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

FDA Bhawan, Kotla Road, New Delhi – 110 002, India, Dated 7 100 002

Office Memorandum

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

This is in continuation to this office earlier letter even no. dated 22.08.2024, wherein State/UTs Drugs Controller cum Licensing Authorities were requested to direct all the manufacturers of Human Vaccine/Sera under their 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.

However, it has been observed that licences for CLAA endorsement are still forwarded by some SLAs in physical mode instead of ONDLS portal.

In this regard, you are hereby directed to send all the Joint Inspection letters/reports of facilities for 28D/28DA licences or additional products endorsement only through ONDLS portal.

Further, it may be noted that no physical files of licences will be accepted by the CDSCO (HQ) after 11th April, 2025.

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

This is for strict compliance by all CDSCO Zonal/Sub-Zonal offices.

Yours faithfully,

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

To:

All Zonal/Sub Zonal offices of CDSCO.

Copy to:

- All State/UTs Drugs Controller cum Licensing Authorities.
- 2. All manufacturers of Human Vaccines/Sera.
- Director(Admin.), CDSCO(HQ).
- 4. CDAC Noida (ONDLS team).
- 5. DDC(I), CRU, CDSCO(HQ).