

Brazilian regulator denies permission to import Russian COVID vaccine

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Brazil's health regulator on Monday denied a request from several states to import Russia's Sputnik V coronavirus vaccine, saying it did not have the data needed to verify the jab's safety and efficacy.

"We will never allow millions of Brazilians to be exposed to products without due verification of quality, safety and efficacy, or at minimum, facing the grave situation we are now going through, that the benefits will outweigh the risks," said Antonio Barra Torres, president of federal health regulator Anvisa.

Anvisa said its experts had flagged "uncertainties" about the jab, which has not yet been approved by the European Medicines Agency (EMA) or the United State's Food and Drug Administration (FDA).

Anvisa, which received a request last month for emergency use of the Russian formula, has not released its findings, or cited the specific information it determined was lacking.

Russia registered Sputnik V last August ahead of large-scale clinical trials, prompting concern among experts over the fast-track process.

But later reviews have been largely positive, *The Lancet* medical journal publishing results showing it to be safe and more than 90 percent effective.

Experts at Anvisa said the medical journal's study had a different scrutiny process from the regulatory body.

"A journal does not have the same objectives of determining whether or not to approve the use of a [vaccine](#)," said Gustavo Mendes, one of Anvisa's technical managers.

Brazil has recorded more than 390,000 COVID-19 deaths, the second-highest number globally, behind only the US. But the government has struggled to secure enough [vaccine doses](#) for the country's 212 million people.

So far, it has managed to administer over 38 million vaccine doses.

But the country's outbreak, which has sickened more than 14.3 million people, has continued to surge, pushing hospitals to the [breaking point](#).

In an attempt to speed up their vaccine rollout, about a dozen states in the north and northeast of Brazil had signed contracts with Russia's RDIF sovereign fund to acquire more than 30 million doses of the Sputnik V vaccine. The [federal government](#) had ordered 10 million more.

"I hope that the Sputnik V vaccine process adapts its information and quickly resolves any compliance problems because millions of people need access to safe and effective vaccines," said Meiruze Freitas, one of Anvisa's directors.

The Brazilian regulator gave the green light to two COVID-19 vaccines—AstraZeneca and Coronavac—in January, and has also approved both Pfizer-BioNTech and Johnson & Johnson's shots, which have yet to arrive in the country.

The Sputnik vaccine has so far been approved for use in 60 countries, including more than 10 in Latin and Central America.

Argentina signed a deal with Russia earlier this month to become the first Latin American country to produce Sputnik V shots, and will aim for full-scale production to start in June.

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