



Recent Analysis of Major Indian Drug Safety Alerts and Recalls: Impact on Pharmacovigilance Policies and Consumer Protection

Neeta Verma¹, Aditi Tripathi¹, Abhash Kumar¹, Deep Das¹

1. Department of Pharmacovigilance, Ichelon Consulting Group, Gurugram, 122018

Abstract

Background: Drug recalls are critical measures to protect patients' safety. These are guided by regulatory frameworks (FDA, EMA, CDSCO, WHO) to reduce the risks due to falsified and Not of Standard Quality (NSQ) drugs. Product recall procedures are not well defined in developing nations like India.

The objective of this structured review is to analyze major drug recalls (valsartan, ranitidine, metformin, remdesivir, digene, cough syrup, and eye drops) along with details of some minor recalls that occurred in 2015-2025. This also provides a comparison between the FDA/EMA and India in recall processes and policy response.

Methods: The search strategy included "drug recall," "pharmacovigilance," "regulatory response," "India," "CDSCO," "FDA," "EMA," and "WHO" in PubMed, Scopus, Google Scholar, regulatory websites, and news portals from 2015 until 15 September 2025. Non-English literature, case reports, and duplicates were excluded from the PRISMA screening method.

Results: The total record screened, $n = 176$, included $n = 65$, identifying 7 major recalls and 4 minor recalls. The leading causes of these recalls were nitrosamine, diethylene glycol (DEG)/ethylene glycol (EG) impurities, microbial contamination, labeling issues, GMP failures, and falsified products. Between 2015 and 2025, the FDA recalled 3718 vs. India's 2 recalls. There is insufficient data to correlate defective products with outcomes.

Conclusion: These findings demonstrated fragmented state-center execution, no central recall portal, underreporting of adverse drug reports (ADRs), limited public awareness, and weak Indian government enforcement.

These findings highlight patient risk, supply shortage, and the need for stronger regulatory enforcement. This article provides, to our knowledge, the first India-focused structured review comparing FDA/EMA vs. India, calling for a national recall portal and PvPI/CDSCO integration.

Keywords: Drug recall, Pharmacovigilance, Nitrosamine impurities (NDMA, NDEA), Substandard and falsified medicines (NSQ, SF), Diethylene glycol / ethylene glycol contamination, Regulatory policy response - India (CDSCO, PvPI), FDA/EMA comparative analysis, Patient safety and risk communication

1. Introduction

Marketing holders or regulatory bodies voluntarily recall defective products. Hazardous drugs, contamination, stability issues, false or inferior products, and labeling errors are common reasons.¹

Globally, recalls preserve public health and improve regulations. Most countries have recall frameworks for effective recall. Beyond quality control, global regulatory authorities consider recall as a key pharmacovigilance (PV) tool for patient safety and harm prevention.² Different countries have drug recall guidelines in place. In the US, drug recall guidelines are defined in 21 CFR Parts 7, 107, and 1270; in Europe, under quality defect and recall information; in Canada, in section 25 of the Natural Health Products Regulations (NHPR); in South Africa, by SAHPRA; and in India, under Schedule M paragraphs 27 and 28.^{3,4}

Recall frequency statistics are limited in India. The FDA recorded 3,718 recalls (\approx 330/year) from 2012 to 2023. From 2020 to 2022, Canada recalled 220, Australia 25, South Africa 25, and India 2. Most of them were Class II due to pollutants (37%), controls (28%), regulatory violations (19%), and labeling (15%).^{5,6} Lack of a public recall portal makes it difficult to track recalls in India.⁷ Lack of transparency in its recall system is eroding Indian pharmaceuticals' reputation globally.

India is the third-largest manufacturer of generic pharmaceuticals and the foremost global provider of these medications. It accounts for 20% of the global supply in volume, fulfilling 40% of the generic demand in the USA and 25% of the market in the United Kingdom. India manufactures \sim 60,000 generic products across \sim 60 distinct medicinal categories. Indian pharmaceuticals meet worldwide demand by providing cost-effective healthcare solutions.⁸ Yet, despite India's global strength, its systemic weaknesses remain evident. In India, there is no national recall portal. Only NSQ bulletins document these recalls intermittently. This restricts traceability, unlike the comprehensive recall systems of the US FDA and EMA. There is fragmented oversight between the CDSCO (central) and state regulators.⁷ Therefore, it is imperative to tackle systemic deficiencies, especially underreporting and insufficient public awareness, which require further research on quality and safety.

Under the direction of CDSCO and DCGI, the Pharmacovigilance Programme of India (PvPI) oversees the ADR monitoring program; it collaborates closely with WHO to ensure that the program is operated efficiently and in accordance with international standards. However, this is still not mature and faces many challenges. Despite having the second-largest population in the world, only 176,342 ICSRs were submitted to VigiBase in 2024.⁹ The underreporting is due to various factors, including the reluctant attitude of health care professionals (HCPs), limited awareness, inadequate communication channels for wide dissemination of information, less sensitization from HCPs and pharmacists for ADR reporting, and an easy portal to report ADR.^{10, 11}

There are not many Indian articles that look at recall data and structured approaches. Most articles rely on FDA, EMA, and WHO statistics, which lack transparency, particularly in India. Recall studies underrepresent India, despite its status as a global supplier.⁴ Establishing a set timeframe that encompasses the most important recall events and policy changes is crucial for filling in these gaps.

