

File No. X11026/39/2024-BD(VAC)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi- 110002
Dated:

22 AUG 2024

To

All State/UTs Drugs Controller cum Licensing Authorities.

Subject: Grant of manufacturing licences for human vaccines/sera (Form 28D/Form 28DA) and endorsement of additional products in the licence through ONDLS portal-Regarding.

Sir/Madam,

As you are aware that the Online National Drugs Licensing System (ONDLS) portal has been developed by CDAC in coordination with States for processing of application and online licensing of Sale/Manufacturing license. Recently, CDAC has also developed online portal for submission and processing of the applications for grant of manufacturing licence for human vaccines/sera & endorsement of additional products in licence and other CLAA items on the ONDLS Portal.

In this regard, you are requested to direct all the human vaccine/sera manufacturers under your jurisdiction to submit application for grant of manufacturing licences for human vaccines/sera (Form 28D/Form 28DA) and endorsement of additional products in the licence through ONDLS portal only.

Further, it may be noted that physical files will not be accepted for these applications henceforth.

In case of any difficulties, CDAC may be contacted at uttamkumar@cdac.in or ondlssupport-noida@cdac.in for any assistance regarding processing/submission of applications on ONDLS portal.

This is for your information and necessary compliance.

Yours faithfully


(Dr. Rajeev Singh Raghuvanshi)
Drug Controller General (India)

Copy for information to:

1. All Zonal/Sub Zonal offices of CDSCO for necessary compliance and coordination with respective State/UTs Licensing Authorities in the matter.
2. Joint Secretary, Drugs Regulation, MoHFW.
3. Director CDAC Noida with request to assist the States for onboarding on the ONDLS Portal.