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EMA ends rolling review of CVnCoV COVID-19 vaccine following withdrawal by CureVac AG

EMA has ended the rolling review of CVnCoV, CureVac AG's COVID-19 vaccine, after the company informed the Agency that it was withdrawing from the process.

Since February 2021, EMA's human medicines committee (CHMP) has been reviewing data on CVnCoV as part of a rolling review, whereby the company submits data as they become available in order to speed up the evaluation of an eventual marketing authorisation application.

At the time of the company's withdrawal, EMA had received non-clinical (laboratory) data, data from ongoing clinical studies, data on the quality and manufacturing process of the vaccine and the risk management plan (RMP).

Although EMA was speeding up its review of the data, some questions about the vaccine's quality, impacting the benefit-risk balance of the vaccine, and the fact that results of the main study showed only a modest vaccine efficacy in adults still remained to be satisfactorily addressed.

In its letter to EMA, the company stated that it withdrew because it decided to focus its efforts on a different COVID-19 vaccine development programme. The withdrawal means that EMA is no longer reviewing data on the vaccine and will not conclude this review. The company retains the right to request another rolling review or submit a marketing authorisation application in the future.

People who have taken part in clinical trials with CVnCoV and have questions about their vaccination status, the EU digital COVID certificate or travel restrictions associated with vaccination should contact the relevant authorities in their country of residence.

EMA will continue to expedite its review of data on COVID-19 vaccines and treatments during this ongoing pandemic. EMA is working closely with developers, providing advice early in the development process and reviewing data on a rolling review basis when appropriate.

More about the vaccine

Like other vaccines, CVnCoV was developed to prepare the body to defend itself against infection with SARS-CoV-2, the virus causing COVID-19.

The SARS-CoV-2 virus uses proteins on its outer surface, called spike proteins, to enter the body's cells and cause COVID-19. CVnCoV contains a molecule called messenger RNA (mRNA) which has

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instructions for making the spike protein. The mRNA is contained in tiny particles of fats (lipids) that prevent it from being broken down too quickly.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily 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) against it.

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

The mRNA from the vaccine does not stay in the body but is broken down shortly after vaccination.

More about rolling reviews

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, such as the COVID-19 pandemic. Normally, all data on a medicine's 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, the CHMP reviews data as they become available from ongoing studies. Data are assessed during so-called 'rolling review cycles' – there is no pre-defined number of cycles, as the process is driven by the data becoming available. Once the CHMP decides that sufficient data are available, the company can submit a formal application for marketing authorisation. By reviewing the data as they become available, the CHMP can reach an opinion on the medicine's authorisation sooner.

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.