The recall strategy in India is poor when compared to that of the developed world. Although India issued guidelines on the Recall and Rapid Alert System in 2012 (revised in 2017), the system remains underdeveloped. As drug recalls due to any reason are being managed by the drug regulation at the state level, overseen by the drug controller of each respective state, it is complex. Recall is being done in a fragmented and uneven manner. The same drug can be withdrawn from one state, but another will continue selling it. Other reasons included the limited expertise of the union health ministry, the absence of transparent or mandated law to disclose the information of drug recall, financial gains being more important than process, and weak enforcement of recall law by the regulator.^{6, 12-16}

Considering India's role as one of the largest global suppliers of generic drugs, fragmented recalls and inadequate public reporting not only endanger Indian patients but also pose consumer safety risks at the international level.

The timeframe of 2015 has been selected as Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), which provides affordable medicine, was initiated in 2015, so the risk of distribution of adulterated or falsified products increases.⁸ Many drugs, including domperidone, Digene, and ceftriaxone injection, have

been recalled since 2015. Major recalls like the valsartan contamination (2018-2019), ranitidine (2019-2020), dexamethasone recall, metformin recall in 2020, remdesivir injection during Covid-19 (2021), and cough syrup recall manufactured by Maiden Pharma in 2022 happened worldwide, but there is readily available data related to these recalls that can give insight into post-recall measures.¹⁷⁻²⁵ All the literature is mainly based on FDA, EMA, and WHO data. This period also marks significant CDSCO regulatory reforms and the expansion of the PvPI, making 2015-2025 an appropriate timeframe to analyze recall trends in India.

The objective of this structured review is to analyze major drug recalls (valsartan, ranitidine, metformin, remdesivir, digene, cough syrup, and eye drops) along with details of some minor recalls that occurred in 2015-2025. This also provides the comparison between the FDA/EMA and India in the recall process and policy response. This article provides, to our knowledge, the first India-focused structured review comparing FDA/EMA vs. India, calling for a national recall portal and PvPI/CDSCO integration.

2. Methodology

Database and Sources: Used PubMed, Scopus, Google Scholar, FDA, EMA, WHO, CDSCO, handsearching journals, grey literature, and news portals from 2015 until 15 September 2025.

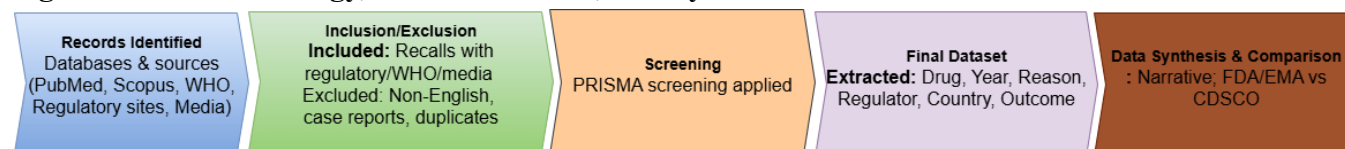
Search strategy: Key words and Boolean combinations were “valsartan” AND “recall,” “ranitidine” AND “recall,” “ranitidine” AND NDMA, “cough syrup” AND “death,” “eye drop” AND “contamination,” “Drug recall,” “nitrosamine impurities,” “metformin recall,” “remdesivir AND COVID-19 and NSQ,” “falsified drug,” “eye drop contamination,” “cough syrup DEG/EG,” “digene recall,” “Drug recall India overview,” “Pharmacovigilance evolution India,” and “Drug Safety India review articles,” “drug recall” AND India AND CDSCO, “pharmacovigilance” AND “drug alert” AND India, “regulatory response” AND “CDSCO” AND “recall,” “History of Pharmacovigilance India,” “PVPI Program Development,” “CDSCO Pharmacovigilance Guidelines,” “CDSCO Recall Alert,” “Valsartan Recall India,” “Ranitidine NDMA Recall CDSCO,” “Cough Syrup Recall DEG India WHO,” WHO alerts, FDA and EMA comparisons, “CDSCO Reaction to Drug Recall,” “Label Update CDSCO,” “CDSCO Recall Classification,” “EMA Drug Recall Process,” “India vs. US Recall Regulatory,” “Consumer Trust Drug Recall India,” “Impact of Drug Recall on Indian Pharma,” “Pharmacovigilance Improvement Strategies India,” “Drug Recall AI System,” and “Risk Communication CDSCO.”

In total, 176 records were screened, of which 65 were included, identifying 7 major recalls and 4 minor recalls.

Eligibility Criteria:

Figure 1 describes the methodological workflow, including search strategy, inclusion/exclusion criteria, screening, data extraction, and synthesis. Records were identified from scientific databases, regulatory websites, headhunting search of journals and media sources. Relevant recalls were identified using predefined criteria, and key variables such as drug, year, reason, regulator, country and outcome. The final dataset was synthesized using systematic approach and narratively with comparative analysis of regulators (FDA, EMA, and CDSCO). Please see **Figure 1** for further details

Figure 1: Search Strategy, Data Extraction, and Synthesis workflow



3. Evolution of India's PV Framework

According to WHO, pharmacovigilance (PV) is defined as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.”²⁶ In humans, the role of PV begins from first-in-human trials with smaller populations and extends to broader population scales, with many and complex individual differences playing a role. Some drug-food interactions, drug-drug interactions, hypersensitivity, severe ADRs such as anaphylaxis, and long-term toxicity of the drug may appear in phase IV that were previously unrecognized. A formal adverse

drug reaction (ADR) monitoring system in India was initiated in early 1986 with 12 regional centers (several were based in Delhi, Mumbai, Kolkata, Chandigarh, Lucknow, and Pondicherry).²⁷⁻²⁸

