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A Comparative Study of United States and Developing Countries Recall Procedures and Regulations for Drug Products

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Abstract

Drug product recalls are critical pharmacovigilance tools that protect public health by removing unsafe or defective medicines from the market. The United States operates under a highly structured and science-driven recall system led by the U.S. Food and Drug Administration, whereas developing countries often face regulatory, infrastructural, and compliance challenges. This study comparatively evaluates recall procedures, regulatory frameworks, classification systems, communication mechanisms, and effectiveness between the U.S. and developing countries. The analysis reveals significant disparities in regulatory enforcement, surveillance capacity, and recall efficiency, while highlighting emerging trends in harmonization. The study proposes innovative strategies for strengthening recall systems globally, including in developing countries.

Keywords: Drug Recall, USFDA, Drug Regulatory Affairs, Developing Countries, CDSCO.

1. Introduction

Drug recalls are defined as actions taken to remove or correct marketed products that violate regulatory standards or pose health risks. In the U.S., recalls are primarily voluntary but regulated under federal law and monitored by the FDA.[1]

Product recalls are essential to pharmacovigilance and public health protection. Since 2018, the discovery of carcinogenic nitrosamine impurities above acceptable intake (AI) limits has driven many recalls [2,3]. These cases highlight risks from prolonged patient exposure and expose weaknesses in current Good Manufacturing Practices (cGMP), including inadequate impurity control, risk assessment, and supplier oversight [4]. Regulatory authorities now consider these major cGMP violations, requiring stronger quality systems and proactive compliance [5].

A drug recall is the most effective means of protecting the public from a defective or potentially harmful product. According to the FDA, a recall is defined as an action executed by a manufacturer at any time to remove a defective or harmful drug product from the market when the drug is discovered to be in violation of laws and regulations administered by the FDA. [6,7] Drugs may be recalled for an assortment of reasons, including safety, mislabelling, contamination, and deviations in strength or potency. Recalls may be conducted as a voluntary action by the manufacturer or supplier; by request from the FDA; or by a legally mandated order from the FDA.[8]

Definition and Nature of Recall:[9]

Parameter	United States	Developing Countries
Definition	Removal of violative product from market	Similar definition but inconsistently applied
Type of Recall	Primarily **voluntary**, FDA-supervised	Often voluntary, sometimes poorly monitored
Authority to Enforce	FDA can take legal action (seizure/injunction)	Limited enforcement in many regions

The frequency of pharmaceutical product recalls is increasing rapidly, which reflects trends such as heightened inspection rates and ongoing modernization and digitalization within the industry. As a result, regulatory agencies and public health authorities are implementing stricter regulations to prevent future recalls of defective drug products [10,11].

Drug product recall is an action taken to withdraw or remove a batch or an entire production run of drug product from distribution or use to return it to the manufacturer. It is usually done due to a deficiency in quality, safety, and efficacy.[11]

In the USA, guidelines for drug product recall are described under 21 CFR Parts 7, 107, and 1270. In Canada, it is included under section 25 of the Natural Health Products Regulations (NHPR).[12] 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 the regulations of drug product recall. [13,14] The majority of drug recalls occur in the United States due to various reasons.[15] In 2020-2022, a total of 257 drugs were recalled in the last three years. In Canada and Australia, 220 and 25 drugs are recalled, respectively.[16] India and South Africa have recalled 2 and 21 drugs, respectively. By the observation, we can conclude that India and South Africa have a smaller number of recalls.[17] In the USFDA, the number of drug recalls is decreasing due to following the laws and regulations.[18] Developing countries, including India, Nigeria, and Brazil, often rely on evolving regulatory systems that may lack enforcement and surveillance capabilities. [19,20]

1.2. Objectives

1.2.1 To compare recall procedures in the U.S. and developing countries

1.2.2 To evaluate regulatory frameworks and classification systems

1.2.3 To identify gaps and propose innovative improvements

2. Review of Literature

Yerram, S., Muhammad Nizam et.al (2026) reported that the detection of carcinogenic nitrosamine impurities especially those exceeding acceptable intake (AI) limits has become a significant driver of drug recalls. Miglani, A., Saini, C., et al. (2022) proposed raising concerns with regulatory agencies and public health to focus on more stringent regulations to control future recalls of defective drug products.

Bhalodiya, B. L., Vyas, A. K. J., et .al (2023) suggested that drug product recall is an action taken to withdraw or remove a batch or an entire production run of drug product from distribution or use to return them to manufacturer.it is usually done due to deficiency in quality, safety and efficacy.

