12 October 2021
EMA/576752/2021
EMEA/H/C/005845

Questions and answers on end of rolling review for CureVac's COVID-19 vaccine (CVnCoV)

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

The rolling review started on 12 February 2021; the company withdrew on 11 October 2021.

What is CVnCoV and how was it expected to work?

CVnCoV was developed as a vaccine to protect adults against COVID-19, a disease caused by the SARS-CoV-2 virus.

CVnCoV was expected to work by preparing the body to defend itself against infection with SARS-CoV-2. The 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 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.

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, 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, EMA's human medicines committee (CHMP) reviews data as they become available from ongoing studies. Data are assessed during so-called 'rolling review cycles' – there is no pre-defined

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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.

How far had the rolling review process got when the company withdrew?

The company withdrew from the process shortly after the start of the sixth rolling review cycle, which included data from ongoing clinical studies, further data on the quality and manufacturing process of the vaccine and an updated version of the vaccine's proposed risk management plan (RMP), which contains important information about the vaccine's safety and how to minimise any potential risks.

In the previous rolling review cycles, the company had provided non-clinical (laboratory) data, initial data on the quality of the vaccine, the initial RMP and preliminary clinical data from early studies in adults.

As the Agency was still evaluating the data provided by the company, it had not yet made any recommendations. 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.

What were the reasons given by the company for withdrawing?

In its letter notifying the Agency of the withdrawal, the company stated that it decided to focus its efforts on a different COVID-19 vaccine development programme.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using CVnCoV.

If you are in a clinical trial and need more information about this vaccine, speak with your clinical trial doctor.

If you have received CVnCoV in a clinical trial and you have questions about the implication of this withdrawal on your vaccination status, the EU digital COVID certificate or travel restrictions associated with vaccination, please contact the relevant authorities in your country of residence.