Govt expert panel recommends market approval to Covaxin, Covishield for adults

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The Indian drug regulator's subject expert committee recommended full approval for Covishield and Covaxin vaccine against Covid-19.

The subject expert committee (SEC) has advised that the Drugs Controller General of India upgrade the status of the two shots from restricted use in emergencies for adults to Serum Institute of India and Bharat Biotech for their COVID-19 vaccines Covaxin and Covishield with conditions for the adult population.

According to the Central Drugs Standard Control Organisation (CDSCO), "SEC of CDSCO has recommended for the upgrade of Covishield and Covaxin status from restricted use in emergency situations to grant of new drug permission with conditions in the adult population, DCGI will evaluate the recommendations and give its decision."

The market authorisation for vaccine means that it can be authorized for use without reservation and conditions.

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— CDSCO_INDIA_INFO (@CDSCO_INDIA_INF) January 19, 2022

"SEC of CDSCO has recommended for upgrade of covishield and covaxin status from restricted use in emergency situations to grant of new drug permission with conditions in adult population, DCGI will evaluate the recommendations and give its decision," CDSCO said later in a tweet.

"The Subject Expert Committee (SEC) on COVID-19 of the Central Drugs Standard Control Organisation (CDSCO) which reviewed SII and Bharat Biotech's application for the second time on Wednesday has recommended granting regular market approval to Covishield and Covaxin subject to certain conditions," an official source said to news agency PTI.

The recommendations will be sent to DCGI for final approval.

Covaxin and Covishield received emergency use authorisation in India in January 2021, with more than a combined 1.5 billion doses having been administered so far, according to government data.

The Serum Institute of India and Bharat Biotech vaccines have to be administered in two doses. These vaccines have to be stored at 2-8 degrees celsius.

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