Ministry of Health and Family Welfare

Union Ministry of Health Proposes Incorporation of Good Storage and Distribution Practices into Drugs Rules, 1945

GSDP Framework to Enhance Regulatory Oversight and Accountability in Pharmaceutical Supply Chain

Proposed Measures to Ensure Quality, Safety and Integrity of Pharmaceutical Products from Manufacturer to Patient

Posted On: 19 NOV 2026 1:02PM by PIB Delhi

The Union Ministry of Health and Family Welfare has proposed the incorporation of Good Storage and Distribution Practices (GSDP) guidelines for pharmaceutical products into the Drugs Rules, 1945. The proposal aims to ensure that the quality, safety, efficacy and integrity of pharmaceutical products are maintained throughout the distribution chain, from the manufacturer or importer to the point of supply to the patient.

The proposed framework builds upon the GSDP guidance developed by the Central Drugs Standard Control Organisation (CDSCO). The guidelines seek to ensure the quality and identity of pharmaceutical products at every stage of the distribution process, including procurement, purchasing, storage, distribution, transportation, documentation and record-keeping.

Maintaining appropriate storage and distribution conditions is essential to preserving the quality and integrity of pharmaceutical products beyond the manufacturing stage. The proposed GSDP framework seeks to address potential risks associated with their handling and movement across the supply chain, including deterioration, contamination, mix-ups, falsification, diversion and unauthorised distribution.

The incorporation of GSDP requirements into the Drugs Rules, 1945, is expected to strengthen the regulatory framework governing pharmaceutical distribution and support effective regulatory oversight, inspection and enforcement by the Central and State drug-control authorities. It will also promote robust documentation, record-keeping and traceability, while enhancing accountability among manufacturers, importers, wholesalers, distributors, stockists and other entities involved in the distribution process.

The proposed guidelines will further strengthen assurance that pharmaceutical products remain within specified quality and environmental conditions during storage and transportation, thereby reducing the risk of deterioration, contamination, mix-ups, falsification, diversion and unauthorised distribution. This will support the availability of pharmaceutical products of assured quality to patients and healthcare providers.

The proposed amendment represents an important step towards strengthening India's pharmaceutical quality-management system and ensuring that the quality established at the manufacturing stage is maintained throughout the supply chain until the product reaches the patient.

Stakeholders and members of the public are invited to submit their objections and suggestions, if any, to the Under Secretary (Drugs Regulation), Ministry of Health and Family Welfare, Government of India, U-6, Work Hall, C Wing, First Floor, Kartavya Bhawan-1, New Delhi - 110001, or via email at drugsdiv-mohfw[at]gov[dot]in.

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