India joined the WHO Program for International Drug Monitoring in 1997, under the management of the Uppsala Monitoring Centre (UMC), Sweden. Aligarh, Chandigarh, Lucknow, Kolkata, New Delhi, and Pondicherry (six centers) served as ADR monitoring centers. Only Mumbai and New Delhi were actively participating; thus, ADR reporting was poor. Therefore, in November 2004, the Government of India launched the National Pharmacovigilance Programme (NPvP) with the help of World Bank funding for 5 years, which was temporarily suspended after the end of funding.²⁸

On 20 January 2005, Schedule Y was modified and updated by the Drug Controller of India to include the obligation of pharma firms for their drugs and also to monitor the adverse effects from clinical trials. A mandatory 15-day reporting period for unexpected responses to drugs is mentioned in Schedule Y. However, there is no information on how these ADRs will be identified; follow-ups are not discussed in Schedule Y. Therefore, medical firms in India followed the International Conference of Harmonization (ICH) E2F guidelines for the management of spontaneous data on goods. No robust post-marketing PV was established yet.^{27,29}

In July 2010, under the supervision of the Ministry of Health, a nationwide ADR monitoring program, the Pharmacovigilance Programme of India (PvPI), was launched. Initially, the All India Institute of Medical Sciences, New Delhi, was the National Coordination Centre (NCC), which was shifted to the Indian Pharmacopoeia Commission (IPC), Ghaziabad. Adverse Drug Reaction Monitoring Centers (AMC) were set up for the collection, reporting, and follow-up of ADRs via VigiFlow. A total of 150 AMCs were categorized into four zones: North, South, East, and West.²⁸

From 2011 onward, the Indian Pharmacopoeia Commission (IPC) became the official body for the central body coordinating pharmacovigilance activities in India. It coordinates all AMCs/MDMCs through VigiFlow. It collects, analyzes, and forwards ADR data to WHO UMC. It publishes annual performance reports and drug safety alerts and provides signal detection and regulatory recommendations through PIL changes.³⁰

In 2014, NCC-PvPI made some important recommendations regarding the change in labeling of carbamazepine due to an increase in ADR reporting of Stevens-Johnson syndrome (SJS). Between 2014 and 2015, a total of 34,306 ADR reports were received from AMCs, non-AMCs, and pharmaceutical companies.³¹

Although the national helpline (1800-180-3024) was established, early challenges included under-reporting by physicians, as they felt their judgment was being questioned. Under-reporting also occurred due to issues faced by coordinators while reporting ADRs. In 2014-2015, only 27 reports were received from consumers, and 336 were from unknown senders. Lack of trained staff, limited reach, and under-reporting were the major challenges during this period.³¹⁻³²

Every year, PvPI publishes an annual report covering April through March.

From April 2015 until March 2024 (the most recent annual performance report of PvPI), many advancements were made. On 22 May 2015, an ADR reporting mobile application for Android users was launched. On 6 July 2015, the Materiovigilance Program of India (MvPI) was launched to monitor the safety of medical devices. On 14 November 2015, the Benefit-Risk Assessment Cell was inaugurated. On 8 March 2016, an amendment to the Drugs & Cosmetics Rules was made, which mandated a pharmacovigilance system for manufacturers to report ADRs to the licensing authority.^{31,33}

From 2016 to 2017, a National Regulatory Authority (NRA) Assessment was successfully completed. The NCC-PvPI collaborated with the Indian Council of Medical Research (ICMR) and the Medical Council of India (MCI). Active surveillance for bedaquiline began at PvPI.³⁴

On 18 July 2017, the Pharmacovigilance Programme of India (PvPI) was designated a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services. On 29 September 2017, the "Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products" was released.

Recommendations for PIL (Prescribing Information Leaflet) updates included:

- Cefixime & Tinidazole-induced Ophisthotonus
- DPP-4 Inhibitors for Arthralgia.
- Sulfasalazine for Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis.
- Terbinafine for Acute Generalized Exanthematous Pustulosis.

On 30 October 2017, the formal launch of the WHO-CC at NCC-PvPI, IPC, in Ghaziabad, occurred. On 15-16 March 2018, a two-day National Workshop on Good Pharmacovigilance Practices (GvPs) was held in Mumbai in technical collaboration with the USFDA. On 21-23 March 2018, the 2nd Annual Meeting of SEARN Countries was held in Colombo, Sri Lanka, where PvPi proposed a support/services action plan to member countries.³⁵

Between April 2018 and March 2019, 18 drug-ADR combinations for inclusion in Prescribing Information Leaflets (PILs) to the Central Drugs Standard Control Organization (CDSCO) were recommended by PvPI.³⁶

Between April 2019 and March 2020, eight recommendations were made by the Signal Review Panel (SRP) for inclusion in PILs, with orders issued by CDSCO for chloroquine (SJS/TEN) and proton pump inhibitors (acute kidney injury). The sixth Asia-Pacific PV Training Course was organized, with 14 participants from 6 countries.³⁷

Between April 2020 and 2021, 50 Medical Device Adverse Event Monitoring centers (MDMCs) were enrolled under MvPI. A total of 150 MDMCs were enrolled under MvPI, and 3,868 MDAE reports were received during the index period. 16 monthly Drug Safety Alerts were issued by IPC, NCC-PvPI. The SRP recommended Tinidazole (fixed drug eruption) as a signal and Tramadol (urinary retention) for PIL updation. PvPI IPC was re-designated as a WHO-Collaborating Centre. 4 signals were recommended, and 4 PIL changes were submitted to CDSCO. 15 drug safety alerts were issued. The SRP suggested that mefenamic acid, doxycycline, minoxidil, and cephalosporin class can cause fixed From 17 to 23 September 2021, the 1st National Pharmacovigilance Week was celebrated. Five recommendations concerning medical device safety were forwarded to CDSCO.³⁸

