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EMA: Developments for Sputnik V and Janssen COVID-19 Vaccines

The European Medicines Agency (EMA) has launched a rolling review of the Russian Sputnik V vaccine and is convening to potentially finalise the COVID-19 Vaccine Janssen's marketing authorisation.

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According to the EMA's Committee for Medicinal Products for Human Use (CHMP) , Sputnik V (Gam-COVID-Vac) triggers the production of antibodies and immune cells that target the SARS-CoV-2 coronavirus and may help protect against the disease.

The vaccine was developed by Russia's Gamaleya National Centre of Epidemiology and Microbiology and has two components comprising different viruses belonging to the adenovirus family. Ad26 is used in the first dose and Ad5 is used in the second to boost the vaccine's effect. For each component separate submissions have been made by R-Pharm Germany GmbH, the EU applicant for the vaccine.

The rolling review stage allows EMA for the accelerated assessment of a promising medicine during a public health emergency, by reviewing data as they become available from ongoing studies. Once there is enough evidence that the benefits outweigh the risks, the company can submit a formal application for marketing authorisation.

In the case of Sputnik V, it is noted that "it should take less time than normal to evaluate an eventual application because of the work done during the rolling review".

The announced cost of one dose of the Sputnik V vaccine for international markets is less than $10 . Two EU member states, Hungary and Slovakia, have already agreed on the vaccine deliveries while there have been reports that authorities in the Czech Republic, Austria, Italy and Cyprus are also looking into the possibility to order doses from Russia.

In the meantime, on 11 March 2021, CHMP is convening in an extraordinary meeting to evaluate the marketing authorisation application by Janssen-Cilag International N.V. for its COVID-19 Vaccine Janssen. "The aim of the meeting is to conclude the evaluation, if possible," EMA's announcement says.

Up to date, EMA has authorised three vaccines for use in the EU, i.e. those developed by Pfizer/BioNTech, Moderna and AstroZeneca. Besides Sputnik V, two more medicines are under rolling review: CVnCoV developed by CureVac AG and NVX-CoV2373 by Novavax.

Source: EMA

Image credit: The Gamaleya National Center of Epidemiology and Microbiology

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