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Media and Public Relations

News announcement

Clarification on Sputnik V vaccine in the EU approval process

The European Medicines Agency has to date not received an application for a rolling review or a marketing authorisation for the vaccine developed by the Gamaleya National Centre of Epidemiology and Microbiology in Russia, the Sputnik V vaccine (Gam-COVID-Vac), despite reports stating the opposite.

The developers have received scientific advice from EMA providing them with the latest regulatory and scientific guidance for the development of their vaccine. In line with the Agency's transparency policy, the vaccine is included in the list of COVID-19 medicines and vaccines that have received scientific advice from the Agency.

EMA is in dialogue and collaborating with the company to define the next steps. The developers have expressed their interest that the vaccine be considered for a rolling review. This ad-hoc procedure can only be used during emergencies such as the current pandemic. It allows EMA to assess data on a vaccine or a medicine as they become available, while the development is still ongoing. The formal marketing authorisation procedure can then take place in a very short timeframe. Rolling review is reserved for the most promising medicines and vaccines. EMA's Human Medicines Committee (CHMP) and the COVID-19 EMA pandemic Task Force (COVID-ETF) need to give their agreement first before developers can submit their application for initiation of the rolling review process.

EMA will promptly inform the public of any new assessments of COVID-19 vaccines or medicines started by the Agency. EMA always publishes a news announcement when, following agreement by CHMP and COVID-ETF, an application for rolling review is received from the developers and the assessment starts. Similarly, EMA publishes a news announcement when it receives a valid application for marketing authorisation. The list of treatments and vaccines for COVID-19 under evaluation is updated in parallel to the publication. This means that if EMA has not communicated, the status of a given COVID-19 medicine/vaccine remains unchanged.

EMA is committed to applying the same regulatory approach and scientific rigour to all vaccine applications that meet European requirements for safety, efficacy and quality and is in dialogue with more than 50 vaccine developers from across the globe.

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