On 18 September 2023, during the inaugural ceremony of the National Pharmacovigilance Week Celebration, the "Performance Report 2022-2023" of the Pharmacovigilance Programme of India (PvPI) was officially released (PvPI annual report 2022-2023).³⁹

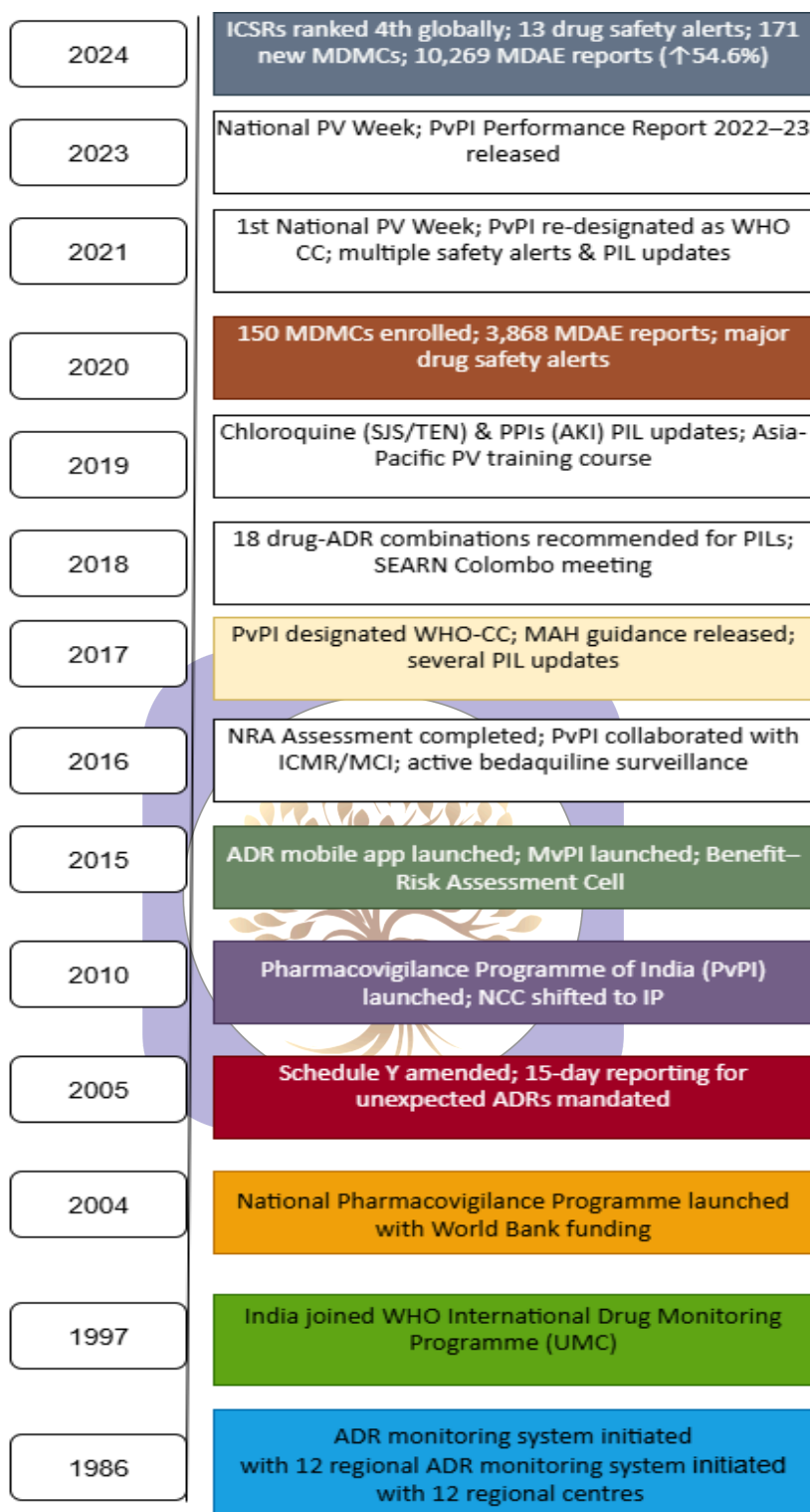
From April 2023 to March 2024, India ranked 4th globally in ICSR submissions to VigiBase during this period (contributing 3.6%). 13 drug safety alerts were issued, and 7 recommendations (including 3 signals) were sent to CDSCO for inclusion in Prescribing Information Leaflets (PILs). 16 recommendations on the safe use of medical devices were forwarded to CDSCO. 171 new MDMCs were recognized. PvPI/IPC and AMCs published 32 research articles.⁴⁰

Every year, a minimum of 202 adverse drug reaction monitoring centers (AMCs) are included with the current AMC center, as there are 695 across the country. Participation in the training program increased among MAH, healthcare professionals, and other stakeholders. Increase in MDAE reports: between 2020 and 2021, the COVID-19 vaccine was the highest reported active ingredient, and it accounted for 78.9% of vaccine ICSR. Reporting of ICSR increased to 116,342 ICSRs with an average completeness score greater than 0.8 out of 1 for most of the year. Physicians reported most of the ICSR and most of the ADR were reported for patients aged between 18 and 44 years. In the 2024 annual report, the Materiovigilance Programme of India (MvPI) received and analyzed 10,269 MDAE reports, marking a 54.6% increase from the previous year.³³⁻⁴⁰

CDSCO, the central regulatory authority under MoHFW, authorizes drug recalls and rapid alerts. It issues circulars/newsletters for recalls (e.g., metformin, pantoprazole). It implements PvPI/IPC recommendations (e.g., label/PIL changes) and coordinates with state regulators for recall execution.¹²

Figure 2 describes the pharmacovigilance program of India, highlighting developments before the establishment of Schedule Y and the advancements after its implementation, including major PvPI milestones. Please see *Figure 2* for further details.

