INDIA NEWS

Dr Reddy's Labs gets approval for phase 3 trials of Sputnik Light in India

Sputnik V vaccine is developed by Russia's Gamaleya Institute with assistance from Russia's sovereign wealth fund, RDIF, that is also marketing the vaccine globally. RDIF entered a partnership with Dr Reddy's Labs to market first 250 million doses of the vaccine and conduct trials required for grant of regulatory approvals

By Rhythma Kaul
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Representational Image. (Getty Images/iStockphoto)

India's drugs regulator has granted permission to Dr Reddy's Laboratories to conduct phase 3 clinical trials for Sputnik Light, the single dose and first component of the Russian made Sputnik V vaccine against Coronavirus disease (Covid-19).

The subject expert committee (SEC) of the Central Drugs Standard Control Organisation, in its 172nd meeting last month, recommended the drugs controller to grant approval to conduct bridging studies in India for the single-dose variant of Sputnik V, after going through updated safety, immunogenicity and efficacy data from phase 3 trials that happened in Russia.

The subject expert committee (SEC) in June asked Dr Reddy's to submit data from trials in Russia before seeking permission to conduct trials locally.

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"In light of the recommendations of the SEC dated 30.06.21, the firm presented updated safety, immunogenicity and efficacy data of phase III clinical trial of SARS-CoV-2 virus vaccine (Sputnik Light)— single dose vaccine conducted in Russia along with the proposal to conduct phase III clinical trial. The committee noted that the firm has now presented the safety and immunogenicity along with the longevity of the antibodies which gives a measure of persistence of antibodies in the participants," read minutes of the meeting that HT has accessed.

Sputnik V is one of the six Covid-19 vaccines that have been granted emergency use approval by India's drugs regulator.

It is a two-dose shot (but two unidentical doses unlike other two-dose vaccines) that is 91.6% effective in preventing serious illness as was found in phase 3 clinical trials.

Starting initially in Hyderabad on May 14 this year, Dr Reddy's did a soft launch on pilot basis in select cities to check logistical arrangements including cold chain facilities.