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

EMA has recommended granting a conditional marketing authorisation 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.

"With this latest positive opinion, authorities across the European Union will have another option to combat the pandemic and protect the lives and health of their citizens," said Emer Cooke, EMA's Executive Director, adding, "this is the first vaccine which can be used as a single dose".

Results from a clinical trial involving people in the United States, South Africa and Latin American countries found that COVID-19 Vaccine Janssen was effective at preventing COVID-19 in people from 18 years of age. This study involved over 44,000 people. Half received a single dose of the vaccine and half were given placebo (a dummy injection). People did not know if they had been given COVID-19 Vaccine Janssen or placebo.

The trial found a 67% reduction in the number of symptomatic COVID-19 cases after 2 weeks in people who received COVID-19 Vaccine Janssen (116 cases out of 19,630 people) compared with people given placebo (348 of 19,691 people). This means that the vaccine had a 67% efficacy.

The side effects with COVID-19 Vaccine Janssen in the study were usually mild or moderate and cleared within a couple of days after vaccination. The most common ones were pain at the injection site, headache, tiredness, muscle pain and nausea.

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.

Where to find more information

The product information for COVID-19 Vaccine Janssen contains information for healthcare professionals, a package leaflet for members of the public and details of conditions of the vaccine's authorisation.

An assessment report with details of EMA's evaluation of COVID-19 Vaccine Janssen and the full risk management plan will be published within days. Clinical trial data submitted by the company in the

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application for marketing authorisation will be published on the Agency's clinical data website in due course.

More information is available in an overview of the vaccine in lay language, including a description of the vaccine's benefits and risks and why EMA recommended its authorisation in the EU.

How COVID-19 Vaccine Janssen works

COVID-19 Vaccine Janssen works by preparing the body to defend itself against COVID-19. It is made up of another virus (an adenovirus) 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 adenovirus passes the SARS-CoV-2 gene into the vaccinated person's cells. The cells can then use the gene to produce the spike protein. The person's immune system will recognise the spike protein as foreign and produce antibodies and activate T cells (white blood cells) to target it.

Later, if the person comes into contact with SARS-CoV-2 virus, the vaccinated person's immune system will recognise the spike protein on the virus and be ready to defend the body against it.

The adenovirus in the vaccine cannot reproduce and does not cause disease.

Conditional marketing authorisation

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. CMAs allow authorisation of medicines that fulfil an unmet medical need on the basis of less complete data than normally required. This happens if the benefit of a medicine or vaccine's immediate availability to patients outweighs the risk inherent in the fact that not all the data are yet available.

A CMA guarantees that the approved medicine or vaccine meets rigorous EU standards for efficacy, safety and quality and is manufactured in approved, certified facilities in line with high pharmaceutical standards for large-scale production.

Once a CMA has been granted, companies must provide further data from ongoing or new studies within pre-defined deadlines to confirm that the benefits continue to outweigh the risks.

Monitoring the safety of COVID-19 Vaccine Janssen

In line with the EU's safety monitoring plan for COVID-19 vaccines, COVID-19 Vaccine Janssen will be closely monitored and subject to several activities that apply specifically to COVID-19 vaccines. Although large numbers of people have received COVID-19 vaccines in clinical trials, certain side effects may only emerge when millions of people are vaccinated.

Companies are required to provide monthly safety reports in addition to the regular updates required by legislation and conduct studies to monitor the safety and effectiveness of the vaccines as they are used by the public. In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will give more information on the vaccine's long-term safety and benefit in the general population.

These measures will allow regulators to swiftly assess data emerging from a range of different sources and take any necessary regulatory action to protect public health.

Assessment 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.