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DCGI issues restricted emergency approval of COVID-19 vaccines

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SII and Bharat Biotech vaccines have to be administered in two doses



The Subject Expert Committee of the Central Drugs Standard Control Organization (CDSCO) met on 1st and 2nd January, 2021 and made recommendations in respect of proposal for Restricted Emergency Approval of COVID-19 virus vaccine of Serum Institute of India (SII) and Bharat Biotech as well as Phase III clinical trial of Cadila Healthcare Ltd.

The Subject Expert Committee consists of domain knowledge experts from the fields of pulmonology, immunology, microbiology, pharmacology, paediatrics, internal medicine, etc.

Serum Institute of India, Pune has presented a Recombinant Chimpanzee Adenovirus vector vaccine (Covishield) encoding the SARS-CoV-2 Spike (S) glycoprotein with technology transfer from AstraZeneca/Oxford University.

On the other hand, Bharat Biotech has developed a Whole Virion Inactivated Corona Virus Vaccine (Covaxin) in collaboration with ICMR and NIV (Pune), from where they received the virus seed strains. This vaccine is developed on Vero cell platform, which has well established track record of safety and efficacy in the country & globally.

Cadila Healthcare has developed a Novel Corona Virus-2019-nCov-Vaccine using DNA platform technology. The firm initiated Phase-I/II clinical trial in India in more than 1000 participants which is ongoing. The interim data suggests that the vaccine is safe and immunogenic with three doses when administered intradermally. Accordingly, firm has sought permission to conduct Phase-III clinical trial in 26000 Indian participants, which has been recommended by the Subject Expert Committee.

SII and Bharat Biotech vaccines have to be administered in two doses. All the three vaccines have to be stored at 2-8° C.

The Prime Minister, Narendra Modi has called the Drugs Controller General of India (DCGI) approval of Serum Institute and Bharat Biotech vaccines a decisive turning point to strengthen a spirited fight against corona.

"DCGI granting approval to vaccines of Serum Inst of India and Bharat Biotech accelerates the road to a healthier and COVID-free nation. Congratulations India. Congratulations to our hardworking scientists and innovators", he said.