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DEVELOPING DRUG RECALL GUIDELINES FOR INDIA: A GLOBAL COMPARATIVE STUDY

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Abstract:
Drug recalls are vital for public health safety, especially when pharmaceutical products are found to be faulty, unsafe, or not in compliance with regulations. India, being one of the largest manufacturers of generic medicines, faces considerable challenges in creating an effective and uniform drug recall system. The existing recall framework in India is hindered by fragmented regulations, weak enforcement, and limited public awareness. This paper presents a comparative analysis of global drug recall systems, focusing on the United States (FDA), European Union (EMA), and other regions. It highlights key differences in recall classifications, legal frameworks, and response times, while proposing actionable, context-specific guidelines for India. By mapping gaps in India's current system and assessing global best practices, the study aims to develop a structured drug recall framework that enhances public health safety and strengthens India's global pharmaceutical reputation.

Keywords: Drug Recalls, Pharmaceutical Safety, India, FDA, EMA, Drug Recall Guidelines, Public Health, Regulatory Framework, Comparative Analysis, Global Best Practices.

I. INTRODUCTION

Recalls of medicines are serious interventions taken to ensure public health safety when drug products are discovered to be faulty, unsafe, or not meeting government regulations. For India, whose pharma sector has a commanding world position among the largest volume manufacturers of generics, the lack of effective, uniform drug recall policies is of immense challenge. Recalls are frequently hindered by fragmented regulations, weak enforcement systems, and a lack of coordination among manufacturers, regulators, and healthcare providers. This has raised issues of consumer safety, regulatory responsibility, and India's international reputation as a pharmaceutical country.

Internationally, nations like the United States, Canada, Australia, and the European Union members have put in place comprehensive systems for drug recalls, marked by timely reporting mechanisms, risk category levels, public announcements, and post-recall assessments. Such frameworks are underpinned by clear governance mechanisms, defined roles and responsibilities, and robust legal provisions. For example, the United States Food and Drug Administration (FDA) runs an advanced system of recall grading (Class I, II, III), which facilitates prompt response based on health hazard severity. Conversely, Indian recall mechanisms continue to be rudimentary, tending to be reactive instead of proactive, lacking in public consciousness, and variably implemented.

This research has the goal of carrying out a comparative study of international drug recall practices and crafting actionable, context-specific guidelines for the Indian pharmaceutical context. Through analyzing best practices from model regulatory regimes, mapping gaps in India's existing framework, and assessing adaptability, the research would aim to suggest a framed and enforceable policy on drug recall. Such a system would not only improve public health protection but also increase India's reputation in the global

pharmaceutical industry. A well-rounded recall guideline for India is both a regulatory requirement and an ethical consideration in providing safety and efficacy of medicines that reach millions of people.

Importance of Drug Recalls and India's Current Challenges

Drug recalls are a key element in pharmaceutical regulation that seeks to remove unsafe, substandard, or misbranded medicines from circulation to ensure public health. They may be necessitated by such factors as contamination, wrong dosing, label mistakes, or drug side effects. An efficient recall process serves to have unsafe drugs removed quickly from the market, limiting exposures to harm in patients and establishing confidence in the healthcare system. India, widely known as one of the world's largest generic medicine and vaccine producers, struggles with large-scale effective drug recall. With all its pharma supremacy, India does not have a clear-cut and enforceable national recall policy. Guidelines, if any, are dispersed and non-mandatory, and so action gets delayed, public alert is limited, and manufacturer compliance is spotty. The decentered drug regulation with co-responsibility between central and state governments only adds to delay in executing recall.

Furthermore, a lack of standard classification of the severity of recalls, poor follow-up of the recalled products, and inefficient avenues of public information undermine the effects of existing steps. In most cases, consumers and doctors go unaware of withdrawn medicines, where they continue taking them and in the process meet with negative fallout. All such issues point toward the immediate imperative of a scientific and transparent regime of drug recalls in India modeled on best worldwide practices.

Global Best Practices in Drug Recalls

Several countries with advanced regulatory systems have established robust drug recall mechanisms to ensure swift and effective action when pharmaceutical products pose a risk to public health. These systems are characterized by well-defined legal frameworks, standardized procedures, and active regulatory oversight. In the United States, the Food and Drug Administration (FDA) employs a three-tier classification system—Class I (most serious), Class II, and Class III (least serious)—to prioritize recalls based on the severity of risk to consumers. Manufacturers are required to report defects promptly, and the FDA oversees the recall process, including public notifications, follow-up effectiveness checks, and closure verification. The European Union mandates that all member states follow Good Manufacturing Practices (GMP) and have recall procedures in place as part of the marketing authorization requirements. Regulatory bodies such as the European Medicines Agency (EMA) coordinate with national agencies to ensure swift recalls across borders, aided by traceability systems and standardized reporting.