Figure 2: Pharmacovigilance milestones in India



4. Major Drug Recalls in India (2015-2025)

4.1 Overview Table

Table 1 describes the major drug recalls from 2015–2025, including drug name, year(s), indication, recall class or limit (if any), reason for recall, scope of recall, regulatory action, outcome, and impact. The table highlights high-impact cases such as nitrosamine-related recalls (valsartan, ranitidine, metformin), contamination incidents (cough syrups with DEG/EG, eye drops with microbial contamination), and falsification or quality failures (remdesivir, digene gel). These events triggered global regulatory alerts,

market withdrawals, export bans, and stricter oversight measures, reflecting both patient safety concerns and evolving pharmacovigilance responses. Please see **Table 1** for further details.

Table 1: Overview of major drug recalls (2015-2025)

Drug	Year(s)	Indication/ Recall class/limit (If available)	Reason	Scope/ Regulatory Action	Outcome /Impact
Valsartan	2018-2019	antihypertensive Class II	Nitrosamides (NDMA and NDEA impurity)	Global / FDA, EMA, WHO, CDSCO alert	Multiple recalls / temporary shortage
Ranitidine	2019-2020	Acid suppression / H2-blocker Class II	NDMA impurity	Global suspension / CDSCO instructed to decreased shelf-life to 2-years and mandatory stability test	FDA market withdrawal in 2020; EMA suspensions; CDSCO risk-based storage/expiry advice
Cough Syrups	2019-2024	Multi-ingredient paediatric cough/ fever syrup Zero tolerance limit	DEG/EG contamination	WHO alerts / India state actions	Export bans, deaths / Misitory measures special courts, harsher penalties
Metformin	2020-2022	Antidiabetic Class II	NDMA impurity	CDSCO + global alerts	Multiple lot recalls; temporary shortage / labelling monitoring
Remdesivir	2020-2021	Antiviral Quality incidents and falsified alerts	Counterfit/falsif ied	US quality actions; India state-level issues	Patient harm, shortage and black-market pricing, calls for tighter GMP and procurement oversight
Digene Gel	2021	Antacid	Quality failure	Abbot voluntary recall; Goa FDA show cause; CDSCO nationwide alert to stop distribution	Product withdrawals by Abbot / questions on multinational QC / CDSCO confirmation, not only Abbott
Eye drops	2022-2023	Artificial tears	Microbial contamination	FDA warning/CDSC O suspension of manufacturing at implicated site	Global patient harm / Global scrutiny of sterile GMP

Sources: Data from FDA (2018–2025)^{25, 125}; EMA (2018–2020)^{16,45, 101}, WHO Medical Product Alerts (2022–2024)^{23,69,107}, CDSCO annual reports (2019–2025)³³⁻⁴⁰, and published studies¹⁷⁻²⁵.

4.2 Detailed Case Narratives

4.2.1 Valsartan (2018–2019)

Valsartan is an angiotensin II receptor antagonist. It is given in monotherapy and in combination for hypertension, heart failure, and post-myocardial infarction. In June 2018, EU authorities received a recall notification from Zhejiang Huahai Pharmaceutical, China (an Active Pharmaceutical Ingredient [API] manufacturer), about the detection of N-nitroso dimethylamine (NDMA), also known as dimethyl nitrosamine, impurities in valsartan (Choi et al 2023).⁴¹ NDMA is classified as a probable human carcinogen by the International Agency for Research on Cancer (IARC), WHO.⁴² In 2018, an alert was generated by the FDA regarding the voluntary recalls of many drug formulations containing valsartan as an active ingredient. From 2018 to 2019, multiple batches of valsartan (finished products) were recalled, including those manufactured by Teva, Mylan, Torrent, and Aurobindo.⁴³⁻⁴⁴ Valsartan was recalled in India after a global recall. The EMA set specific limits for nitrosamines in sartan products, including valsartan with NDMA \leq 96 ng/day and NDEA \leq 26.5 ng/day.⁴⁵ The valsartan recall led to antihypertensive drug shortages and major shifts in prescribing in the EU and US.⁴¹ EMA/FDA also issued nitrosamine guidance reforms.⁴⁶⁻⁴⁷

4.2.2 Ranitidine (2019–2020)

Ranitidine is an H₂-receptor antagonist (H₂RA), which decreases the amount of acid created in the stomach and is used to treat gastric ulcers and acid reflux. It was noticed that N-nitroso dimethylamine (NDMA), a probable human carcinogen, is in multiple products, including valsartan, metformin, and ranitidine. Ranitidine is the second drug in which NDMA impurities were found after sartan. In 2019, a Valisure petition alerted the FDA to elevated NDMA.⁴⁸⁻⁵¹

