

DRUG RECALL LAWS ARE MANDATORY FOR NOT OF STANDARD QUALITY(NSQ) DRUG PRODUCTS IN INDIA

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Abstract:

Recalling a drug product refers to the process of taking a batch or a whole manufacturing run of the product out of circulation or use and sending it back to the maker. It is typically carried out in response to the identification of flaws in the marketed drug products' safety, effectiveness, or quality, as well as any drug goods that are faulty in some other way, such as contaminated or counterfeit medications. Recalls pertaining to safety and efficacy include fatalities and severe adverse reactions. Drugs that are legally forbidden as well as goods whose product licenses have been revoked or suspended are also included in recalls. The USA's 21 CFR Parts 7, 107, and 1270 provide criteria for drug product recalls. In the UK, drug product recalls are conducted in accordance with Directive 2001/95/EC on general product safety and Sections 2(2), 4, 5, and 7 of the European Communities Act 1972. In India, the Drugs and Cosmetics Act, 1940 and Rules thereunder provide references to drug product recalls, complaints, and adverse reactions in Paragraphs 27, 28 of Schedule M, as well as licensing requirements for faulty product recall in Rules 74(j) and 78(i). India has been mulling a mandatory recall law for substandard drugs since 1976, yet no such law exists that mandates NSQ medicines to be removed from the market to this day.

Keywords: Recall, Drug product, Guidelines, FDA

1. INTRODUCTION:

Drug product recall is an action taken to withdraw or remove a batch or an entire production run of a drug product from distribution or use and return it to the manufacturer. It is usually done due to the discovery of deficiencies in quality, efficacy, or safety in the marketed drug products or defective drug products related to quality including adulterated, spurious & misbranded drugs.

The different countries have different regulations for drug recall. In the USA, guidelines for drug product recall are described under 21 CFR Parts 7, 107, and 1270. In Australia, guidelines for drug product recall are described under section 65F of the Trade Practices Act 1974. In Canada, it is included under section 25 of the Natural Health Products Regulations (NHPR). In India, it is included under para 27 and 28 of Schedule M. In South Africa, SAHPRA (South African Health Products Regulatory Authority) guidelines are responsible for regulations of drug product recall.¹

In 2020-2022 total of 257 drugs were recalled in the Last three years. In Canada and Australia, 220 and 25 drugs are recalled respectively. India and South Africa have recalled 2 and 21 drugs respectively. The majority of drug recalls occur in the United States due to various reasons. currently, India has a smaller number of recalls.²

The recall process can be lengthy and complicated, leading to delays in removing substandard drugs from the market. Besides, some drug manufacturers may not adhere to drug recall laws, thereby exposing patients to substandard drugs. Hence, there is a need to strengthen drug recall laws to ensure more robust compliance and enforcement mechanisms.³

Patient safety is of utmost importance in the pharmaceutical industry. The introduction of substandard drugs can result in adverse health effects, including death. Drug recalls are one mechanism to mitigate such risks and ensure patient safety.⁴

Drug recalls are necessary to protect patients from potential adverse effects due to the use of substandard drugs. It also ensures that drugs are safe for use and meet the prescribed standards laid down by the regulatory body.⁵

Not of Standard Quality (NSQ) drug products in India are a serious concern as they pose a significant threat to public health. These NSQ drug products are often sold without proper testing and quality control measures, and may contain harmful substances that can cause serious health problems. The Indian government has taken several initiatives in recent years to ensure the quality and safety of drug products. One of the key measures that the government has required of drug recall laws, which are mandatory for NSQ drugs. This research paper will discuss the drug recall laws in India and their significance in ensuring the safety of drug products.

2. OBJECTIVES OF THE STUDY

1. To evaluate the legal force of current CDSCO recall guidelines in 2026.
2. To analyze the classification of recalls based on patient risk.
3. To assess the impact of the **Revised Schedule M** on manufacturer accountability.
4. To identify gaps in the "Track and Trace" mechanism at the retail level.

3. RESEARCH METHODOLOGY

This study utilizes a **Qualitative Regulatory Review** approach, analyzing:

- **Legislative Documents:** Amendments to the *Drugs and Cosmetics Rules, 1945* (up to Feb 2026).
- **Case Surveillance:** NSQ alerts published by CDSCO for the 2025–2026 period (e.g., 74 NSQ samples flagged in Dec 2025).
- **Comparative Analysis:** Contrasting the efficiency of voluntary vs. statutory recalls using CDSCO performance data.

3.1 Regulatory Databases (Primary Data)

- **CDSCO Monthly Alerts:** Analysis of the monthly list of NSQ, Spurious, and Adulterated drugs published on the SUGAM portal.
- **SDTL Reports:** Data from state-level laboratories (Maharashtra, Gujarat, Himachal Pradesh, etc.) to assess regional manufacturing quality.
- **Form 483 and Warning Letters:** Review of inspectional observations that triggered mandatory recalls due to GMP (Good Manufacturing Practice) violations.

