



F.No.1-9/2025 DD(BD)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
(Division of Biological Evaluation & Research)
Prime Minister's National Health Complex, Chak Shahzad



Islamabad, the 17th July, 2025

CIRCULAR

SUBJECT: DISPOSAL OF APPLICATIONS OF BIOLOGICAL PRODUCTS

The Drug Regulatory Authority of Pakistan (DRAP) initiated a pivotal transition to an online submission platform for registration applications in November 2023. This digital transformation was subsequently extended to all other registration application types including Post Registration variations (PRV). This strategic shift underscores DRAP's commitment to enhancing transparency, efficiency, ensuring data integrity, and reinforcing regulatory compliance. The primary objectives of this initiative are to streamline document management, mitigate administrative burdens, curtail review timelines, and expedite the overall evaluation process.

2. The Division of Biological Evaluation & Research has diligently reviewed and processed all biological product applications and dossiers submitted in physical form up to December 2023. The outcomes of these evaluations have been presented to the Registration Board in its various meetings, and the minutes of these meetings are publicly accessible on DRAP's official website.

3. Despite DRAP's comprehensive efforts to clear the backlog of physical submissions, we recognize that a limited number of applications may have been inadvertently overlooked. To ensure the complete resolution of all pending cases including the post registration variations, stakeholders and applicants are hereby directed to notify the Division of Biological Evaluation & Research of any unaddressed hard copy dossiers/applications submitted prior to December 2023. Such notifications must be submitted exclusively through online portal via a "General Request," accompanied by authentic and verifiable proof of the original submission.

4. Please be advised that the deadline for submitting these applications is August 15, 2025. Submissions received after this date will not be considered. Your cooperation in this matter is crucial for the efficient conclusion of this transitional phase.

Muneeb Ahmed Cheema
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Deputy Director (BE&R)

Distribution:

1. Pakistan Pharmaceutical Manufacturers Association (PPMA), House No. 474, Street No. 34, Sector I-8/2, Islamabad.

2. Pharma Bureau,
Chamber of Commerce Building Talpur Road,
Karachi
3. Pakistan Chemists & Druggist Association (PCDA),
Suit No.504, 5th Floor, Mashriq Center, near Civic Center,
Block 14 Gulshan-e-Iqbal, Karachi.
4. Pakistan Veterinary Pharmaceuticals Association,
674 P Block, Johar Town,
Lahore.

Through e-office:

1. Director (MIS), DRAP Islamabad with request to upload on DRAP's website.
2. Director (Biological Drugs), DRAP Islamabad.
3. Director (PE&R)/ Chairman Registration Board, DRAP Islamabad.
4. PS to CEO DRAP, Islamabad.