



No.14-1/2022-PEC  
Government of Pakistan  
**Drug Regulatory Authority of Pakistan**  
Ministry of National Health Services, Regulations & Coordination



Islamabad, 01<sup>st</sup> August, 2025

**NOTIFICATION**

Subject: - **Quality-Based Incentivisation of Applications for Local Manufacturers**

The Drug Regulatory Authority of Pakistan is endeavoring to cultivate a functional and efficient regulatory landscape that supports the growth and quality standards of Pakistan's pharmaceutical industry. As a testament to this proactive approach, DRAP is pleased to introduce a quality-based priority review mechanism, designed to incentivize local manufacturers for the submission of comprehensive and scientifically robust drug registration dossiers

2. In furtherance of this objective, the Authority, in its 206<sup>th</sup> meeting held on June 04, 2025, approved the following eligibility criteria for drug registration applications to qualify for quality-based priority review:

- i. **Comprehensive Dossier Submission:** Submission of a complete Form 5F dossier (CTD) without availing any data exemptions specified in current guidance documents.
  - ii. **Robust Drug Product Stability Data:** Inclusion of comprehensive drug product stability data, encompassing detailed impurity profiles and and/or degradation studies, prepared strictly in accordance with applicable pharmacopoeial requirements or established international guidelines.
  - iii. **Inclusion of Bioequivalence Studies:** Dossiers that incorporate duly conducted and acceptable bioequivalence studies.
3. Applications submitted on above referred criteria will receive priority in the evaluation and processing queues, reflecting DRAP's commitment to acknowledging and rewarding manufacturing excellence and sound scientific principles.
4. This decision is hereby circulated for the information, and compliance by all relevant stakeholders.

**(Hafiz M. Ali Tayyab)**  
Additional Director (PE&R)/  
Secretary, Registration Board

**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.