REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press Release

EMA starts first rolling review of a COVID-19 vaccine in the EU

EMA's Human Medicines Committee (CHMP) has started the first "rolling review" of a COVID-19 vaccine, which is being developed by the company AstraZeneca in collaboration with the University of Oxford.

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.

A rolling review is one of the regulatory tools that the Agency 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, the CHMP reviews data as they become available from ongoing studies, before deciding that sufficient data are available and that a formal application should be submitted by the company.

The CHMP's decision to start the rolling review of the vaccine is based on preliminary results from non-clinical and early clinical studies suggesting 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 in later rolling review cycles. All the available data on the safety of the vaccine emerging from these studies, as well as data 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. The rolling review process has been used previously in the assessment of the COVID-19 medicine, Veklury (remdesivir).

How is the vaccine expected to work?

The vaccine, called COVID-19 Vaccine AstraZeneca, is expected to work by preparing the body to defend itself against infection with the coronavirus SARS-CoV-2. This virus uses proteins on its outer surface, called spike proteins, to enter the body's cells and cause disease. COVID-19 Vaccine AstraZeneca is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making the SARS-CoV-2 spike protein. The adenovirus itself cannot reproduce and does not cause disease. Once it has been given, the vaccine delivers the SARS-CoV-2 gene into cells in the body. The cells will use the gene to produce the spike protein. The person's immune system will treat this spike protein as foreign and produce natural defences −antibodies and T cells- against this protein. 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 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.

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What is a rolling review?

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Ministry of Health

2 October 2020