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China Vaccine Trial Halted in Brazil After Serious Adverse Event

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6-8 minutes



A worker inspects Coronavac vaccine syringes in Beijing. Chinese vaccine developers have been at the forefront of the global race to create an effective immunization against the virus.

Photographer: Kevin Frayer/Getty Images

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The decision to suspend [Sinovac Biotech Ltd.](#)'s coronavirus vaccine trials in Brazil's largest state has baffled local researchers and prompted speculation that the move could be political.

Sao Paulo's Instituto Butantan, which partnered with Sinovac to produce the vaccine locally, said there's no relation between an incident with a volunteer and the shot. The health agency Anvisa, which made the decision, didn't consult with researchers beforehand, Dimas Covas, head of the institute, said at a press conference Tuesday.

"It's impossible, just impossible, that what happened has any

relation with the vaccine,” Covas said.

Anvisa suspended tests with the so-called Coronavac shot after a “serious adverse event” that occurred on Oct. 29, according to a statement late Monday. The study was interrupted in accordance with regulations while an analysis is conducted on whether trials should continue, it said. On Tuesday, the agency stuck to its decision, which it defined as “technical, ethical and precautionary.”

Sinovac’s vaccine has become the focus of an [escalating feud](#) in Brazil. President Jair Bolsonaro stepped up criticism of Coronavac last month, saying China lacks credibility to come up with solutions for the coronavirus crisis and that people wouldn’t feel safe with the shot “due to its origin.”

Sao Paulo Governor Joao Doria, who has gone from Bolsonaro ally to rival, has pledged to quickly deliver a vaccine to the state’s 44 million people.



Joao Doria

Photographer: Rodrigo Capote/Bloomberg

Brazilians will choose their city council members and mayors in municipal elections this Sunday, and political analysts will be scrutinizing the results for what it means ahead of the 2022 presidential vote when Doria may be a challenger.

[How Covid Cash Boosts Bolsonaro Allies in Brazil Vote: QuickTake](#)

Adding to the political noise was a post by Bolsonaro on his Facebook account responding to a supporter where he appeared to celebrate the decision and wrote, “another win for Bolsonaro.” He’s taken an antagonistic approach to China publicly while still continuing to strengthen trade ties.

Brazil has the third-most coronavirus cases in the world with 5.6 million infections and the second-most deaths with nearly 163,000 fatalities. It ranks fourth in per-capita deaths.

Unanimous Decision

Sinovac said in a [statement](#) on its website that it’s confident of the safety of its vaccine.

The Butantan researchers hinted that the participant could have died in a traffic accident, but declined to give details, citing confidentiality agreements involved in the trials. They didn’t say whether the volunteer was taking the vaccine or a placebo, but said the person last received the shot weeks before the adverse event.

“The time between receiving the shot, or the placebo, and this event, was not a day or two, it was more than three weeks,” said Joao Gabbardo, a former health ministry official who is now part of Sao Paulo’s Covid task force. “A medication could not have caused vertigo in a patient allegedly hit by a car almost a month after they take it.”

Anvisa, the central government health agency, said in a separate press conference that it does not have enough evidence to allow the study to continue, and that it had no information about the potential cause of death being suicide as reported by local media.

“Our position won’t change until we have raw data that confirms that allegation,” said Gustavo Mendes, the agency’s chief of medications. “With the information we had, it was a unanimous decision to suspend the tests. We can’t take risks.”

Vaccine Race

Halts to investigate serious adverse events are not uncommon in large-scale drug trials and two western developers -- [AstraZeneca Plc](#) and [Johnson & Johnson](#) -- have paused their vaccine trials in recent months due to such incidents, only to restart them after investigation. Serious adverse events that occur in drug trials include death, immediate risk of death, long term or serious incapacitation, and hospitalization.

But China has already started administering its vaccines, including Coronavac, to hundreds of thousands of people under an expansive emergency use approval, making the prospect of a safety issue being detected at this stage more concerning. Last month, China’s science ministry [said](#) its companies have inoculated about 60,000 volunteers in final-stage trials, but there have been no reports of serious adverse events.

[China Defends Giving Experimental Vaccines to Thousands](#)

Chinese vaccine developers have been at the forefront of the global race to create an effective immunization against the virus. The push has taken on vital importance as countries look to move beyond Covid-19 and more definitively re-open their

economies. Vaccine development processes that usually take years have been compressed into months by global players, encouraged by politicians wanting a quick fix to the pandemic that has sickened more than 50 million.

The Chinese setback in Brazil comes as Pfizer Inc. and BioNTech SE released early findings showing that a vaccine they are developing prevented more than 90% of symptomatic infections in the trial of tens of thousands of volunteers, boosting hope for a quick neutralization of Covid-19.

— *With assistance by Jose Orozco, Dong Lyu, Ney Hayashi Cruz, and Rachel Chang*

(Updates with Anvisa comments starting in fourth paragraph.)