Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
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London
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United Kingdom

www.gov.uk/mhra

24 October 2023

Dear [redacted]

FOI 23/707

Thank you for your email of 26 September 2023, where you requested the following under the Freedom of Information Act:

"..disclosure of all formal epidemiological studies that have been undertaken by the MHRA, or which the MHRA has instructed Pfizer and Moderna to carry out, designed and powered specifically to test the association between cases of recorded exposure to Covid vaccines and subsequent injury and/or death due to:

a) myocarditis, pericarditis and endocarditis?
b) Menstrual disorders (period problems) and unexpected vaginal bleeding
c) Safety of COVID-19 vaccines in those breastfeeding
d) Safety of COVID-19 vaccines in pregnancy "

We can confirm that we hold some of the information requested.

In terms of formal epidemiological studies undertaken by the MHRA which are designed and powered specifically to test the association between COVID-19 vaccines and the topics listed in a) to d) above, MHRA are currently undertaking a study entitled "Safety of COVID-19 vaccination during pregnancy in England: a cohort study" using data from the Clinical Practice Research Datalink https://cprd.com/safety-covid-19-vaccination-during-pregnancy-england-cohort-study.

The protocol and results from this study will be published in the future and thus provision of this information is exempt under Section 22 of the FOI Act. Section 22 of the Act allows public authorities to refuse requests where the authority intends to publish the information at a future and states that:

"Information is exempt if, at the time when the public authority receives a request for it:

(a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not),
(b) the information was already held with a view to such publication at the time when the request for information was made, and

(c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in paragraph (a)."

It is the MHRA's intention to publish details and findings of this study in a peer reviewed journal upon completion.

As Section 22 is a qualified exemption, we have considered whether the public interest in maintaining the exemption is greater than public interest in disclosing the requested information.

We appreciate that there is a strong public interest in disclosure of information concerning a study evaluating the safety of COVID-19 vaccine use in pregnancy. However, we consider it is the right decision to manage the availability of the information by planning and controlling its publication. There could be harm arising from early disclosure of information concerning this study, without proper analysis and the opportunity for internal review and external peer review to ensure scientific rigour. It is also the case that large numbers of pregnant women have received a COVID-19 vaccine in the UK and globally, with no safety concerns becoming apparent in terms or maternal or fetal health or adverse pregnancy or infant outcomes. Therefore on this occasion, we consider that the greatest public interests lies in maintain this agreed schedule of publication, and the public interest therefore favours maintaining the section 22 exemption.

The MHRA have not undertaken any formal epidemiological studies concerning COVID-19 vaccines and any of the other safety topics mentioned in a) to d).

The MHRA have not instructed Pfizer and Moderna to carry out any formal epidemiological studies to test the association between cases of recorded exposure to Covid vaccines and injury or death in relation to the safety topics listed in a) to d). Therefore the MHRA do not hold this part of the requested information.

Neither Pfizer or Moderna are undertaking formal epidemiological studies assessing whether there is an increased risk of endocarditis or menstrual disorders/heavy menstrual bleeding. However, the respective companies are conducting other studies assessing some of the safety topics in points a) to d). Although these fall outside the scope of your request, which asked for formal epidemiological studies undertaken by the MHRA, or which the MHRA has instructed Pfizer and Moderna to carry out, to assist we provide further details of these studies below.

The studies the COVID-19 vaccine manufacturers have been requested to carry out are listed in the risk management plan (RMP) for the respective vaccine. For both Pfizer and Moderna COVID-19 vaccines, which are authorised in the UK via the European Commission Decision Reliance Procedure (ECDRP) route, the RMP approved in the UK is aligned to the EU RMP.

The RMPs for the Pfizer COVID-19 vaccine (Comirnaty) and for the Moderna COVID-19 vaccine (Spikevax) can be viewed on the European Medicines Agency (EMA) website:

Comirnaty | European Medicines Agency (europa.eu)

Spikevax (previously COVID-19 Vaccine Moderna) | European Medicines Agency (europa.eu)

For Pfizer, there are post authorisation safety studies included in the RMP which aim to assess whether vaccinated individuals experience increased risk of myocarditis and pericarditis, to assess whether pregnant women receiving the Pfizer COVID-19 vaccine experience increased risk of

pregnancy and infant safety outcomes and to assess the safety of maternal immunisation during breastfeeding. These studies were either proposed by Pfizer or requested by EMA or the US FDA.

For Moderna, there are post authorisation safety studies included in the RMP which aim to assess whether vaccinated individuals experience increased risk of myocarditis and pericarditis and to assess whether pregnant women receiving the Moderna COVID-19 vaccine experience increased risk of pregnancy and infant safety outcomes. These studies were either proposed by Moderna or requested by EMA or the US FDA.

I hope this information is helpful.

Yours sincerely,

FOI Team,

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
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Cheshire
SK9 5AF