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Answer given by Ms Kyriakides
on behalf of the European Commission
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The safety and effectiveness of COVID-19 vaccines will continue to be monitored as they are used across the Member States and globally, through the pharmacovigilance system, additional studies by the company and independent studies coordinated by European authorities. Marketing authorisation holders are expected to submit monthly summary safety reports. The safety monitoring plan for COVID-19 vaccines[1] outlines how new information after the rollout of vaccines will be collected and reviewed. These measures will allow regulators to swiftly assess data from a range of different sources and take appropriate regulatory action to protect public health, if needed.

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee will evaluate summary safety reports submitted monthly and communicate the outcomes on its website[2] shortly after, to ensure that all new information collected post-marketing will be promptly reviewed and shared with the public in a timely manner.

First monthly summary safety report for COVID-19 vaccine was published on 29 January 2021[3].

Under a conditional marketing authorisation (CMA), the companies that market COVID-19 vaccines will continue to provide results from the additional studies, which are specific obligations of the marketing authorisation. These studies include collection of safety data. A CMA is valid for one year and can be renewed. The annual renewal includes assessment of the available data.

[1] https://www.ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf
[2] https://www.ema.europa.eu/en/committees/prac/prac-agendas-minutes-highlights
[3] https://www.ema.europa.eu/en/news/first-covid-19-vaccine-safety-update-published