



**REPUBLIC OF CYPRUS
MINISTRY OF HEALTH**

COVID-19: latest safety data provide reassurance about use of mRNA vaccines during pregnancy

Vaccination remains a major pillar of the response to COVID-19, particularly as variants of the virus continue to spread in EU/EEA countries. EMA's COVID-19 task force (ETF) highlights the growing evidence indicating that mRNA COVID-19 vaccines do not cause pregnancy complications for expectant mothers and their babies.

The task force undertook a detailed review of several studies involving around 65,000 pregnancies at different stages. The review did not find any sign of an increased risk of pregnancy complications, miscarriages, preterm births or adverse effects in the unborn babies following mRNA COVID-19 vaccination. Despite some limitations in the data, the results appear consistent across studies looking at these outcomes.

Studies also showed that COVID-19 vaccines are as effective at reducing the risk of hospitalisation and deaths in pregnant people as they are in non-pregnant people. The most common side effects of the vaccines in pregnant people also match those in the overall vaccinated population. They include pain at the injection site, tiredness, headache, redness and swelling at the site of injection, muscle pain and chills. These effects are usually mild or moderate and improve within a few days of vaccination.

Given that so far pregnancy has been associated with a higher risk of severe COVID-19 particularly in the second and third trimesters, people who are pregnant or might become pregnant in the near future are encouraged to get vaccinated in line with national recommendations.

Most of the information so far has come from mRNA vaccines (Comirnaty and Spikevax). EMA will also review data for other authorised COVID-19 vaccines as they become available.

Initial clinical trials do not generally include pregnant people. As a result, data on the use of vaccines as any other medicines during pregnancy, are not usually available at the time of the authorisation but are obtained afterwards. Animal studies with the COVID-19 vaccines did not show any harmful effects in pregnancy or post-natal development. The review of real world evidence suggests that the benefits of receiving mRNA COVID-19 vaccines during pregnancy outweighs any possible risks for expectant mothers and unborn babies.

EMA's human medicines committee (CHMP) will consider the latest data from the manufacturers of mRNA COVID-19 vaccines during pregnancy with a view to updating the recommendations in the product information for the vaccines where applicable.

Monitoring the safety of vaccines

In line with the EU's safety monitoring plan for COVID-19 vaccines, those vaccines are closely monitored, and relevant new information emerging is continuously collected and promptly reviewed. Although very large numbers of people have already received COVID-19 vaccines, certain side effects may still emerge as more and more people are included in vaccination programmes. EMA's safety committee, PRAC will continue to monitor safety in pregnancy.



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The companies are required to provide regular updates and conduct studies to monitor the safety and effectiveness of their vaccines as used by the public. Authorities also conduct additional studies to monitor safety and effectiveness of the vaccines, including their use in pregnancy.

These measures allow regulators to swiftly assess data emerging from a range of different sources and take appropriate regulatory action to protect public health if needed.

Ministry of Health

19 January 2022