



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

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Islamabad, 19<sup>th</sup> February, 2026

**NOTIFICATION**

**Subject: SUBMISSION OF SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) AND PATIENT INFORMATION LEAFLET (PIL)**

The Drug Regulatory Authority of Pakistan (DRAP), established under the DRAP Act, 2012, ensures the availability of safe, effective, and quality therapeutic goods. Central to its mandate is the continuous harmonization of its regulatory standards with international best practices, which is reflected in its pursuit of WHO Benchmarking and PIC/S membership.

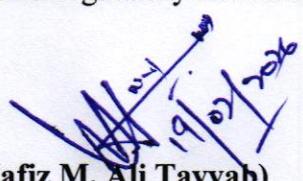
2. As part of the strategic Institutional Development Plans (IDPs) identified through the WHO Benchmarking audit, DRAP is strengthening regulatory processes and documentation. A key IDP is standardized product information to provide clear, consistent, and scientifically sound data for healthcare professionals and patients, supporting rational prescribing, safe dispensing, informed use, and global pharmacovigilance standards.

3. The Authority, during its 206<sup>th</sup> meeting held on 4<sup>th</sup> June, 2025, deliberated upon the recommendations put forth by the Registration Board in its 340<sup>th</sup> meeting on 1<sup>st</sup>-2<sup>nd</sup> October, 2024. Consequently, it was decided that the submission of **Summary of Product Characteristics (SmPC)** and **Patient Information Leaflet (PIL)** shall be made **mandatory for all drug registration applications**. Recently, the Registration Board in its 353<sup>rd</sup> meeting held on 14<sup>th</sup>-15<sup>th</sup> January, 2026 has also approved the roadmap for submission of SmPC and PIL for already registered drugs and biologicals.

4. Resultantly, all pharmaceutical companies are hereby informed that the submission of a **Summary of Product Characteristics (SmPC)** and a **Patient Information Leaflet (PIL)** is **mandatory** for:

- i. **Drug registration application w.e.f 15<sup>th</sup> October 2025 as already notified vide letter of even No. 18<sup>th</sup> July, 2025.**
- ii. **Renewal application w.e.f 01<sup>st</sup> April, 2026.**

5. DRAP remains committed to facilitating a functional and efficient regulatory environment while upholding the highest standards of public health.

  
**(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.