NDMA can also lead to kidney illness and liver damage. Unlike other drugs, NDMA impurities occurred due to the intrinsic instability of ranitidine; in ranitidine, NDMA levels could increase when stored at high temperatures that may occur during distribution, handling, or even normal storage conditions. In 2019, Aurobindo Pharma USA initiated voluntary nationwide recall of 38 lots of ranitidine tablets 150 mg, ranitidine capsules 300 mg and ranitidine syrup 15 mg/mL due to detection of NDMA impurities.⁵² In April 2020, the FDA requested immediate withdrawal of all ranitidine; following this, the EMA and Health Canada also recommended suspension of all ranitidine, stating that ranitidine has limited shelf-life stability.^{14, 52-54} India never banned ranitidine; on 24 July 2025, CDSCO advised manufacturers to adopt risk-based measures such as modifying storage conditions and reducing the expiry date to 2 years. In India, ranitidine is still not banned; however, routine monitoring of NDMA levels in both the active pharmaceutical ingredient (API) and finished formulation is mandated. Recalls in various countries lead to a shortage of ranitidine and an increase in the purchase of non-ranitidine H₂RAs.⁵⁴⁻⁵⁵

These nitrosamine-related findings, along with the valsartan case, triggered global regulatory reforms on nitrosamine risk assessment and control.

4.2.3 Cough Syrups (2019–2024)

Cough is a common condition in children, and parents often give over-the-counter cough syrup or prescribed cough syrup. A pediatric cough syrup combination of paracetamol (analgesic and antipyretic) with chlorphenamine maleate (antihistamine) and phenylephrine hydrochloride (nasal decongestant) and/or dextromethorphan syrup (cough suppressant) is allowed. Combinations are allowed with safe pharmaceutical-grade excipients such as glycerin or propylene glycol, used as solvents or carriers to ensure the medicine's efficacy and safety. However, in multiple instances it was noticed that the manufacturer used harmful solvents, especially diethylene glycol (DEG) (in higher quantities, around 34% concentration was found in many batches) and ethylene glycol (EG), which are not safe for human consumption and whose toxicity can lead to acute kidney injury and death. One case of death was reported due to consumption of paediatric syrup COLDBEST-PC, manufactured by Digital Vision Pharma Kashmir.⁵⁶

Gambia lawsuit against Maiden Pharma due to the death of 70 children due to Maiden Pharma cough syrup.⁵⁷ 19 deaths due to cough syrup were reported in Uzbekistan due to Marion Biotech 2023. Indian police also arrested three employees and are looking for two directors after finding 22 to 36 syrup samples of adulterated and spurious drugs. WHO related this death to 141 children's deaths in Gambia, Uzbekistan, and Cameroon in 2022 due to contaminated cough syrup and reported 15 countries may have had tainted syrup on sale, made by different companies and containing high levels of DEG or EG.⁵⁸ In 2022, WHO alerted the substandard quality of Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup, and Magrip N Cold Syrup from Maiden Pharma (Haryana). In all this cough syrup, there were

unacceptable levels of DEG and EG. WHO also raised the concern that these cases are found in Gambia, but these may have reached other countries via the informal market.²³ In 2024, many African countries, such as Nigeria, Kenya, Rwanda, South Africa, Tanzania, and Zimbabwe, recalled a batch of Johnson & Johnson's Benylin Paediatric Syrup due to the detection of high levels of DEG (a toxic substance) in the batch.⁵⁹ Based on the investigation conducted, which revealed a violation of GMP, the state govt. of Haryana issued a notice and stopped all the manufacturing activity at Maiden Pharma at Sonipat, Haryana. CDSCO, in coordination with the State Drug Controller, Uttar Pradesh, began investigating Marion Biotech, and after a test and analysis, the manufacturer license was suspended for Marion Biotech.⁶⁰

Action taken by CDSCO and the Ministry of Health and Family Welfare. States/UTs have set up special courts for speedy disposal. Stringent penalties for manufacturers of spurious and adulterated drugs; certain offenses have also been made cognizable and non-bailable. States/UTs have set up special courts for offenses under the Drug and Cosmetic Act for speedy disposal and pre-inspection of manufacturing facilities are both important. The applicant shall submit the result of the bioequivalence study along with the application for the grant of a manufacturing license for the oral dosage form of some drug.⁶¹

The reluctance of Indian pharma companies to provide a guarantee to WHO on the safety and quality of these products is raising a concern about Indian manufacturers.

4.2.4 Eye Drops (2022–2023)

Patients use artificial eye drops to lubricate their eyes. In 2023, patients reported vision loss and death due to 10 different brands of eye drops, mainly Ezricare artificial tears and Delsam Pharma, distributor of Global Pharma Artificial Tears. This is an over-the-counter drug intended to be sterile, but it resulted in adverse events, including hospitalization, one death with bloodstream infection, and permanent vision loss. Contaminated product causes contagious eye disease, and symptoms may include yellow, green, or clear discharge from the eye; eye discomfort; pain; the sensation of a foreign particle in the eye; increased light sensitivity; and blurry vision. The FDA and CDC issued a warning to consumers and healthcare practitioners about purchasing EzriCare Artificial Tears or Delsam Pharma's eye drops manufactured by Global Pharma Artificial Tears, Tamil Nadu, due to potential drug-resistant bacterial contamination (*Pseudomonas aeruginosa* bacteria).⁶² CDSCO suspended the manufacturing of eye drops and issued a recall due to violations of the company's current good manufacturing practice (CGMP), including lack of appropriate microbial testing and formulation issues. Investigations are ongoing by the FDA and CDC.⁶²⁻⁶⁴ An outbreak in the US led to a global warning about Indian sterile manufacturing. The outbreak was caused by carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), an uncommon and highly drug-resistant strain that is difficult to treat and associated with severe outcomes.

4.2.5 Remdesivir Injections (2020–2021)

Remdesivir is a broad-spectrum antiviral drug that was approved or authorized for emergency use to treat COVID-19. Veklury® (remdesivir 100 mg for injection) is available for the treatment of adult and pediatric patients ≥ 12 years old, weighing ≥ 40 kg, after hospitalization or for non-hospitalized mild-to-moderate COVID-19 and at high risk for progression of severe COVID-19. In 2021 and 2024, Gilead Sciences Inc., Canada, received consumer complaints about the presence of glass particles in this. After investigation, glass particles were found in two lots in 2021 and one lot in 2024, resulting in drug recalls. No adverse event was reported due to Veklury® (Gilead, branded remdesivir).^{22, 65}

In May 2021, in several states, many patients experienced fevers, chills, and drastic drops in blood oxygen levels after receiving the antiviral remdesivir COVID-19 injection of Zydus Cadila. Investigation suggested the presence of endotoxin in specific batches. Death linked to remdesivir was also reported in many states; however, except for Bihar, no other states conducted essential tests or enforced recall. Even the Gujarat regulator did not act effectively to stop the tainted drug circulation in the market. In 2020, the Maharashtra Govt. recalled one batch of remdesivir due to a quality issue. These resulted in a shortage of supply.⁶⁶⁻⁶⁷ WHO also alerted about the circulation of 2 batches of falsified Remdesivir injections by Gilead Pharma in the US (a regulated country) and 2 additional batches in India and Guatemala (developing-country markets).⁶⁸⁻⁶⁹

This incident exposed outdated drug quality standards, significant regulatory gaps, and poor oversight of pharmaceutical manufacturing and government procurement systems, leading to avoidable patient harm.

This case drove home the importance of stringent regulations for quality control and better accountability mechanisms in India's drug regulatory framework. Additionally, patient exploitation was observed as a result of the high prices of black-market medicine, which stemmed from a shortage in supply and demand for emergency use.⁷⁰⁻⁷¹ This incident also calls for stronger GMP oversight, supply chain transparency, and global vigilance of the drug.

4.2.6 Digene Gel (2021)

Digene is an antacid that is available in pink liquid or pill form. It can be prescribed for gastritis and acid reflux. This is one of the OTC drugs.

In August 2023, Abbott Laboratories in Goa, India, recalled its antacid Digene Gel syrup after receiving complaints about taste and odor. The issue was due to cross-contamination and a hygiene lapse in the Goa facility. During inspection, inspectors flagged contamination risks and sanitization issues at its factory. Abbott received a warning from Goa Food and Drug, Jyoti J. Sardesai, on 11 September, saying, "I intend to cancel the product permission for all variants of Digene Gel/suspend the licenses held by you for a period deemed fit." This recall affected 179 batches of 7.6 million bottles, many of which may already have been consumed.^{17, 24, 72- 73}

DCGI and CDSCO also requested all zonal and state drug controllers to be vigilant on the movement, sale, distribution, and stock of the said Digene Gel. No serious adverse events were officially reported; however, healthcare professionals were informed to discontinue the affected product to avoid any adverse event. This raised a question about the multinational quality control of the drugs operating in India.^{24, 74} This incident emphasized the need for stricter surveillance of multinational pharmaceutical manufacturing in India.

4.2.7 Metformin (2020-2022)

Metformin is one of the oldest diabetic drugs, and it is among the most widely prescribed in India.⁷⁵ Dimethylamine (DMA) is used in the synthesis of metformin, which is also a precursor of NDMA. Thus, there is always a possibility of NDMA in metformin, and chances of elevation increase after extended storage or in certain formulations. In 2020, the FDA asked to look into the risks of metformin-containing ER products after learning about reports of higher NDMA levels in some extended-release versions. Private laboratories conducted an investigation and found that 42% of batches in several lots exceeded the acceptable limit of 96 nanograms.⁷⁶ As a result, many companies worldwide, like in Singapore and Canada, started a voluntary recall of the product after the announcement of the recall by the FDA in May 2020.⁷⁶ EMA stated they did not find any impurities and advised them to continue the medication.⁷⁷ Many US-based manufacturers of metformin, including Apotex and Amneal, also recalled metformin ER tablets.^{78, 79}

Many Indian manufacturers recalled Metformin ER tablets, including⁷⁶⁻⁸³

- Lupin Pharma (July 2020, 492,000 500 mg and 369,000 bottles of 1000 mg ER tablets) Maksans Pharma (June and October 2020; 500 and 750 mg ER metformin: more than 76 lots)
- Granules India (July 2020: 750 mg metformin ER)
- Sun Pharma (Sep-Oct 2020; one lot of Riomet ER 500 mg suspension)
- Cadila Healthcare via Viona (late 2021/early 2022: 33 lots of 750 mg ER; earlier 2 lots in mid-2021).

CDSCO also found many drugs along with metformin were of low quality and requested a recall.⁸⁴

This created worry in the patient, as stopping metformin abruptly is not recommended; therefore, the FDA advised patients to continue this and discuss with a healthcare professional any replacement or different treatment option. FDA also recommended the healthcare professional continue to prescribe metformin where clinically appropriate.⁸³

Note: Indian manufacturers conducted numerous GMP- or compliance-related recalls between 2015 and 2025 (e.g., Glenmark, April 2025; Granules, July 2025)²⁵. These events were excluded from our review because they occurred only in the US, and no details from WHO, EMA, or CDSCO were available.

