Medicines & Healthcare products
Regulatory Agency

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

11th May 2023

Dear

FOI 23/276

"…2000 pregnant women who took the injections for covid offered their data. Please can you share the results of this data monitoring?"

Thank you for your recent FOI request relating to the Yellow Card Vaccine Monitor and asking for the results of this monitoring activity.

In May 2020, the COVID-19 Vaccine Safety Surveillance Expert Working Group (EWG) advised the Medicines and Healthcare products Regulatory Agency (MHRA) on its safety monitoring strategy for COVID-19 vaccine(s). The EWG considered proposals and methodologies for MHRA-led vigilance activities and based on this advice the MHRA developed a four-stranded approach to vigilance which was endorsed by the Commission on Human Medicines[1]. One strand related to targeted active monitoring of vaccinees.

The MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes, including the Yellow Card scheme. As part of our signal detection processes adverse reaction reports received by the Yellow Card scheme are assessed and cumulative information reviewed at regular intervals, this routine monitoring includes reports of suspected side effects received via the Yellow Card Vaccine Monitor. Any emerging evidence relating to possible risks associated with vaccines is carefully reviewed and, if appropriate, regulatory action would be taken.

Since the assessment of reports received via the Yellow Card Vaccine Monitor is an ongoing and routine process, we don't routinely produce assessments however please find attached our paper to the Pharmacovigilance Expert Advisory Group (PEAG) in August 2021, outlining the progress of the Yellow Card Vaccine Monitor programme in line with our

[1] https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance

COVID-19 Vaccine Safety Surveillance Strategy. Please note to maintain patient confidentiality some information has been redacted from this paper.

As you have mentioned, the Yellow Card Vaccine Monitor enrolled pregnant women to support analysis of the safety of COVID-19 vaccines in pregnancy. Yellow Card Vaccine Monitor data, in combination with monitoring outlined in the COVID-19 vaccine safety surveillance strategy[2] contributed to the assessment that the COVID-19 vaccines are safe and effective during pregnancy and breastfeeding[3].

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,
Safety and Surveillance

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, 4-T, 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

[2] https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance
[3] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting