Dy. No. 419/2026-E-DIR (QA&LT)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
****

Islamabad, dated, **10th** November 2026

SUBJECT: **MANDATORY COMPLIANCE, DATA ACCURACY, AND SYSTEM VERIFICATION FOR 2D BARCODING AND SERIALIZATION REQUIREMENTS**

In continuation of earlier directives and following the notification of amendments to the Drugs (Labelling & Packaging) Rules, 1978 vide **S.R.O. 963(I)/2026** dated **9th June 2026** as well as circular **No. 1-2/2026-CEO(DRAP)** dated **8th October 2026**. Wherein the Drug Regulatory Authority of Pakistan emphasizes that full implementation of 2D Data Matrix barcoding and serialization has taken effect from **9th October 2026**. This initiative is central to DRAP's Strategic Plan for the National Regulatory System (2026–30) to secure the pharmaceutical supply chain, prevent spurious/unregistered products, and enable seamless traceability. All manufacturers and importers are hereby directed to ensure regulatory compliance and maintain data integrity in DRAP's Track and Trace System. All finished drug products (locally manufactured or imported) produced on or after 9th October 2026 shall comply with 2D barcoding and serialization standards. Stock manufactured prior to this date remains exempted and permitted for sale until exhaustion.

2. Importers and manufacturers shall ensure that every data entry submitted into DRAP's Track and Trace system is correct, verified, and a true depiction of the actual information printed on physical commercial packs *(manufacturing and expiry date, batch number, MRP and serial number)*. Registration holder is responsible for correctness of information and any discrepancy between the digital records uploaded to the system and the physical labelling on the pack will be treated as misreporting and a direct violation of regulatory requirements.

3. Federal Inspectors of Drugs (FID) and Field Offices of DARP shall perform compliance verification visits across manufacturing plants, importer premises and supply chain channels. During these inspections, inspectors shall inspect physical batches and cross-check the submitted data against DRAP's Track and Trace system. It is hereby directed to initiate legal action under the DRAP Act, 2012, the Drugs Act, 1976, and the rules framed thereunder, in case of any non-compliance, inaccurate data submission or falsification.

4. All licensed pharmaceutical manufacturers and importers are hereby advised to immediately review, validate, and strengthen their internal operational and IT reporting protocols to guarantee continuous, flawless, and true-to-print data submissions without exception.

10/11/2026

Ch. Zeeshan Nazir Bajar
Director (QA&LT)

Distribution:

1. Chairman, Pakistan Pharmaceutical Manufacturers' Association (PPMA), Karachi to circulate this notification among their members for compliance.
2. Executive Director, Pharma Bureau, Karachi to circulate this notification among their members for compliance

3. Chairman, Pakistan Chemist and Druggist Association (PCDA), Karachi.
4. All Licensed Pharmaceutical & Biological Manufacturers
5. All Authorized Importers of Finished Drugs & Biologicals

Copy to:

1. SPS to Chief Executive Officer, DRAP, Islamabad.
2. Director (MIS), DRAP for system monitoring and audit reporting.
3. Director (PE&R), DRAP, Islamabad.
4. Additional Directors, DRAP Field Offices / Officer Incharge (Islamabad, Lahore, Karachi, Peshawar, Quetta) for compliance through Field force and circulation of letter to all Manufacturers and Importers within their area of jurisdiction.

Ijaz Mustafa
Deputy Director-MIS-IV
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