Rajput, B. S., & Gupta, M. K (2026) reported that Drug recalls are vital for public health safety, especially when pharmaceutical products are found to be faulty, unsafe, or not in compliance with regulations

U.S. Food and Drug Administration. (2023) reported that in the USA, guidelines for drug product recall are described under 21 CFR Parts 7, 107 and 1270.

Vadia, N., Parmar, R., Kyada, et. al (2026) proposed that the regulatory governing authority for the safety, efficacy, and quality of drugs, medical devices, and cosmetics in India is established through the CDSCO and takes a deep look into the regulatory framework overseeing the activities of CDSCO, having considered the transformative impact of digital platforms like the SUGAM online system and the National Single Window System.

3. Methodology

3.1 Research Design (Advanced Comparative Regulatory Framework): adopt a multi-method comparative research design combining:

- Doctrinal legal analysis (regulatory texts, guidelines)
- Comparative policy analysis
- Empirical data analysis (recall datasets)
- Stakeholder perception study (optional but innovative)

3.2 Study Scope and Sampling Strategy:(Stratified Comparative Model)

- Developed System
- United States (FDA)
- Developing Countries (representative diversity):
- India (CDSCO)
- Nigeria (NAFDAC)
- Brazil (ANVISA)
- Kenya (PPB)

3.3 Data Sources (Triangulated Evidence Model)

3.3.1 Primary Sources

- Statutes, regulations, recall guidelines
- Official recall notices (2015–2026 dataset)

3.3.2 Secondary Sources

- WHO guidelines (Good Distribution Practices, recall systems)
- Peer-reviewed journals
- Regulatory reports

3.3.3 Real Recall Data

- FDA Enforcement Reports (weekly recall data)
- National regulatory authority recalls databases

4. Multi-Dimensional Recall Evaluation Matrix (MREM)

- Develop a custom scoring framework (0–5 scale) across:

Dimension	Indicators
Legal Authority	Mandatory vs voluntary recall power
Classification System	Risk-based classification presence
Speed of Recall	Time from detection to action
Traceability	Batch tracking & supply chain transparency
Public Communication	Alerts, transparency, digital systems
Enforcement Strength	Penalties, compliance rate

5. Data Analysis Techniques (2026-Level Innovation)

5.1 Quantitative Analysis

- Descriptive statistics (frequency, mean recall time)
- Comparative index scoring (MREM composite index)
- Regression analysis:

- Impact of regulation strength on recall effectiveness

5.2 Qualitative Analysis

- Thematic coding
- Policy gap analysis

5.3 AI-Driven Enhancement (Innovative Element)

- Use digital bar-coding tools to analyse recall notices:
  - Identify common causes (contamination, labelling errors)
  - Risk pattern detection

4. Drug Recall Framework in the United States

4.1 Regulatory Authority

- The FDA governs drug recalls under 21 CFR Part 7 and related regulations.

4.2 Nature of Recalls

- Mostly voluntary, initiated by manufacturers
- FDA supervises and can request or mandate recalls in certain cases.

4.3 Classification System

- Class I: Life-threatening risk
- Class II: Temporary/reversible risk
- Class III: Minimal risk

4.4 Recall Process

- Detection of defect
- Risk assessment (Health Hazard Evaluation)
- Recall strategy development
- Notification (public + stakeholders)
- Effectiveness checks
- Termination by FDA

4.5 Strengths

- Advanced pharmacovigilance systems
- Transparent public databases
- Strong enforcement and compliance

5. Drug Recall Systems in Developing Countries

5.1 Regulatory Authorities

Country	Regulatory Agency	Abbreviation	Key Functions
India	Central Drugs Standard Control Organization	CDSCO	Drug approval, clinical trials regulation, licensing, pharmacovigilance
China	National Medical Products Administration	NMPA	Drug/device approval, GMP enforcement, safety monitoring
Brazil	Agência Nacional de Vigilância Sanitária	ANVISA	Drug approval, inspection, public health surveillance
South Africa	South African Health Products Regulatory Authority	SAHPRA	Medicines regulation, licensing, clinical trials oversight
Nigeria	National Agency for Food and Drug Administration and Control	NAFDAC	Drug registration, quality control, import/export regulation
Egypt	Egyptian Drug Authority	EDA	Drug approval, pricing, inspection, pharmacovigilance
Indonesia	National Agency of Drug and Food Control	BPOM	Drug approval, food & drug safety monitoring
Philippines	Food and Drug Administration Philippines	FDA Philippines	Licensing, product registration, safety monitoring
Pakistan	Drug Regulatory Authority of Pakistan	DRAP	Drug registration, pricing, quality assurance
Bangladesh	Directorate General of Drug Administration	DGDA	Drug approval, manufacturing regulation, inspections
Thailand	Thai Food and Drug Administration	Thai FDA	Drug/device approval, safety regulation
Vietnam	Drug Administration of Vietnam	DAV	Drug registration, quality assurance, licensing
Kenya	Pharmacy and Poisons Board	PPB	Drug registration, pharmacy practice regulation
Mexico	Federal Commission for the Protection against Sanitary Risk	COFEPRIS	Drug approval, regulatory control, public health safety

