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: **SUBMISSION OF SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) AND PATIENT INFORMATION LEAFLET (PIL) ALONGIWTH CTD DOSSIER (FORM 5-F).**

The Drug Regulatory Authority of Pakistan (DRAP) is established under the DRAP Act, 2012, with the fundamental mandate to ensure the availability of safe, efficacious, and quality therapeutic goods in the country. A core principle of DRAP's regulatory framework, consistent with its enabling legislation and global commitments, is the continuous harmonization of its regulatory standards with international best practices. This pledge is reflected in DRAP's ongoing pursuit of international accreditations, including the WHO Benchmarking for National Regulatory System (NRS) and membership in the Pharmaceutical Inspection Co-operation Scheme (PIC/S), both of which necessitate adherence to rigorous global benchmarks for regulatory oversight.

2. As part of the strategic Institutional Development Plans (IDPs) identified through the WHO Benchmarking audit, DRAP is actively strengthening its regulatory processes and documentation requirements. A key IDP finding highlights the critical need for standardized product information to ensure clear, consistent, and scientifically sound data for healthcare professionals and patients, facilitating rational prescribing, safe dispensing, informed use, and alignment with global pharmacovigilance and risk management standards.

3. The Authority, during its 206th meeting held on 4th June, 2025, deliberated upon the recommendations put forth by the Registration Board in its 340th meeting on 1st-2nd October, 2024. Consequently, it has been decided that the submission of **Summary of Product Characteristics (SmPC)** and **Patient Information Leaflet (PIL)** shall be made **mandatory** for all drug registration applications. These documents shall form an integral part of the Form-5F (Common Technical Document) dossier, under Section 1.5.14, in accordance with DRAP's already published guidance document available on DRAP website (https://encr.pw/HtCCw). To facilitate a smooth transition for all stakeholders, the mandatory submission of SmPC and PIL will be implemented in a phased manner:

i. **For imported finished pharmaceutical and biological products:** This requirement shall be implemented for applications submitted on or after **15th September, 2025**.

ii. **For locally manufactured pharmaceutical and biological products:** This requirement shall be implemented for applications submitted on or after **15th October, 2025**.

4. 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.

Copy for information to: -

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