No. 3-6/2024-I&V-II(M-340)
Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
****

Islamabad, 29th October, 2024

CIRCULAR

SUBJECT: **SUBMISSION OF SUMMARY OF PRODUCT CHARACTERISTICS (SMPC) & PRESCRIBING INFORMATION (PI) AND PATIENT INFORMATION LEAFLET (PIL)**

I am directed to refer to the subject cited above, Registration Board in its 340th meeting held on 1st October to 2nd October, 2024, deliberated the subject matter and decided as under:

"*Submission against section **1.5.14** (Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient Information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP) of Form 5F is mandatory for the imported finished drug products.*"

2. It is hereby circulated for compliance and information of all stakeholders.

Muhammad Sarfraz Nawaz
Deputy Director (I&V-II)

Distribution: -

1. Chairman, Pakistan Pharmaceutical Manufacturer's Association, Islamabad.
2. Executive Director, Pharma Bureau, Karachi.
3. Executive Director, PCDA, Karachi.

Through E-Office:

1. Director Pharmaceutical Evaluation & Registration Division/ Chairman, Registration Board.
2. Director, Biological Evaluation & Research DRAP Islamabad.
3. PS to Chief Executive Officer, DRAP, Islamabad.
4. Director (MIS), DRAP for uploading on DRAP's website.
5. Director QA&LT for forwarding to Additional Director / Officer In-charge DRAP Karachi, Lahore, Islamabad, Peshawar, Quetta for circulation to pharmaceutical units located in their respective area of jurisdiction.
6. Office file.

Deputy Director (I&V-II)