



Sinopharm's COVID vaccine is being trialled in Egypt, Jordan, Argentina and elsewhere.

ARAB NATIONS FIRST TO APPROVE CHINESE COVID VACCINE

The United Arab Emirates and Bahrain say the vaccine is effective, but no data have been made public.

By David Cyranoski

Two Arab nations have become the first countries to approve a Chinese COVID-19 vaccine, a significant boost for China's plans to roll out its vaccines worldwide. The United Arab Emirates (UAE) approved a vaccine developed by Chinese state-owned Sinopharm on 9 December, and Bahrain followed days later. But researchers say a lack of publicly available data on the safety and efficacy of the vaccine could hinder the company's plans to distribute the vaccine in a range of other countries.

The Sinopharm vaccine is probably safe and effective, and could be a great help in fighting the pandemic, says Jin Dong-Yan, a virologist at the University of Hong Kong. But he notes that there is a lack of available clinical-trial data, and adds that confidence in the vaccine's safety and efficacy will be key to its successful international distribution.

"Chinese state-run companies, like Sinopharm, can produce billions of doses. They have the capacity and expertise," he says. "They need to have an open and transparent system, but they are not good at doing that."

The UAE and Bahrain are also the first countries to grant full approval to sell a COVID-19

vaccine. Russian officials have licensed two vaccines, but the approvals are conditional and subject to the results of ongoing phase III trials. In China, Sinopharm's vaccine has been widely deployed under emergency-use authorization, but full approval is expected very soon. The United States and the United Kingdom have issued emergency authorizations for a COVID-19 vaccine made by Pfizer of New York City and BioNTech of Mainz, Germany.

Data gap

UAE regulators said in a press release that they had approved an inactivated vaccine developed by Sinopharm's Beijing Institute of Biological Products. The approval was based on company data stating that the efficacy of the two-dose vaccine was 86% in final-stage testing, which included a trial in 31,000 people in the UAE, according to the press release. The vaccine had been granted emergency-use authorization in September. Bahrain officials did not state whether they approved the same Sinopharm vaccine, but it is thought to be the same jab, because they, too, reported 86% efficacy. Some 7,700 people participated in Sinopharm trials there.

The UAE press release also states that 99% of those vaccinated developed neutralizing

antibodies to SARS-CoV-2 and that the vaccine prevented moderate and severe disease in everyone vaccinated.

But scientists not involved in developing and approving the Chinese vaccines are finding it hard to make sense of the data behind the latest announcements. The UAE reported the phase III efficacy data before Sinopharm did, and the company has yet to confirm that they are correct. Neither the UAE, Bahrain nor Sinopharm have released the data used to make the 86% efficacy claims. "They give no real data. That's a bit weird," says Zhengming Chen, an epidemiologist at the University of Oxford, UK. "It's difficult to tell how well the vaccine works. I hope it is real."

Sinopharm did not respond to *Nature's* request for more detail on its trial results.

Scientists would like to see data on the number of infections in the groups that received the vaccine and in those that were given a placebo. Such data are used to calculate a vaccine's effectiveness – and have been released by the makers of several other leading coronavirus vaccines, including Pfizer and BioNTech. They released some detailed data in a press release in November, before the UK authorization, and published the phase III trial results on 10 December (F. P. Polack *et al. N. Engl. J. Med.* <https://doi.org/ghn625>; 2020).

International orders

Chinese state media have reported that Sinopharm has vaccine orders from more than 100 countries, including many in Africa, but few details of such deals have been reported. Sinopharm's vaccine is also undergoing phase III testing in countries including Egypt, Jordan and Argentina, so they are likely to be among the next to consider approving it.

Other countries are probably also planning to rely on China for vaccines, because the United States and European nations have pre-purchased billions of doses of the vaccines being developed closer to home, says Jin. Sinopharm's jab is also appealing because it uses inactivated virus and – unlike the Pfizer-BioNTech vaccine – does not need to be stored at extremely cold temperatures, making it easier to transport and distribute.

Chen thinks that there will be some resistance to Chinese vaccines if the companies do not allow independent analysis of the safety and efficacy data. "I don't think other countries will follow suit unless there is really convincing, robust data. You need really strong scientific evidence that can be scrutinized to convince people," says Chen. In the United States, the Food and Drug Administration has an independent committee that evaluates vaccine trial data and makes its findings public, before making a recommendation to the regulator.

Jin worries that countries might have to choose between accepting the vaccine without independent analysis or not getting a vaccine.

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