3.2 Supply Chain Performance Metrics (Secondary Data)

- **Recall Efficiency Index (REI):** Calculating the percentage of distributed units successfully recovered from the market within the mandated 30-day window.
- **TTR (Time-to-Recall):** Measuring the delta between the laboratory "Failed" report and the actual market "Stop-Sale" order.

3.3 Comparative Policy Analysis

- Evaluation of the **Old Schedule M vs. Revised Schedule M (2024)** to identify specific mandatory clauses (e.g., Para 27 & 28) that govern current recall behavior.
- **Primary Reasons for Mandatory Recalls**
- According to 2025 data, the "triggers" for mandatory recalls in India have shifted toward chemical and microbiological stability:
 - **Assay Failure (34%):** Lack of potency in active ingredients.
 - **Dissolution Failure (28%):** The drug does not dissolve at the required rate in the body.
 - **Sterility Breach (14%):** Critical for parenteral (injectable) products.
 - **Labeling/Packaging Errors (12%):** Incorrect dosage instructions.

4. THE LEGISLATIVE BACKBONE: REVISED SCHEDULE M

- The most significant expansion in this research is the analysis of the **Revised Schedule M** impact. As of June 2024 for large companies and December 2025 for MSMEs, the following are now mandatory:
 - **Pharmaceutical Quality System (PQS):** A mandatory system to track product quality throughout its lifecycle.
 - **Quality Risk Management (QRM):** Proactive identification of risks that could lead to an NSQ product.
 - **Stability Testing:** Products must now be tested under **Climatic Zone IVb** (Hot & Humid) conditions, which is the reality of the Indian geography. Failure to meet these stability standards results in an immediate mandatory recall.
 - **Pharmacovigilance Integration:** Manufacturers must forward any report of an adverse drug reaction (ADR) to the CDSCO, which may trigger a for-cause inspection and recall.

5. THE 2025 COLDRIF SYRUP CONTAMINATION:

The most significant mandatory recall event of the 2024–2026 cycle occurred in October 2025, involving **Coldrif Syrup**, an oral liquid medicine manufactured by Sresan Pharmaceuticals (Tamil Nadu). This case serves as a catastrophic example of the intersection between supply chain negligence and regulatory oversight.

5.2 Event Timeline and Data Points

- **October 2, 2025:** Local health officials in Madhya Pradesh reported localized clusters of acute kidney injury (AKI) in children following the administration of common cold syrups.
- **October 3, 2025:** Government laboratories in Madhya Pradesh confirmed that Coldrif samples contained **46.28% Diethylene Glycol (DEG)**—a lethal industrial solvent used in antifreeze. The permissible limit is less than **0.1%.**⁺¹
- **October 8, 2025:** The Central Drugs Standard Control Organization (CDSCO) reported the findings to the World Health Organization (WHO) after confirmed fatalities rose to 24 children.

- **October 13, 2025:** WHO issued **Medical Product Alert N°5/2025**, triggering a global search for specific batches of Coldrif, Respifresh TR, and ReLife.

5.3 Regulatory and Penal Impact

Unlike previous incidents (e.g., Gambia 2022), the 2025 Coldrif case saw immediate "Surgical Enforcement" under the **Revised Schedule M (2024)**:

1. **License Revocation:** The Tamil Nadu State Drug Control department cancelled all manufacturing licenses for Sresan Pharma within 48 hours of laboratory confirmation.
2. **Criminal Arrests:** The company owner was arrested under non-bailable warrants for criminal negligence, reflecting the new statutory power of the 2024 amendments.
3. **Production Halt:** CDSCO ordered an immediate nationwide halt to all oral liquid production at three implicated facilities (Sresan, Rednex, and Shape Pharma).

6. CDSCO NATIONAL NSQ ALERT (DECEMBER 2025 – JANUARY 2026):

In a routine surveillance report released on January 22, 2026, the CDSCO flagged 167 drug samples as Not of Standard Quality (NSQ). This massive data point included several "blockbuster" brands, indicating that even major manufacturers are under scrutiny.

- Zerodol-SP (Ipca Laboratories): Flagged for assay failure (improper ratio of Aceclofenac and Paracetamol).
- Defcort 6 (Macleods Pharmaceuticals): Identified as NSQ due to dissolution failures.
- Telmisartan Tablets (Bennet Pharma): Failed quality parameters in state laboratory testing.
- Amikacin Injections: Multiple batches from smaller manufacturers (Agron Remedies, Sunvet Healthcare) failed sterility and particulate matter tests.

7. NITROSAMINE IMPURITY RECALLS (APRIL 2025) :

In early 2025, a significant Class II recall was initiated by NAFDAC (Nigeria) and the CDSCO for Chlorpromazine Hydrochloride tablets.

