

WHO set to restart Sputnik COVID vaccine analysis

October 7 2021



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The World Health Organization said on Thursday it was about to restart the process of approving Russia's Sputnik V COVID-19 vaccine following a series of problems with the dossier.



WHO authorisation has been sought for the Sputnik V jab created by Russia's Gamaleya research institute, which is already being used in 45 countries, according to an AFP count.

Several COVID-19 vaccines have been given the WHO <u>green light</u> for emergency use during the pandemic: Pfizer-BioNTech, Janssen, Moderna, Sinopharm, Sinovac and AstraZeneca in various plants.

For Sputnik V, "the process was put on hold due to the lack of some legal procedures", said Mariangela Simao, the WHO assistant director-general for access to medicines, vaccines and pharmaceuticals.

"In negotiations with the Russian government, this problem is about to be sorted out," she told a press conference.

"As soon as the legal procedures are finished, we are able to restart the process."

WHO emergency use listing is the green light that gives countries, funders, procuring agencies and communities assurance that a vaccine has met international standards.

The listing paves the way for countries to approve and import a vaccine for distribution quickly, especially those states without an internationalclass regulator of their own.

Dossier incomplete

Sputnik V is already being used in countries including Algeria, Argentina, India, Iran, Mexico, Pakistan, the Philippines, Sri Lanka, the United Arab Emirates, Venezuela and Russia itself.

"There are still the issues around complete information on the dossier



that has to be provided by the applicant," said Simao.

"Then there is also the issues regarding the final finalisation of the inspections in the different manufacturers in Russia, but I'm happy to say that the about the process is about to be restarted."

In June, the WHO said it conducted nine inspections of Sputnik V manufacturing sites and uncovered various problems at the Pharmstandard Ufa Vitamin Plant in Ufa, southern Russia.

Moscow insisted the problems had since been resolved.

Russia is among the countries hardest-hit by the coronavirus pandemic, with the fifth-highest number of recorded deaths according to an AFP tally on Thursday: 213,549 fatalities from 7,690,110 cases.

Several Russian vaccines including Sputnik V have been available for months, but authorities have struggled to immunise a <u>vaccine</u>-sceptic population.

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Citation: WHO set to restart Sputnik COVID vaccine analysis (2021, October 7) retrieved 2 July 2024 from <u>https://medicalxpress.com/news/2021-10-restart-sputnik-covid-vaccine-analysis.html</u>

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