FOI 23/492 – report on Covid-19 vaccine safety in pregnancy

MHRA RESPONSE
14 July 2023

Dear

Thank you for your request of 07 April. We are handling your request under the provisions of the Freedom of Information Act and we apologise for the delay in response.

You requested:

> I watched a presentation on YouTube by Dr June Raine, with a section on Covid 19 safety strategy.
> Dr June Raine says, at 13.42
> 'establishing a vaccine monitor to look more closely at a cohort...that's going to be very important such as pregnancy'
> https://www.youtube.com/watch?v=G4OIYjjyUlU
>
> Dr June Raine appears to have made a similar comment for the Welsh Assembly in a recording relating to the yellow card system. An image of her associated presentation slide is attached. Dr June Raine stated that '2000 pregnant women volunteering to share their data, giving us a denominator'.
>
> At least twice Dr June Raine has stressed the importance of such a study, so presumably it went ahead.
>
> Please can you confirm whether this study of 2000 pregnant women, relating to Covid 19 vaccination, went ahead?
> If it did go ahead, was there ever an associated report or analysis? Are there raw data from this cohort regarding this study?
>
> If so, can you direct me to any study outcomes that may have been published. If the study was completed but the results were not published, I would like to make a Freedom of Information Request to be able to view the resulting data. I am happy to receive an excel or word document, or pdf.

We confirm that we hold the information you have requested. However, we consider the information to be exempt under Section 22 (Information held with a view to its future publication) as we are working on publishing the information you have requested.

Section 22 is a qualified exemption and as a result we have considered the public interest in applying this exemption. We acknowledge that there is significant interest in the safety of medicines in those who are pregnant, including vaccines for COVID-19. However, we do have publicly available information on our position on the use of COVID-19 vaccines in those who are pregnant. This position is based on analysis of

all Yellow Card data rather than the subset of data which relates to Yellow Card Vaccine Monitor, to which your request relates. Given this we do not consider that the public interest is best served by releasing the information to you ahead of its formal publication.

Our position on the safety of COVID-19 vaccines in pregnancy can be found on our website via the link below (please follow the link and scroll down to the section entitled 'Comments on safety in specific populations'):

https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

It may be helpful to explain the process for assessment of data arising from the Yellow Card Vaccine Monitor programme. Data arising from this element of the Covid-19 vaccine surveillance strategy is continuously assessed alongside other data we collect or have access to, to support our signal detection activities, as such there are not regular reviews of this data source in isolation. The MHRA is developing a scientific publication of Yellow Card Vaccine Monitor, however, in order to provide some information in the interim I have attached an interim review of the Yellow Card Vaccine Monitor data that was presented to our Pharmacovigilance Expert Advisory Group in July 2021. You will note that at this stage 1197 individuals had reported that they were pregnant. Final numbers of registrations as well as analysis of outcomes will be included in our scientific publication in due course. Please note that there is some information redacted in this document. We have applied these redactions under Section 40 (2) of the Freedom of Information Act. The redacted information is personal data (names of members of staff), and its disclosure would lead to the identification of individuals. The staff names withheld are those of members of staff below a certain level of seniority; this is consistent with our approach to the disclosure of staff names.

Whilst we appreciate that you have requested an Internal Review, we have not treated this reply as that review as you have not yet had a chance to consider our response, given the delay.

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
MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU