriage and stillbirth were also low in comparison to how commonly these events occurred in the UK outside of the pandemic. There is no pattern from the reports to suggest that any of the COVID-19 vaccines used in the UK, or any reactions to these vaccines, increase the risk of miscarriage, stillbirths, congenital anomalies or birth complications.

You can read more about the safety review of COVID-19 vaccines in pregnancy here.

The product information for monovalent and bivalent COVID-19 Vaccine Pfizer/BioNTech reflects that the available data are reassuring on safety and that the vaccines can be used during pregnancy.

As the UK Health Security Agency (UKHSA) is a separate government agency to the MHRA, we are not in a position to answer your question asking why the UKHSA is promoting use [of the Pfizer COVID-19 vaccine] in [pregnant women].

Please be assured that ensuring access to safe and effective medicines for pregnant women is a key priority for the MHRA and we keep information from all sources under close and continual review, taking action to minimise risks and protect public health were necessary.

I hope this information is helpful.

Yours sincerely,

FOI Team,

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Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF