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EMA recommends COVID-19 Vaccine Janssen for authorisation in the EU

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Janssen vaccine is the only single-dose vaccine under recommendation at present



EMA has recommended granting conditional marketing authorization for COVID-19 Vaccine Janssen to prevent COVID-19 in people from 18 years of age.

After a thorough evaluation, EMA's human medicines committee (CHMP) concluded by consensus that the data on the vaccine were robust and met the criteria for efficacy, safety and quality. COVID-19 Vaccine Janssen is the fourth vaccine recommended in the EU for preventing COVID-19.

The safety and effectiveness of the vaccine will continue to be monitored as it is used across the EU, through the EU pharmacovigilance system and additional studies by the company and European authorities.

COVID-19 Vaccine Janssen is an adenovirus vaccine that has been modified to contain the gene for making the SARS-CoV-2 spike protein. This is a protein on the SARS-CoV-2 virus which it needs to enter the body's cells.

The European Commission will now fast-track the decision-making process to grant a decision on the conditional marketing authorisation for COVID-19 Vaccine Janssen, allowing vaccination programmes to be rolled out across the EU. Conditional marketing authorisation (CMA) is used as the fast-track authorisation procedure to speed up approval of treatments and vaccines during public health emergencies in the EU.

Monitoring the safety of COVID-19 Vaccine Janssen

During the assessment of COVID-19 Vaccine Janssen, the CHMP had the support of EMA's safety committee, PRAC, who assessed the risk management plan of COVID-19 Vaccine Janssen, and the COVID-19 EMA pandemic task force (COVID-ETF), a group that brings together experts from across the European medicines regulatory network to facilitate rapid and coordinated regulatory action on medicines and vaccines for COVID-19.