X-11026/07/2020-PRO
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Public Relation Office)

FDA Bhawan, Kotla Road
New Delhi, 110002
Dated: 1st June, 2021

NOTICE

Guidance for approval COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL)

In light of the huge vaccination requirements in India in the wake of the recent surge of COVID-19 cases and the need for increased availability of imported vaccines to meet the national requirements even though the domestic manufacturing of COVID-19 vaccines is getting augmented, in partial modification of this office Notice of even number dated 15.04.21, as per recommendation of NEGVAC, it has been decided that for approval of COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL) and which are well established vaccines from the stand point that millions of individuals have already been vaccinated with the said vaccines, the requirement of conducting post approval bridging clinical trials and the requirement of testing of every batch of the vaccine by the Central Drugs Laboratory (CDL), Kasauli can be exempted, if the vaccine batch/lot has been certified and released by National Control Laboratory of Country of Origin.

However, scrutiny and review of their Summary Lot Protocol & Certificate of analysis of Batch/Lot shall be undertaken by CDL Kasauli for Batch release as per the standard procedures and the requirement of assessment on the first 100 beneficiaries for 7 days for safety outcomes before the vaccine is rolled out for further immunization programme, along with other procedures for filing of applications and timelines for processing of the applications, etc. as laid down in the notice dated15.04.21 shall remain the same.

V.G Somani

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

All Stake holders through CDSCO website.