

File No. X-11026/65/2020-BD
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi 110 002, India
Dated: 31/4/2020

CIRCULAR

To

1. The Director, Central Drugs Laboratory (CDL), Kasauli, Himachal Pradesh-173204.
2. All Zone/Sub Zone offices of CDSCO and State Licensing Authorities
3. All Human Vaccine manufacturers

Subject: Procedure for lot release of Human vaccine in view of prevailing COVID-19 pandemic-regarding.

References:

1. E-mail of domestic manufacturer dated 01.04.2020.
2. This Directorate's letter to all port offices vide file no. DCGI/Misc/2020(101) dated 25.03.2020.
3. This Directorate's order issued vide File No. X-11026/11/2017-BD dated 15.02.2017.

Sir/Madam,

With reference to the subject cited above, this is to inform that this Directorate has received a representation from domestic manufacturer of Human Vaccine wherein it has been requested to grant permission for testing and lot release of Human vaccine on the basis of internal quality system and approval of batch summary protocol by Central Drugs Laboratory (CDL), Kasauli due to current situation of lock-down and constraints in supply management due to COVID-19 pandemic situation in the country.

In this regard, the matter has been examined in light of requirements & availability of essential Human vaccines in the country and it is decided that the manufacturer shall send the samples as per usual procedures to CDL, Kasauli for evaluation when logistics are restored. Till such time, CDL, Kasauli may carry out lot release activity for Human vaccines manufactured domestically by review of summary lot protocol on case by case basis. The lot release is subject to the condition that manufacturer shall forward summary lot protocol of each batch/lot to CDL, Kasauli through e-mail along with certificate of analysis and an undertaking that Human Vaccine released in the market shall be recalled in case of quality failures. However CDL, Kasauli may not issue lot release certificate wherever it is of the opinion that data is insufficient to take the decision. This procedure may be followed till the situation returns to normal.

In order to ensure continued availability of vaccines, being an essential drug, and due to the prevailing outbreak of COVID-19, lock down announced by Government of India, logistic problem, man power problem at each level including laboratory, this order is being issued in the public interest.

Yours faithfully,



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

Copy to:

1. PPS to Directorate General of Health Services, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi – 110 011.
2. PPS to the Joint Secretary (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi – 110 011.