



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 RISK MANAGEMENT PLANS (RMP) AND INITIATION OF ACTIVE SURVEILLANCE BY REGISTRATION HOLDERS.**

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. One of the important Institutional Development Plan (IMP) is compulsory submission of Risk Management Plan (RMP) alongwith new drug including biologicals and vaccines as is required under Pharmacovigilance Rules, 2022. RMP is a detailed description of the risk management system, which includes a set of pharmacovigilance activities and interventions that are designed to identify, characterize, prevent or minimize risks relating to a drug, including the assessment of the effectiveness of these activities and interventions.

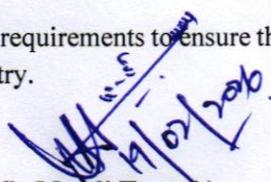
3. Resultantly, the Registration Board, in its 353<sup>rd</sup> meeting held on 14-15<sup>th</sup> January, 2026, has decided, in accordance with Rule 11(11) of the Pharmacovigilance Rules, 2022, that all registration holders (importers and manufacturers) shall submit the Risk Management Plans (RMPs) approved by the reference regulatory authorities as part of the registration dossier for all new drug products at the time of application to the Registration Board. Furthermore, a copy of the approved RMP should also be submitted to the National Pharmacovigilance Centre (NPC), DRAP, following registration of the product.

4. Furthermore, the Board decided that registration holders should take all necessary measures to initiate and/or implement active surveillance of the following types of medicines and vaccines, and accordingly submit the data to the National Pharmacovigilance Centre, DRAP:

- Introduction of new vaccine or biological, including monoclonal antibodies;
- New active substance;
- New drugs for the treatment of HIV, tuberculosis, malaria and hepatitis;
- Orphan drugs for the treatment of rare diseases.
- If active surveillance is a condition of registration, and
- Medicine was authorised under exceptional circumstances, emergency conditions or EUA.

5. The Board also directed MAH holders to report any newly identified risk alongwith complete RMP for already registered drugs to National Pharmacovigilance Centre, DRAP via email at npc@dra.gov.pk.

6. All registration holders are hereby advised to comply with the above requirements to ensure the safety, efficacy, and quality of medicines and vaccines available in the country.

  
**(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.