01 December 2020
EMA/636204/2020

EMA starts rolling review of Janssen's COVID-19 vaccine Ad26.COV2.S

EMA's human medicines committee (CHMP) has started a rolling review of Ad26.COV2.S, a COVID-19 vaccine from Janssen Vaccines & Prevention B.V.

The CHMP's decision to start the rolling review is based on preliminary results from laboratory studies and early clinical studies in adults. These studies suggest that the vaccine triggers the production of antibodies and immune cells that target the SARS-CoV-2 coronavirus.

The company is currently conducting trials in people to assess safety and immunogenicity (how well the vaccine triggers a response against the virus), and effectiveness. EMA will evaluate data from these and other clinical trials as they become available.

The rolling review will continue until enough evidence is available for a formal marketing authorisation application.

EMA will assess the vaccine's compliance with the usual standards for effectiveness, safety and quality. While EMA cannot predict the overall timelines, it should take less time than normal to evaluate an eventual application because of the work done during the rolling review.

How is the vaccine expected to work?

Like other vaccines, Ad26.COV2.S is expected to prepare the body to defend itself against infection. The vaccine contains genetic instructions for a protein known as spike (S) protein which is present on the surface of SARS-CoV-2 coronavirus. When a person is given the vaccine, their cells will read the genetic instructions and produce the spike protein. The person's immune system will then treat this protein as foreign and produce natural defences — antibodies and T cells — against it. If later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the virus and be prepared to attack it. The antibodies and immune cells can work together to kill the virus, prevent its entry into the body's cells and destroy cells that are infected, thus helping to protect against COVID-19.

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What is a rolling review?

A rolling review is a regulatory tool that EMA uses to speed up the assessment of a promising medicine during a public health emergency. Normally, all data on a medicine or vaccine's effectiveness, safety and quality and all required documents must be ready at the start of the evaluation in a formal application for marketing authorisation. In the case of a rolling review, EMA's human medicines committee (CHMP) reviews data as they become available from ongoing studies. Once the CHMP decides that sufficient data are available, the company should then submit a formal application. By reviewing the data as they become available, the CHMP can come to an opinion on the medicine's authorisation sooner.

During the rolling review, and throughout the pandemic, EMA and its scientific committees are supported by the COVID-19 EMA pandemic task force (COVID-ETF). This group brings together experts from across the European medicines regulatory network to advise on the development, authorisation and safety monitoring of medicines and vaccines for COVID-19 and facilitate quick and coordinated regulatory action.