

# India greenlights Sputnik V, will fast-track approval for other virus shots

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India has authorised the emergency use of Russia's Sputnik V COVID-19 vaccine and will fast-track approval for other shots already

passed by other major countries, authorities said Tuesday, as infection rates soared to a new record high.

The government has faced mounting calls to approve more vaccines during the surge among the 1.3 billion population and a slower-than-expected mass inoculation drive.

Sputnik V is the third drug to be approved by India after Oxford-AstraZeneca's Covishield and Covaxin, which was developed by Indian firm Bharat Biotech.

The SEC expert panel said the Russian vaccine should be authorised "in emergency situations" and this has been accepted, the health ministry said in a statement.

G.V. Prasad, co-chair of pharmaceutical company Dr. Reddy's Laboratories, said his firm was "very pleased to obtain the emergency use authorisation".

"With the rising cases in India, vaccination is the most effective tool in our battle against COVID-19," he added.

## **Post-approval trials**

The health ministry also said it would expedite the approval of vaccines not made in India—unlike the first three—to "expand the basket of vaccines for domestic use and hasten the pace and coverage of vaccination".

The jabs will need to have already been granted emergency-use authorisation by regulators, such as the US Food and Drug Administration, the European Medicine Agency and others in Britain and Japan or the World Health Organisation, the ministry said.

A requirement for pre-approval clinical trials would be replaced by post-authorisation trials.

Vinod K. Paul, a member of the government advisory body NITI Aayog, said during a health ministry briefing that "we hope and invite vaccine makers like Pfizer, Moderna, Johnson and Johnson and others" to apply for licences "at the earliest possible" opportunity.

"I think it's significant... it's basically one more step to opening vaccinations to the private sector, and it's good, because the government sector alone will not be able to take care of the load," virologist Shahid Jameel told AFP.

"So if Pfizer or Moderna wants to bring in their vaccines through a supplier, not a manufacturer, then it is now possible."

India on Monday reported more than 161,000 new cases—the seventh-consecutive day that more than 100,000 infections have been recorded. That took the country's total to almost 13.7 million.

Local authorities have imposed night curfews and clamped down on movement and activities.

In India's financial capital Mumbai, authorities have ordered the construction of three more 2,000-bed field hospitals in the next six weeks. The number of beds for COVID-19 patients has also been ramped up in New Delhi.

Sputnik V, backed by the Russian Direct Investment Fund (RDIF), already has production agreements in India to produce 852 million doses.

RDIF chief executive Kirill Dmitriev said in a statement that the approval was a "major milestone" after "extensive cooperation" on

clinical trials of the shot in India.

Dmitriev told Indian broadcaster NDTV that the first doses could be ready by late April or May, with ramped up production by June.

"We believe by June, we will really be at good production capacity in India and will become a very meaningful player in vaccination programme in India," he added.

India, home to the world's biggest vaccine manufacturer, kicked off its inoculation drive in mid-January and has administered more than 108 million shots so far.

But the government's ambitious goal of vaccinating 300 million people by the end of July has been hit by reports of shortages in some states and vaccine hesitancy.

The government has also slowed its export of jabs due to the rise in cases.

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