DRAP Amends Drugs (Labeling and Packaging) Rules 1986: Mandatory Bar-coding and Serialization Framework Notified

The Drug Regulatory Authority of Pakistan (DRAP) has issued S.R.O. 963(I)/2026, dated 9 June 2026, finalizing amendments to the Drugs (Labeling and Packing) Rules, 1986. The amendments were made under section 23 of the Drug Regulatory Authority of Pakistan Act, 2012, read with clauses (a) and (t) of section 7 thereof, and section 43 of the Drugs Act, 1976, and follow the draft version DRAP had earlier circulated for comment under Notification No. F.13-1/2025-LA, dated 27 June 2025.

The core of the amendment is a revised rule 3A, which introduces a mandatory machine-readable barcode requirement, applying to all drugs manufactured or imported for the domestic market or for export, at different packaging levels, so that products can be identified, tracked, traced so that spurious and counterfeit products can be kept out of the supply chain. The requirement takes effect four months after issuance of the notification, meaning the compliance clock starts running from 9 June 2026 rather than from the date any individual company completes its own preparations.

The rules set out fairly granular, packaging-level requirements. Secondary packaging must carry a barcode encoding a unique global product identification code in GTIN format, along with the batch or lot number and expiry date, and separately, serialization on secondary packaging using random numbers embedded in the GS1 Data-Matrix. The Policy Board has been given discretion to extend the timeline for these two secondary-packaging requirements if needed. Where imported drugs don't already conform at the time of import, the importer must arrange, prior Registration Board approval, to have the GS1 Data-Matrix printed at a locally licensed facility before the drug reaches the market.

Tertiary packaging (logistic units) is treated differently and given considerably more runway: The Serial Shipping Container Code requirement on tertiary packs becomes mandatory only six years after the notification's issuance. Once it applies, homogenous products will need a GS1-128 linear barcode encoding the GTIN, expiry date, batch or lot number, and SSCC, while heterogeneous products need only the SSCC encoded in the same barcode type. Separately, wherever a drug is sold directly in its primary packaging without being packed into secondary packaging, barcode labeling becomes mandatory on that primary pack as well.

The rules also require all manufacturers and importers to submit product and company information to DRAP's database, per the new Schedule-III, and give the Registration Board discretion to exempt specific drugs or classes of drugs from the rule in exceptional circumstances. DRAP has also reserved

the right to adopt alternative track-and-trace standards beyond GS1, provided any such standard is globally recognized, and to issue further implementation guidelines.

Importantly, the amended rule 3A(7) confirms that this framework applies only to allopathic drugs, including biologicals, for human and veterinary use, and does not extend to alternate medicines, OTC non-drug products, nutraceuticals, medical devices, medical gases, or radiopharmaceuticals.

A new rule 15 has also been inserted, providing that fees for the track-and-trace system will be notified separately under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022.

For manufacturers and importers, the practical takeaway is that the four-month runway to comply with the secondary-packaging barcode and serialization requirements is now fixed and running, while the more resource-intensive SSCC and tertiary-packaging obligations sit on a much longer six-year horizon. Companies should treat these as two separate compliance tracks with very different timelines, rather than a single project to be executed all at once.