

## Brazil approves Pfizer COVID vaccine for widespread use

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Brazil's health regulatory agency said Tuesday it had approved the Pfizer-BioNTech COVID-19 vaccine for widespread use, as the country races to secure enough doses to contain one of the world's worst outbreaks.

"It gives me great pleasure to announce that after a 17-day review, (regulators) have granted the first approval in the Americas for widespread use of a vaccine against COVID-19," said Antonio Barra Torres, the director of federal health regulator Anvisa, underlining that the approval was definitive and not only for emergency use.

However, the vaccine is not yet available in Brazil, which is so far using two others: Chinese-developed CoronaVac and one developed by Oxford University and British-Swedish pharmaceutical firm AstraZeneca.

The approval came a day after <u>media reports</u> said Pfizer representatives had told Brazilian senators that the country's regulatory requirements were excessively strict.

Pfizer has objected to the government's insistence on the right to hold the company liable for any side effects the vaccine may cause.

Anvisa's statement did not mention the issue, which has been a sticking point in Brazil's negotiations with Pfizer.

The US company says it offered Brazil around 70 million doses of the vaccine in August, but that negotiations broke down over the liability issue.

President Jair Bolsonaro, whose critics accuse him of fueling anti-vaccine skepticism, joked at one point of the Pfizer-BioNTech vaccine, "If it turns you into an alligator, that's your problem.... They (the companies) don't want to hear about it."

The far-right leader faces criticism for his handling of the pandemic, including vaccine shortages that have forced several cities to halt their immunization drives after a little over a month.

Brazil has vaccinated about 5.9 million people so far, or 2.8 percent of its population of 212 million.

More than 247,000 people have died of COVID-19 in Brazil, the second-highest death toll, after the United States.

## Next step: secure doses

Anvisa had previously granted only emergency approval for COVID-19 vaccines, allowing the public health system to administer them to high-risk groups such as health workers, the elderly and indigenous communities.

Definitive approval will allow the Pfizer-BioNTech vaccine to be sold commercially and administered to all populations in Brazil—if the country strikes a deal to secure it.

The vaccine's "safety, quality and effectiveness



were verified and confirmed by Anvisa's technical team," Torres said in the statement.

"We hope other vaccines will also soon be evaluated and approved."

The vaccine from American pharmaceutical giant Pfizer and its German partner BioNTech is based on novel mRNA technology.

It delivers instructions to the body to help the immune system identify and destroy COVID-19 molecules.

Clinical trials found it is more than 95 percent effective, the best results so far for a <u>vaccine</u> against the new <u>coronavirus</u>.

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