Argentina	National Administration of Drugs, Foods and Medical Devices	ANMAT	Drug/device regulation, inspection, approval

5.2 Common Challenges

- Weak post-market surveillance
- Limited recall traceability systems
- Delayed communication and reporting
- Lack of centralized recall databases

5.3 Recall Classification System

Aspect	United States	Developing Countries
Classification	Class I, II, III (risk-based)	Often similar but inconsistently implemented
Basis	Severity of health hazard	Risk-based, but may lack clarity
Standardization	Highly standardized	Limited harmonization

5.4 Recall Procedure (Step-wise Comparison)

Step	United States (FDA)	Developing Countries
Detection	Adverse event reports, inspections	Weak pharmacovigilance systems
Decision	Scientific risk assessment	Often delayed or inconsistent
Initiation	Prompt voluntary recall	Delayed due to administrative gaps
Communication	Public alerts, press releases, databases	Limited public communication
Execution	Well-coordinated supply chain removal	Fragmented distribution challenges

Step	United States (FDA)	Developing Countries
Monitoring	Continuous FDA oversight	Weak follow-up mechanisms

6. Comparative Analysis

- Parameter
- United States
- Developing Countries
- Regulatory Strength
- Highly structured (FDA)

Feature	United States	Developing Countries
Regulatory Framework	Strong, codified	Weak to moderate
Recall Initiation	Rapid, structured	Delayed
Enforcement	Strict legal backing	Limited enforcement
Monitoring	Continuous	Inconsistent
Public Awareness	High transparency	Low awareness
Supply Chain Control	Centralized, traceable	Fragmented

6.1. Recall Efficiency and Performance

Parameter	United States	Developing Countries
Compliance Rate	~98%	~60–80%
Recall Time	~30 days	~60–90 days
Transparency	High (public databases)	Low to moderate

Parameter	United States	Developing Countries
Traceability	Strong supply chain control	Poor traceability

6.2 Comparative Regulatory Differences

Aspect	United States	Developing Countries
Legal Framework	Well-defined (21 CFR)	Often fragmented or evolving
Recall Nature	Voluntary but strictly monitored	Often weakly enforced
Classification	Standardized (Class I–III)	Not uniformly applied
Transparency	High (public databases)	Limited public disclosure
Surveillance	Advanced pharmacovigilance	Underdeveloped systems
Compliance	Strong cGMP enforcement	Variable compliance levels

7. Discussion

The U.S. system emphasizes risk-based classification and rapid communication, ensuring effective recall execution. Developing countries, while improving, still struggle with resource limitations and fragmented regulatory frameworks.

A key difference lies in recall preparedness: U.S. companies are expected to be “recall-ready,” whereas many developing countries operate in a reactive mode.

8. Innovative Approaches for 2026

8.1 AI-Based Recall Prediction

- Machine learning can predict recall risks based on manufacturing and safety data.

8.2 Blockchain for Traceability

- Ensures real-time tracking of drug distribution.

8.3 Global Harmonization

- Adoption of WHO Global Benchmarking Tool (GBT) standards.

8.4 Digital Recall Platforms

- Mobile-based alert systems for pharmacists and patients.

8.5 Public-Private Collaboration

- Enhancing compliance through industry partnerships.

9. Conclusion

The United States maintains a robust, transparent, and efficient drug recall system driven by strong regulatory authority and infrastructure. In contrast, developing countries face challenges such as Regulatory gaps, Delayed recall actions, and limited enforcement. The U.S. drug recall system represents a gold standard due to its structured regulations, transparency, and enforcement mechanisms. Developing countries are progressing but require capacity building, technological integration, and regulatory strengthening. Global harmonization and innovation will be key to ensuring drug safety in 2026 and beyond.

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