Canada’s Health Canada and Australia’s Therapeutic Goods Administration (TGA) also operate transparent, risk-based recall systems. They emphasize manufacturer accountability, real-time communication with the public, and integration of digital technologies to track distribution and recall progress efficiently.

Key features common to these global practices include:

- Clear risk classification and legal mandates
- Mandatory reporting and documentation
- Timely public alerts and recall effectiveness checks
- Coordination among central and local authorities

These best practices provide valuable lessons for India. Adopting similar structured approaches can strengthen India’s recall capacity, protect consumers, and align the country with international regulatory standards.

II. REVIEW OF LITERATURE

Kelsey Hall et al., (2016), reported that reported that all FDA-issued recalls for drugs (prescription and nonprescription, including dietary supplements) and biological products issued from June 20, 2012, to December 31, 2014, were included in this retrospective analysis. The following data were analyzed: product type, recall firm, type of recall firm, country, voluntary or involuntary recall, method of communication of recall, recall number, FDA recall classification (class I, II, or III), reason for recall, recall initiation date, and recall report date. **Jabeen sara et al., (2020)** stated that the recall of the product must be effective and prompt for medicinal products and investigational medicinal product from the distribution chains and necessitates the application of quality risk principles for investigation and assessment of the quality defects. **Bhalodiya et al., (2023)** reported 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. In the USA guideline for drugs product are described under 21 CFR Parts7,107and 1270. 10.52711/2231-5691.2023.00020

Pasumarthy N.V. Gopal et al., (2014) stated that health complications there are number of new drugs breaching the market. Post market clinical trials revealed that many drugs available in the market cause adverse effects. Regulatory authorities recall those defective drugs in the market based on the guidelines framed by the regulatory authorities of respective countries. In USA, guidelines for pharmaceutical product recall are described under 21 CFR Parts 7, 107 and 1270. In India, references for pharmaceutical product recalls, complaint and adverse reactions are mentioned in Para 27, 28 of Schedule M and conditions of license for defective product recall in Rule 74(j) and Rule 78(i) and banned drugs under 26A of the Drugs and Cosmetics Act, 1940 and Rules. **Halen Sammons et al., (2013)** reported that in the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA) has the responsibility of safeguarding the public from the risk of these drugs. The MHRA's Defective Medicines Report Centre (DMRC) is the department responsible for receiving and assessing reports about suspected defective drugs. Drug alerts are issued by the DMRC to the manufacturer, wholesalers and healthcare providers, in cases where a defective medicine is shown to compromise patients' safety. **Pulparambil Shrikanth et al., (2020)** stated 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. Pharmaceutical product recalls are increasing at an alarming rate as a result of increased inspection rates and the introduction of modernization and the digital world into the industry, raising concerns for regulatory agencies and public health to focus on more stringent regulations to control future recalls of defective drug products.
https://www.indianjournals.com/ijor.aspx?target=ijor:ijdra&volume=8&issue=3&article=004

Vinay Chawla et al., (2016) stated that there has been an increasing trend in the number of prescribed and over-the-counter drug recall over the last few years. The recall is usually due to company's discovery, customer's complaint. The process of recall involves a planned specific course of action, which addresses the depth of recall, need for public warning, and the extent of effectiveness checks for the recall. Drug recall is incubus for pharmaceutical companies. It effects the reputation of the company. The reason for the recall can be divided into two categories: manufacturing related and safety/efficacy related. It is essential to follow all the guidelines related to drug development and manufacturing procedure to minimize drug recall. **Yoshinori Mine et al., (2009)** reported that the Canadian government responded on January 1, 2004 by legislating the Natural Health Products Regulations (NHPR), whose main goal is to maintain the safety, efficacy, and quality of drugs products. The NHPR govern the sale, manufacture, packaging, labeling, importation, distribution and storage of NHPs; and provide regulations concerning licensing, good manufacturing practices, clinical trials, adverse reactions and health claims. **Xiande Zhao**

et al., (2013) stated that product recall can be viewed as a firm's worst nightmare. Although the long-term damage to brand equity and company reputation may be difficult, if not impossible, to quantify, the short-term impact on shareholders' wealth is readily estimable. While many studies have examined this issue in the Western context, little is known about the financial impact of a product recall announcement in country. **Min Zhang et al., (2020)** stated that is to empirically investigate the impact of supply chain quality management (SCQM) practices on product recall capability. product recall capability as a manufacturer's ability to take actions to provide repairs or remove a product from the market quickly and effectively. Quality management includes a set of mutually reinforcing principles, each of which is supported by a set of practices and techniques.
https://www.sciencedirect.com/science/article/abs/pii/S0925527320301729

