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PAPER CLIPPINGS

18

ಇಲಾಖೆ / ವಿಷಯ : DEPARTMENT / SUBJECT: Covid-19

ಪತ್ರಿಕೆಯ ಹೆಸರು : NAME OF THE NEWS PAPER: The Hindu

ದಿನಾಂಕ : DATE : 21/12/2021

Expert panel gives the go-ahead for Covishield

DCGI committee seeks additional data on Covaxin efficacy

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NEW DELHI

Covishield, the vaccine candidate from the Pune-based Serum Institute of India, was approved by a subject expert committee (SEC) of the Drugs Controller General of India (DCGI) late on Friday.

Bharat Biotech has been asked to furnish more data demonstrating the efficacy of its candidate, Covaxin, an informed source confirmed to *The Hindu*.

The nod for Covishield came at the end of a marathon meeting of the SEC, which began in the morning and went on till late in the evening. The SEC gives its recommendation to the DCGI which is the approving authority for drugs and vaccines.

"Covishield is likely to be practically available for use within the next week," the source said. "Similar to that in the United Kingdom, we've approved the vaccine to be given in two doses 4-12 weeks apart."

Covishield, which is similar to the 'Oxford vaccine' developed by the Oxford University vaccine group and marketed by AstraZeneca, was approved by the health regulator in the U.K. under emergency use conditions on Wednesday. Under this, the company is allowed to prioritize

Welcome job

Panel recommends restricted emergency use of Covishield

■ Covishield is equivalent (but not exactly the same) to the vaccine candidate developed by Oxford University and AstraZeneca

■ The Pune-based Serum Institute of India (SII) is testing the vaccine's efficacy in a double-blinded placebo controlled trial in 1,600 volunteers in India



■ The U.K. had on Dec. 30 granted approval to AstraZeneca for emergency use of the vaccine in that country

■ Interim data based on trials in the U.K. and Brazil suggest that the vaccine protected 70% of the volunteers from showing disease symptoms

4 more found with new strain

Four more cases of the mutant strain of the COVID-19 virus were detected on Friday, taking the total number of those affected by it to 29. Of the four cases, three were found in Bengaluru, while one was detected in Hyderabad. ▶ PAGE 12

ty groups and then the larger public, even though a full safety assessment hasn't been completed.

For Covishield's appraisal, the source said, the nod by the U.K. regulator and data from a Phase-2 trial on 100

Govt. planning awareness drive

As further steps are being cleared for the release of a COVID-19 vaccine in India, the Union Ministry of Health has come up with an elaborate communication strategy to counter issues arising out of vaccine hesitancy, and 'eagerness' among the people. ▶ PAGE 12

volunteers in India, antibody levels generated in the volunteers in response to the vaccine, and safety data from the Phase-1 studies were relied on.

CONTINUED ON ▶ PAGE 10

FROM PAGE ONE

Expert panel gives the go-ahead for Covishield

1903 2/12/21 7/4

In the U.K., the vaccine has been recommended to be given in two doses 4-12 weeks apart. This, even though the vaccine's performance was evaluated in volunteers who were given doses four weeks apart and there's still no clarity on how long the protective effect of a single first dose lasts. The U.K. regulator allowed this after a spike in cases in recent weeks and decided to ensure that maximum people get at least one dose of a vaccine.

SII officials have said India will have a stockpile of 100 million doses as of the first week of January but there is no clarity on how many of these will be available for Indians. A longer dosage interval means that potentially more Indians could get at least a single jab of the vaccine.

Covishield is currently being tested in 1,600 volunteers as part of its Phase-2/3 trial.

However the results from these trials haven't been published or publicised in scientific journals.

"The Phase-3 trial is ongoing and we will continuously keep reviewing the data," the person added. "Other than the case from Chennai of a reported severe adverse event from the vaccine, no other safety events have been reported. We've also conclusively ruled out that the said reaction was directly linked to the vaccine."

The preliminary efficacy data from India seemed to suggest that it was "similar to" what was seen in the U.K. and Brazil which formed the bulk of the data set that the U.K. relied on to accord approval.

Ministry yet to comment

The Health Ministry was yet to comment on the approval accorded but a set of conditions under which the approval was accorded is likely to be spelt out on Saturday.

This is the second time in three days that the committee has met to review applications for emergency use approval by SII, BB and Pfizer India.