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

Islamabad, 01st August, 2025

NOTIFICATION

Subject: - **Borrowing of APIs for Performing Product Development, R&D & Stability Testing Registration Board Decision Thereof.**

I am directed to refer to the office letter of even No. dated 16-01-2023 on the subject captioned above. The Drug Regulatory Authority of Pakistan (DRAP) is persistently extending regulatory flexibilities to facilitate product development to promote indigenous manufacturing of quality products. One of the Notable key relaxation permit the inter-licensee borrowing of Active Pharmaceutical Ingredients (APIs)/Drug Substance (DS) on loan basis from licensed manufacturers, specifically to ensure early access of new products entry into the market, by supporting essential activities such as testing and product development for Form 5F (CTD) dossier submissions.

2. The Authority, during its 206th meeting on June 04, 2025, deliberated the continued scope of this API borrowing facility. While this initial flexibility successfully catalyzed product development and indigenous manufacturing, the broad application of the facility now warrants refinement to ensure enhanced regulatory oversight and robust data integrity across all stages of the pharmaceutical lifecycle. As the industry has increasingly relying on their established API procurement channels and integrating product development as a routine operational component, a more targeted approach to this facility is essential. Consequently, to uphold regulatory accountability and align with the industry's evolved landscape, the Authority has approved a revised procedure. Effective immediately, the borrowing of APIs on a loan basis will be exclusively permitted only to holders of new Drug Manufacturing Licenses (DMLs), and this facility will be limited to a maximum of ten (10) molecules per manufacturing license section.

3. Accordingly, this decision of the Authority is hereby circulated to all relevant stakeholders for compliance and necessary action.

01/08/2025

(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.