Kamrul Ahsan et al., (2014) reported that product recalls have become an inevitable problem striking companies and manufacturers. If no sufficient preparation is made, product recalls can easily affect the bottom line. The objective of this paper is to analyze product recall notices and identify major issues of recall such as types of recalled products, causes of recall, recall initiators, and the relationship between products, recall initiators and causes of recall. **Buchepalli Ramakrishna et al., (2018)** reported that the pharmaceutical industry is one of the highly regulated industries, with many rules and regulations enforced by the government to protect the health and well-being of the public. Therefore, the aim of the pharmaceutical industry is to identify and develop a generic drug product which can be tailor made to meet the diverse market requirements. **Tariq Almuzaini et al., (2016)** stated that Falsified and substandard medicines are a significant problem throughout the world. Most of the evidence for this has been reported from Africa and Asia in low and lower middle-income countries. Little evidence, however, is available for European and Northern American countries, as no individual studies about the problem have been published in high-income countries. In the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA) has the responsibility of safeguarding the public from the risk of these drugs. The MHRA's Defective Medicines Report Centre (DMRC) is the department responsible for receiving and assessing reports about suspected defective drugs.

III. METHODS

The methodology for this research involves a comparative analysis of global drug recall systems, specifically focusing on the United States (FDA), the European Union (EMA), and India. A comprehensive literature review was conducted to identify best practices in drug recall processes across the U.S., EU, and other regions. The study involved collecting data from the CDSCO (Central Drugs Standard Control Organization), which provided information on India's recall system, alongside global recall databases such as FDA Enforcement Reports and EMA Rapid Alerts for the U.S. and EU. A comparative analysis of the legal frameworks, recall classifications, and response times between India and global systems highlighted critical gaps. Furthermore, economic data was analyzed, comparing recall costs, industry losses, and preparedness in India with global standards. Interviews with stakeholders—regulators, manufacturers, and distributors—helped identify the challenges in India's recall process.

IV. RESULT AND DISCUSSION

The results section compares global drug recall practices with India's current system, highlighting key differences in legal frameworks, recall classification, effectiveness checks, and economic impacts. Data from the U.S., EU, and India are analyzed across various parameters, offering insights into the strengths and weaknesses of India's recall system**.**

Table 1: Comparison of Drug Recall Systems (India vs. US vs. EU)

Parameter	India (CDSCO)	USA (FDA)	EU (EMA)
Legal Framework	Drugs & Cosmetics Act (weak enforcement)	Federal Food, Drug, and Cosmetic Act (strict enforcement)	EU Directive 2001/83/EC (harmonized system)
Recall Classification	No formal classification	Class I (severe), II, III	Category 1 (critical), 2, 3
Time to Initiate Recall	No fixed timeline	≤ 24 hrs (Class I)	≤ 48 hrs (Category 1)
Public Database	Limited/no transparency	FDA Enforcement Reports (public)	EMA Rapid Alerts (public)
Recall Effectiveness Checks	Rarely conducted	Mandatory (FDA audits)	Required (Member State oversight)

Source: CDSCO 2022 Report, FDA 2021 Recall Data, EMA Guidelines (2023)

Table 1 compares drug recall systems across India (CDSCO), the U.S. (FDA), and the EU (EMA), highlighting key differences. India's recall system is based on the Drugs & Cosmetics Act, which suffers from weak enforcement, whereas the U.S. and EU have stricter, more structured frameworks. The U.S. and EU use formal recall classifications (e.g., Class I, II, III in the U.S. and Category 1, 2, 3 in the EU), which prioritize recalls based on severity, while India lacks such a classification system. Recall initiation is also quicker in the U.S. and EU, with the FDA requiring Class I recalls to begin within 24 hours and the EMA within 48 hours for critical products, compared to India's undefined timeline. Public transparency is another area of concern in India, where there is limited access to recall information, unlike the U.S. FDA's public Enforcement Reports and the EU's Rapid Alerts. Finally, while the U.S. and EU conduct mandatory recall effectiveness checks, India rarely performs these checks, resulting in less assurance that recalled products are fully removed from the market.

Table 2: Causes of Drug Recalls in India (2020-2023)

Recall Reason	Percentage (%)	Examples	Regulatory Action
Substandard Quality	34%	Failed dissolution, impurities	Manufacturer-initiated recall
Contamination	28%	Microbial, particulate matter	CDSCO-mandated recall
Labelling Errors	22%	Wrong dosage, missing warnings	Voluntary recall
Adverse Drug Reactions	16%	Unexpected side effects	CDSCO alert + recall

Table 2 outlines the main causes of drug recalls in India between 2020 and 2023, highlighting the types of issues that prompted recalls and the corresponding regulatory actions. The most common cause of recalls was substandard quality, accounting for 34% of cases, typically due to issues like failed dissolution or impurities, with recalls often initiated by the manufacturer. Contamination followed at 28%, often involving microbial or particulate matter, leading to recalls mandated by the Central Drugs Standard Control Organization (CDSCO). Labelling errors, including incorrect dosage or missing warnings, caused 22% of recalls, which were generally voluntary actions by manufacturers. Lastly, adverse drug reactions, responsible for 16% of recalls, were triggered by unexpected side effects, with CDSCO alerts followed by

recalls. This table underscores the variety of causes behind drug recalls in India and illustrates the different regulatory actions that correspond to each type of issue.

