6 October 2020
EMA/470333/2020

EMA starts second rolling review of a COVID-19 vaccine

EMA's human medicines committee (CHMP) has started a 'rolling review' of data on a vaccine for COVID-19 known as BNT162b2, which is being developed by BioNTech in collaboration with Pfizer.

The start of the rolling review means that the committee has started evaluating the first batch of data on the vaccine, which come from laboratory studies (non-clinical data). This does not mean that a conclusion can be reached yet on the vaccine's safety and effectiveness, as much of the evidence is still to be submitted to the committee.

The CHMP's decision to start the rolling review of BNT162b2 is based on preliminary results from non-clinical and early clinical studies in adults which suggest that the vaccine triggers the production of antibodies and T cells (cells of the immune system, the body's natural defences) that target the virus.

Large-scale clinical trials involving several thousands of people are ongoing, and results will become available over the coming weeks and months. These results will provide information on how effective the vaccine is in protecting people against COVID-19 and will be assessed once they are available. All the available data on the safety of the vaccine as well as on its quality (such as its ingredients and the way it is produced) will also be reviewed.

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

EMA will complete its assessment according to its usual standards for quality, safety and effectiveness. While the overall review timeline cannot be forecast yet, the process should be shorter than a regular evaluation due to the time gained during the rolling review.

How is the vaccine expected to work?

BNT162b2 is expected to work by preparing the body to defend itself against infection with the coronavirus SARS-CoV-2. The virus uses proteins on its outer surface, called spike proteins, to enter the body's cells and cause disease. BNT162b2 contains the genetic instructions (mRNA) for the spike protein and is covered in small fats (lipid particles) that prevent the mRNA from being degraded. 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: antibodies

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and T cells can work together to kill the virus, prevent its entry into the body's cells and destroy infected cells, thus helping to protect against COVID-19.

What is a rolling review?

A rolling review is one of the regulatory tools 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's effectiveness, safety and quality and all required documents must be submitted 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, before a formal application is submitted. Once the CHMP decides that sufficient data are available, the formal application should be submitted by the company. By reviewing the data as they become available, the CHMP can reach its opinion sooner on whether or not the medicine or vaccine should be authorised.