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EMA receives application for conditional marketing authorisation of COVID-19 Vaccine Janssen

EMA has received an application for conditional marketing authorisation (CMA) for a COVID-19 vaccine developed by Janssen-Cilag International N.V.

EMA's human medicines committee (CHMP) will assess the vaccine, known as COVID-19 Vaccine Janssen, under an accelerated timetable. The Committee could issue an opinion by the middle of March 2021, provided the company's data on the vaccine's efficacy, safety and quality are sufficiently comprehensive and robust.

Such a short time for evaluation is only possible because EMA has already reviewed some data during a rolling review. During this phase, EMA assessed quality data and data from laboratory studies which looked at how well the vaccine triggers the production of antibodies and immune cells that target SARS-CoV-2 (the virus that causes COVID-19). The Agency also looked at clinical safety data on the viral vector used in the vaccine.

EMA is now assessing additional data on the efficacy and safety of the vaccine as well as its quality. If EMA concludes that the benefits of the vaccine outweigh its risks, it will recommend granting a CMA. The European Commission will then issue a decision on whether to grant a CMA valid in all EU and EEA Member States within days.

This is the fourth CMA application for a COVID-19 vaccine since the start of the current pandemic. It comes after EMA's evaluation of vaccines from BioNTech/Pfizer, Moderna and AstraZeneca. These vaccines are now authorised in the EU and are among the tools Member States are using to combat COVID-19.

How is the vaccine expected to work?

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 surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells.

Once it has been given, the vaccine delivers the SARS-CoV-2 spike protein gene into cells in the body. The cells will use the gene to produce the spike protein. The person's immune system will then recognise this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

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If, later on, the person comes into contact with SARS-CoV-2 virus, their immune system will recognise the spike proteins on the virus and be ready to defend the body against it.

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

What is a conditional marketing authorisation?

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. However, the data must show that the benefits of the medicine or vaccine outweigh any risks. 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.

What may happen next?

If the vaccine is approved and marketed, EU authorities will continuously collect and review new information and take action when needed. In line with the EU safety monitoring plan for COVID-19 vaccines, monitoring will include activities that apply specifically to COVID-19 vaccines. Companies for example will provide monthly safety reports in addition to the regular updates required by the legislation, and conduct studies to monitor the safety and effectiveness of COVID-19 vaccines after their authorisation.

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

Key facts on COVID-19 vaccines and more information about how these vaccines are developed, authorised and monitored in the EU can be found on the EMA website.

In its evaluation of COVID-19 vaccines, EMA's scientific committees are supported by the COVID-19 EMA pandemic task force, a group that brings together experts from across the European medicines regulatory network.