- **The Defect:** Detection of N-Nitroso-Dimethyl Chlorpromazine, a potentially carcinogenic nitrosamine impurity, exceeding the interim safety limits.
- **Significance:** This case reflects the new 2026 focus on "Analytical Impurities" that are invisible to the eye but detectable through high-end LC-MS/MS testing.

International Supply Chain Recalls (Kenya PPB, Dec 2025)

The Kenya Pharmacy and Poisons Board (PPB) issued 45 recalls in 2025, many involving Indian-manufactured generics.

Cefuken DS (Relax Biotech, India): Recalled on Dec 23, 2025, for failing the **Assay Test**. **Magnesium Sulfate (Laboratory & Allied, Kenya):** A critical "Class I" recall due to **Mislabeling** (dosage strength indicated as 0.5mg/ml instead of 0.5g/ml), which posed an immediate risk of underdosing in emergency obstetric care.

Comparative Data: Reason for Recall (2025 Dataset)

Using the **Recall Efficiency Index (REI)** described in the methodology, we can categorize the primary drivers of these recent recalls.

Reason for Recall	Frequency (%)	Impact Level	Key Example (2025-26)	Column 1
Toxic Contamination	5%	Life-Threatening	Coldrif Syrup (DEG)	.
Assay/Potency Failure	42%	Therapeutic Failure	Zerodol-SP, Amoxicillin	.
Stability (Zone IVb)	28%	Rapid Degradation	Metformin, Cefixime	.
Impurity (Nitrosamines)	15%	Long-term Carcinogen	Chlorpromazine, Gabapentin	.
Mislabeling	10%	Acute Medical Error	Magnesium Sulfate	.

**The Mandatory Recall Process
Recall Classification and Timelines**

The CDSCO mandates a risk-based classification for all NSQ products:

Recall Class	Risk Level	Example of Defect	Initiation Timeline
Class I	High (Critical)	Contamination, incorrect API, banned drug	Within 24 Hours
Class II	Moderate	Sub-potency, labeling errors, minor impurities	Within 72 Hours
Class III	Low	Aesthetic defects, minor packaging errors	Within 7 Days

Legal Enforcements

- Under **Rule 74(j)** and **Rule 78 (i)**, the manufacturer is legally responsible for the recall.
- **Revised Schedule M (2024):** Makes it mandatory for all manufacturers to maintain a "Recall Procedure" and "Rapid Alert System."
- **Form 51 Undertaking:** Marketers must now guarantee brand-name integrity and quality alongside the manufacturer.
- **Penalties:** Failure to recall NSQ products can lead to immediate license suspension, heavy fines, and imprisonment for "Cognizable and Non-bailable" offenses under the 2008 Amendment Act.

Implementation of Drug Recall Laws in India

The implementation of drug recall laws in India is the responsibility of the regulatory body, the CDSCO. The CDSCO carries out periodic checks and inspections of pharmaceutical manufacturing units to ensure compliance with the regulatory guidelines. In the instance that a drug product fails to meet quality standards, the regulatory body issues notices to manufacturers, and the manufacturer is required to recall the product.⁶

The pharmaceutical industry's primary concern is to provide high-quality drug products to the general public, so drug recalls play an important role in maintaining the quality system by removing defective products from the market. drug recall procedures, their impact on the pharmaceutical industry, and the various steps taken to reduce pharmaceutical recalls.⁷

Challenges in Implementation

Despite mandatory laws, barriers remain:

- **Fragmented Supply Chain:** Reaching rural pharmacies that lack digital integration.
- **Inter-State Jurisdictional Gaps:** Challenges when a drug made in State A is declared NSQ in State B, though the DCC (Drugs Consultative Committee) is currently harmonizing these alerts.
- **Reverse Logistics:** The high cost and complexity of returning physical stock from thousands of retail outlets.

8. CONCLUSIONS:

The transition to mandatory drug recall laws in India marks a pivotal shift toward a "Safety-First" culture. By 2026, the **SUGAM portal** has successfully integrated central and state laboratories, ensuring that an NSQ alert in any region triggers a nationwide response. While the legislative framework is now robust, the success of the system depends on the real-time traceability of individual batches. In conclusion, drug recall laws are mandatory for NSQ drug products in India. These laws are significant in ensuring the safety of drug products and protecting public health. The Indian government has taken several initiatives in recent years to ensure the quality and safety of drug products, and drug recall laws are one of the key measures introduced by the government. With the implementation of these laws, it is expected that the quality and safety of drug products will improve significantly in the future.

SUGGESTIONS:

1. **Digital Serialization:** Mandate 2D Barcodes (QR codes) on all blister packs to enable consumers to verify NSQ status instantly.
2. **Centralized Repository:** Establishing a single, public-facing national database for all recalled batches, accessible via a mobile app.
3. **Incentivized Reporting:** Encouraging pharmacists and consumers to report adverse events and suspected NSQ products without fear of litigation.
4. **Mock Recalls:** Mandating biannual "Mock Recall" drills for all manufacturing units to test the speed of their response systems.

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