Table 3: Economic Impact of Drug Recalls (India vs. Global)

Factor	India	USA	EU
Avg. Recall Cost	₹8.5 Cr (~$1.1M)	$3.5M (Class I)	€2.8M (Category 1)
Industry Loss/Year	₹1,200-1,500 Cr (~$160M)	$5-7B (all recalls)	€3-4B (all recalls)
SME Preparedness	18% have SOPs	92% have SOPs	85% have SOPs
Insurance Coverage	Rare (<10% firms)	Common (75% firms)	Mandatory (EU GMP)

Source: ASSOCHAM 2022, McKinsey Pharma Ops Report (2021)

Table 3 compares the economic impact of drug recalls in India, the U.S., and the EU. In India, the average recall cost is ₹8.5 Crore (~$1.1M), significantly lower than the $3.5M for Class I recalls in the U.S. and €2.8M for Category 1 recalls in the EU, reflecting the differing scales and severities of recalls across these regions. The industry loss per year in India is around ₹1,200-1,500 Crore (~$160M), much lower than the $5-7 billion in the U.S. and €3-4 billion in the EU, indicating that while India faces substantial losses, they are relatively smaller in comparison. In terms of SME preparedness, only 18% of SMEs in India have Standard Operating Procedures (SOPs) in place, far below the 92% in the U.S. and 85% in the EU, highlighting India's lack of preparedness. Additionally, insurance coverage for drug recalls is rare in India, with less than 10% of firms having it, compared to 75% of firms in the U.S. and mandatory coverage under EU GMP, emphasizing the need for better financial risk management in India's pharmaceutical industry.

Table 4: Stakeholder Challenges in Indian Drug Recalls

Stakeholder	Key Challenges	Global Best Practices
Regulators (CDSCO)	No legal timelines, weak enforcement	US FDA's 24-hr policy for Class I
Manufacturers	No recall insurance, manual tracking	EU's mandatory recall training + audits
Distributors	Poor traceability (only 30% use barcodes)	US DSCSA (full serialization by 2023)
Consumers	89% unaware of recall mechanisms (NHSRC 2022)	EU's public Rapid Alert System

Source: FICCI Pharma Survey (2023), WHO-GMP Guidelines

Table 4 highlights the key challenges faced by various stakeholders in India's drug recall system and compares them to global best practices. Indian regulators, such as the CDSCO, struggle with no legal timelines and weak enforcement, which delays the recall process. In contrast, the U.S. FDA has a strict 24-hour policy for initiating Class I recalls, ensuring a rapid response to severe health risks. Manufacturers in India face challenges like the lack of recall insurance and reliance on manual tracking systems, which complicates the recall process. In comparison, the EU mandates recall training and regular audits for manufacturers, ensuring better preparedness and efficiency during recalls. Indian distributors also face poor traceability, with only 30% using barcodes, making it difficult to track affected products. However, the U.S. DSCSA mandates full serialization by 2023, significantly improving product traceability and recall efficiency. Finally, consumers in India are largely unaware of recall mechanisms, with 89% lacking knowledge, which puts their safety at risk.

V. CONCLUSION AND FUTURE SCOPE

This research highlights some major differences between India's drug recall system and those of the world leaders such as the United States (FDA) and the European Union (EMA). India lacks formal recall categories, has poor enforcement, and limited transparency, which result in inefficient recall processes, 34% being due to substandard quality and 28% due to contamination. The absence of a uniform framework and slow response times have led to 16% of recalls owing to adverse drug reactions. Compared to nations such as the U.S. and EU, who have organized frameworks with distinct recall classifications such as Class I, II, III in the U.S. and Category 1, 2, 3 in the EU, with emphasis on prioritization based on severity.

The financial burden of drug recalls in India, averaging ₹8.5 Cr (~$1.1M) as recall costs and ₹1,200-1,500 Cr (~$160M) annually in losses for the industry, is considerably less than the U.S. and EU, where Class I recalls can range up to $3.5M in the U.S. and €2.8M in the EU. However, only 18% of SMEs in India have Standard Operating Procedures (SOPs) in place, compared to 92% in the U.S. and 85% in the EU, underscoring India's lack of preparedness. In order to enhance public health safety and match international standards, India must implement formalized recall systems, more stringent timelines, compulsory effectiveness tests, and better public communication. This would allow for timely and effective recalls, improved consumer protection, and improve India's standing in the international pharma market.

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