REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

EMA starts rolling review of the Sputnik V COVID-19 vaccine

EMA's Human Medicines Committee (CHMP) has started a rolling review of Sputnik V (Gam-COVID-Vac), a COVID-19 vaccine[1] developed by Russia's Gamaleya National Centre of Epidemiology and Microbiology. The EU applicant for this medicine is R-Pharm Germany GmbH.

The CHMP's decision to start the rolling review is based on results from laboratory studies and clinical studies in adults. These studies indicate that Sputnik V triggers the production of antibodies and immune cells that target the SARS-CoV-2 coronavirus and may help protect against COVID-19.

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 formal marketing authorisation application.

EMA will assess Sputnik V's compliance 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.

[1] Sputnik V is made up of two components comprising different viruses belonging to the adenovirus family, Ad26 and Ad5. Separate submissions have been made for each component.

How the vaccine is expected to work:

Sputnik V is expected to work by preparing the body to defend itself against infection with the SARS-CoV-2 virus. This virus uses proteins on its outer surface, called spike proteins, to enter the body's cells and cause COVID-19.

Sputnik V is made up of two different viruses belonging to the adenovirus family, Ad26 and Ad5. These adenoviruses have been modified to contain the gene for making the SARS-CoV-2 spike protein; they cannot reproduce in the body and do not cause disease. The two adenoviruses are given separately: Ad26 is used in the first dose and Ad5 is used in the second to boost the vaccine's effect.

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 spike protein on 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.

What a rolling review is:

A rolling review is a regulatory tool that EMA uses to speed up the assessment of a promising medicine 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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Ministry of Health
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