EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA starts rolling review of COVID-19 vaccine Vidprevtyn

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EMA's human medicines committee (CHMP) has started a rolling review of Vidprevtyn, a COVID-19 vaccine developed by Sanofi Pasteur.

The CHMP's decision to start the rolling review is based on preliminary results from laboratory studies (non-clinical data) and early clinical studies in adults, which suggest that the vaccine triggers the production of antibodies that target SARS-CoV-2, the virus that causes COVID-19, and may help protect against the disease.

EMA will evaluate data as they become available to decide if the benefits outweigh the risks. The rolling review will continue until enough evidence is available for a formal marketing authorisation application.

EMA will assess the compliance of Vidprevtyn with the usual EU 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.

EMA will communicate further when the marketing authorisation application for the vaccine has been submitted.

How is the vaccine expected to work?

Vidprevtyn is expected to prepare the body to defend itself against infection with SARS-CoV-2. It is a protein-based vaccine that contains a laboratory-grown version of the spike protein found on the surface of SARS-CoV-2. It also contains an 'adjuvant', a substance to help strengthen the immune responses to the vaccine.

When a person is given the vaccine, their immune system identifies the spike protein as foreign and makes antibodies against it. If, later, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the viral protein and be ready to defend the body against the virus.

What is a rolling review?

A rolling review is a regulatory tool that EMA uses to speed up the assessment of a promising medicine or vaccine 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 can 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.

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