Ministry of Health and Family Welfare

Press Statement by the Drugs Controller General of India (DCGI) on Restricted Emergency approval of COVID-19 virus vaccine

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The Subject Expert Committee of Central Drugs Standard Control Organisation (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 M/s Serum Institute of India and M/s Bharat Biotech as well as Phase III clinical trial of M/s Cadila Healthcare Ltd.

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

M/s 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. The firm submitted safety, immunogenicity and efficacy data generated on 23,745 participants aged ≥ 18 years or older from overseas clinical studies. The overall vaccine efficacy was found to be 70.42%. Further, M/s Serum was granted permission to conduct Phase-II/III clinical trial on 1600 participants within the country. The firm also submitted the interim safety and immunogenicity data generated from this trial and the data was found comparable with the data from the overseas clinical studies. After detailed deliberations Subject Expert Committee has recommended for the grant of permission for restricted use in emergency situation subject to certain regulatory conditions. The clinical trial ongoing within the country by the firm will continue.

M/s 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.

The firm has generated safety and immunogenicity data in various animal species such as mice, rats, rabbits, Syrian hamster, and also conducted challenge studies on non-human primates (Rhesus macaques) and hamsters. All these data has been shared by the firm with CDSCO. Phase I and Phase II clinical trials were conducted in approx.800 subjects and the results have demonstrated that the vaccine is safe and provides a robust immune response. The Phase III efficacy trial was initiated in India in 25,800 volunteers and till date, ~22,500 participants have been vaccinated across the country and the vaccine has been found to be safe as per the data available till date.

The Subject Expert Committee (SEC) has reviewed the data on safety and immunogenicity of the vaccine and recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations,

especially in case of infection by mutant strains. The clinical trial ongoing within the country by the firm will continue.

M/s Cadila Healthcare Ltd., 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.

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

After adequate examination, CDSCO has decided to accept the recommendations of the Expert Committee and accordingly, vaccines of M/s Serum and M/s Bharat Biotech are being approved for restricted use in emergency situation and permission is being granted to M/s Cadila Healthcare for conduct of the Phase III clinical
trial.

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HFW/DCGI Media statement on COVID Vaccine/3rd January2021/2

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