EN E-000692/2021 Answer given by Ms Kyriakides on behalf of the European Commission (30.4.2021)

There is no evidence that COVID-19 vaccines can affect the fertility of women or men.

The product information of all COVID-19 vaccines which are authorised in the EU include the following statement under section 4.6 Fertility, pregnancy and lactation: 'Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity'.

The safety and effectiveness of vaccines which have received conditional marketing authorisations are rigorously monitored, as for all medicines, through the EU's established medicines pharmacovigilance system. In addition, for COVID-19 vaccines, marketing authorisation holders are expected to submit to the European Medicines Agency (EMA) monthly summary safety reports in addition to regular periodic safety update reports (PSURs). These will include, among others, information on reported suspected adverse reactions, including adverse events of special interest (AESIs).

EMA and the national competent authorities in the EU Member States will continue to identify and evaluate any new information that arises promptly, including any safety signals that are relevant for the benefit-risk balance of these vaccines.