DCGI grants emergency authorisation for single-dose COVID-19 vaccine Sputnik Light

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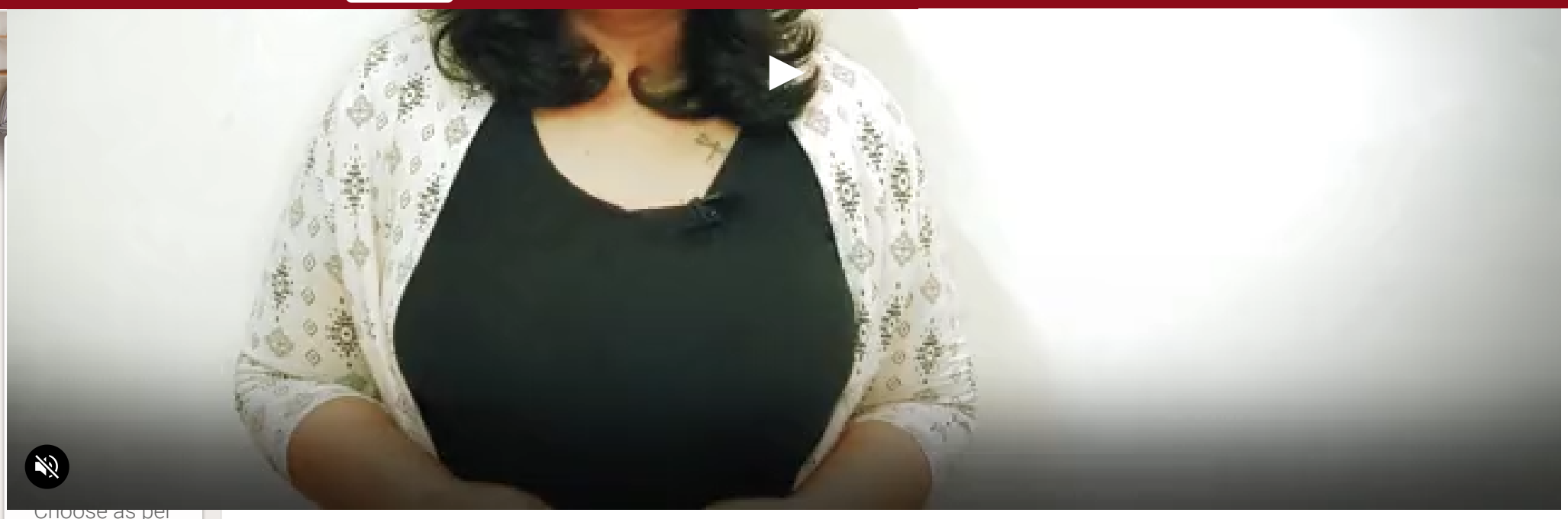
Inputs PTI

Dr Reddy's Laboratories Ltd on Monday, February 7, announced that the Drugs Controller General of India (DCGI) has granted approval to the single-shot Sputnik Light vaccine for restricted use in emergency situation for COVID-19 in India. The drug maker said it had submitted its application for approval to the DCGI in December 2021, in addition to data from clinical trial in Russia, following its Phase-III clinical trial of the single-shot Sputnik Light vaccine in India.

Sputnik Light is a single-dose vaccine and the same as the first component -- recombinant human adenovirus serotype number 26 (rAd26) -- of the two-dose Sputnik V vaccine.

The standalone Sputnik Light vaccine is the latest jab to be approved by the DCGI as part of India's national inoculation effort against COVID-19. Sputnik Light is the second COVID-19 vaccine to be made available in India by Dr. Reddy's.



Sputnik Light has been approved in over 30 countries around the world including Argentina, UAE, Philippines and Russia. In September 2020, Dr. Reddy's partnered with the Russian Direct Investment Fund (RDIF) to conduct clinical trials of Sputnik V and distribute the vaccine in India.

In April 2021, the DCGI granted approval to the two-dose Sputnik V vaccine for restricted use in an emergency situation in India.

Health Minister Mansukh Mandaviya had tweeted on February 6 that the DCGI had granted emergency use authorisation. "DCGI has granted emergency use permission to single-dose Sputnik Light COVID-19 vaccine in India. This is the ninth COVID-19 vaccine in the country. This will further strengthen the nation's collective fight against the pandemic," Mandaviya tweeted.

An official source told PTI in light of recommendations of Subject Expert Committee (SEC) following a meeting on January 31, Dr Reddy's Laboratories presented its proposal for grant of permission to import Sputnik Light for restricted emergency use and booster dose vaccination along with analysis of safety and efficacy data including its benefit against Omicron.

"The SEC on COVID-19 of the CDSCO, which deliberated on the application by Dr Reddy's Laboratories, noted the safety and immunogenicity data presented by the firm from the Indian study is comparable with that of the ongoing Phase-3 clinical trial interim data from Russia," the source said.

The interim data of efficacy trial from Russia has shown 65.4% efficacy, 21 days after immunisation. "After detailed deliberation, the SEC had recommended grant of permission for restricted use in emergency situation subject to various regulatory provisions including," the source said.

Topic tags,

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