The Subject Expert Committee (SEC) of Central Drugs Standards Control Organisation (CDSCO) makes recommendations in respect of Accelerated Approval Process request of M/s Serum Institute of India and M/s Bharat Biotech International Ltd as well as about Phase-III Trials of M/s Cadila Healthcare Ltd

Posted On: 02 JAN 2021 7:22PM by PIB Delhi

The Subject Expert Committee of CDSCO met on 1st and 2nd January, 2021 and made the following recommendations for the consideration and final decision of the Drugs Controller General of India :-

1) Grant of permission for restricted emergency use of vaccine, subject to multiple regulatory conditionalities, to M/s Serum Institute of India, Pune.

2) Grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, specially in the context of infection by mutant strains, to M/s Bharat Biotech International Ltd., Hyderabad.

3) Grant of permission for conduct of Phase-III Clinical Trial Protocol to M/s Cadila Healthcare Ltd, Ahmedabad.

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MV/SJ

HFW/COVID States data/30th November2020/1

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