

## F. No-1-3/2023-NCLB GOVERNMENT OF PAKISTAN DRUG REGULATORY AUTHORITY OF PAKISTAN

### NATIONAL CONTROL LABORATORY FOR BIOLOGICALS (NCLB)

NCLB Building, Prime Minister's National Health Complex, Park Road, Chak Shahzad, Islamabad.



Dated: Islamabad 18th September 2025.

# Subject: MANDATORY SUBMISSION OF LOT RELEASE APPLICATIONS FOR BIOLOGICAL PRODUCTS THROUGH THE ONLINE LOT RELEASE PORTAL.

In alignment with the Government of Pakistan's vision for a "Digital Pakistan" and the Drug Regulatory Authority of Pakistan's (DRAP) ongoing digitization drive to enhance efficiency, transparency, and public service delivery, DRAP is pleased to announce the launch of its Online Portal for submission and issuance of Lot Release Certificate. This initiative is a significant step towards the complete digitalization of regulatory processes, aiming to streamline the submission, review, and approval of lot release applications for human vaccines, plasma-derived products, and anti-sera. The new system will ensure a more efficient and expeditious regulatory oversight, safeguarding public health and facilitating trade in a less paper environment.

- 2. In pursuance of DRAP's mandate to regulate, coordinate, and enforce the provisions of the Drugs Act, 1976 and the Drug Regulatory Authority of Pakistan Act, 2012, all importers and manufacturers of human vaccines, plasma-derived products, and anti-sera, are hereby directed to submit all future lot release applications exclusively through the online portal. The online portal is accessible at the following URL: <a href="https://edrap.dra.gov.pk/lotRelease">https://edrap.dra.gov.pk/lotRelease</a>
- 3. This directive shall come into force with effect from October 01, 2025. All relevant stakeholders are advised to familiarize themselves with the new online submission process to ensure a smooth transition. For any technical assistance or queries, please contact the Mr. Zain Ul Abidin, Deputy Director/ Federal Government Analyst, NCLB Contact Number: 051-9255263.
- 4. This notification is issued with the approval of the CEO, DRAP.

Muhammad Arif Chaudhry

Director, NCLB

#### Distribution: -

- 1. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
- 2. Executive Director, Pharma Bureau, Karachi.
- 3. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi
- 4. Director, MIS Division, with the request to upload on DRAP website.

#### Copy for information to: -

- 1. Director, Pharmaceutical Evaluation & Registration, DRAP, Islamabad.
- 2. Director, Biological Evaluation & Research, DRAP, Islamabad.
- 3. PS to Chief Executive Officer, DRAP Islamabad.
- 4. Office File.

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