

# The National Regulator grants Permission for Restricted Use in Emergency Situations to Sputnik-V vaccine

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The Union Government has been leading the fight against COVID-19 with a proactive and 'Whole of Government' approach, with focus on containment, surveillance, testing, COVID Appropriate Behaviour and vaccination. The countrywide vaccination drive started from 16th Jan 2021. Two vaccines have been approved for Emergency Use Authorisation (EUA) by the National Regulator i.e. Drugs Controller General of India (DCGI). These are "Covishield" manufactured by Serum Institute of India (SII) and "Covaxin" manufactured by Bharat Biotech International Limited (BBIL). Several other vaccines are at various stages of clinical development within the country.

M/s Dr. Reddy's Laboratories Ltd. (M/s DRL) had applied for the grant of permission to import and market Gam-COVID-Vac combined vector vaccine, popularly called Sputnik-V, developed by M/s Gamaleya Institute, Russia for Emergency Use Authorization. The Gam-COVID-Vac combined vector vaccine (Component I & Component II) has been developed by National Research Center for Epidemiology and Microbiology of the Ministry of Health of the Russian Federation, Moscow, Russia and is approved in 30 countries across the world.

M/s DRL has collaborated with National Research Center for Epidemiology and Microbiology of the Ministry of Health of the Russian Federation for obtaining regulatory approval for import for marketing in India. The interim results of Safety immunogenicity and efficacy from Russian Phase III clinical trial have been published in Lancet journal.

M/s DRL was permitted to conduct a Phase-II/III clinical trial in the country. The firm has submitted interim data from the ongoing Phase-II/III clinical trial in the country. The data from the clinical trial is being continuously assessed by the CDSCO in consultation with the Subject Expert Committee (SEC) as a rapid regulatory response. The SEC consists of domain knowledge experts from the fields of pulmonology, immunology, microbiology, pharmacology, paediatrics, internal medicine, etc.

The SEC deliberated on various critical areas for consideration including safety, immunogenicity, efficacy data from overseas clinical studies, indication, age group, dosing schedule, precautions, storage, warnings, adverse effects of special interest, risk benefit evaluation, proposed factsheet, PI, SmPCetc. The approval of the vaccine in Russia along with its conditions/restrictions was also reviewed by the SEC. The SEC noted that the safety & immunogenicity data presented by the firm from the Indian study is comparable with that of the Phase III clinical trial interim data from Russia.

After detailed deliberation the SEC recommended for grant of permission for restricted use in emergency situations subject to various regulatory provisions.

The vaccine is indicated for active immunization to prevent COVID-19 disease in individuals of  $\geq 18$  years of age. The vaccine should be administered intramuscularly in two doses of 0.5 ml each with interval of 21 days. (Day 0: Component I & Day 21: Component II). The vaccine has to be stored at  $-18^{\circ}\text{C}$ . The vaccine comprises of two components I & II, which are not interchangeable. After careful consideration, the recommendations of the SEC have been accepted by the Drugs Control General (India). M/s DRL will import the vaccine for use in the country.

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