These recalls drove home the importance of nitrosamine risk assessment, efficient GMP compliance, and effective patient communication in managing the safety of drugs used for chronic conditions.

4.3 Minor Recalls

In addition to major recalls, quality and labeling issues have led to numerous minor recalls.

Oral contraceptive: In 2017, Lupin Pharmaceuticals recalled one batch of Mibelas 24 Fe oral contraceptive tablets because there was a mistake in the packaging order and lot information.⁸⁵ In 2021 and 2023, Lupin recalled 4,113 cartons and two lots of Tydemy (drospirenone, ethinyl estradiol, and levomefolate calcium tablets, 3 mg/0.03 mg/0.451 mg, and levomefolate calcium tablets, 0.451 mg) due to a subpotent drug.⁸⁶⁻⁸⁸

Pantoprazole: In 2016, Aurobindo Pharma recalled 23,016 bottles of Pantoprazole Sodium delayed-release tablets (USP, 40 mg) after a market complaint reported the presence of one foreign tablet (Montelukast Sodium Chewable Tab, 4 mg) in the product bottle of Pantoprazole.⁸⁹ In 2024, CDSCO classified Pantoprazole Gastro-resistant Tablets produced by Alkem Health as Not of Standard Quality (NSQ) and also identified counterfeit Pantoprazole Gastro-Resistant tablets.⁹⁰ In July 2025, CDSCO identified NSQ due to dissolution issues from Skymap Pharmaceuticals Pvt. Ltd. and Mancare Laboratories Pvt. Ltd., as well as spurious pantoprazole.⁹¹

Ceftriaxone: In 2016 and 2019, Lupin recalled more than 54,000 vials of ceftriaxone antibacterial injection in the US because they did not follow good manufacturing practices and had visible grey particles in the vial.⁹²⁻⁹³

Domperidone: Domperidone tablets by Rainbow Life Sciences were recalled due to quality failure.⁹⁴ In Jul 2025, Zeora DSR (Rabeprazole and Domperidone Capsule) by Sigma Softgel & Formulation, Rantac RD (Rabeprazole and Domperidone Capsule) by Innova Captab Ltd., Paracetamol & Domperidone Dispersible Tablets (Nectar-DT) by Mefro Organic Ltd., and Rabeprazole Sodium & Sustained Release Domperidone Capsules (Rabiet DSR) by ACME Lafotech were found substandard by CDSCO.⁹⁵

However, these recalls were minor compared to ranitidine, valsartan, or other major recalls mentioned. This reflects persistent quality gaps in multinational and domestic pharmaceutical companies. Several CDSCO alerts were categorized as NSQ; however, the recall method is ambiguous, making it difficult to determine which NSQ caused the recall. Still, NSQ drug alerts necessitate vigilance.

5. Regulatory and Policy Responses

FDA: The FDA took the following actions after detection of NDMA impurities in valsartan, ranitidine, and metformin. The action was taken to ensure drug safety and protect public health. FDA issued guidance for the pharmaceutical industries on controlling acceptable level of nitrosamine impurities. This involves addressing nitrosamine impurities in both active ingredients and finished drug products to prevent future contamination. Due to the instability during storage leading to NDMA formation in ranitidine, this was discontinued from the US market, and the practitioner was advised to provide alternative treatment (FDA 2020, ranitidine).⁹⁶ The FDA updated press announcements on NDMA in ARB and metformin (FDA 2023, ARB; FDA 2021, metformin).^{46, 76, 97} FDA regularly updates the public and healthcare professionals about findings and the recall status of the drug. The valsartan recall in 2018 led to an increase in reports of valsartan-related cancer, likely reflecting increased public awareness.^{43, 98-100} FDA also published guidance on “Controls of Nitrosamine Impurities in Human Drugs” (2020, updated in 2023).⁴⁶ The FDA works in coordination with other authorities to maintain transparency in communicating NSQ findings and recalls. Singapore’s HSA and Health Canada also announced a voluntary recall of metformin ER in 2020 following the FDA’s risk evaluation.⁷⁶

EMA: The EMA and other regulatory bodies set stringent limits on the daily intake of NDMA (≤ 96 ng/day) and NDEA (≤ 26.5 ng/day) due to the genotoxic and carcinogenic properties of NDMA and NDEA. The determination was made using linear extrapolation from animal carcinogenic data, animal genotoxicity data, and international guidelines (ICH M7, ICH Q3C, and ICH Q3D).¹⁰¹

EMA also mandated all MAHs to submit nitrosamine risk management by March 2020 (later extended to 2021). EMA provided advice on nitrosamine impurities in medicines and created Q&A guidance for Marketing Authorization Holders (MAHs) to evaluate the risk of nitrosamine formation in their products, implement control strategies, and test for these impurities once the risk is identified. This guidance covers root causes, analytical methods, and risk assessment procedures, with an emphasis on validation and highly sensitive detection methods.^{45, 101-103}

WHO also issued nitrosamine impurities guidelines after the recall of major drugs due to NDMA impurities (WHO 2024).¹⁰⁴ WHO alerted on the nonstandard quality of cough syrup manufactured by certain Indian companies due to the potential of these drugs to pose serious risks. These syrups led to the death of children, especially in the African countries. Indian authorities halted the manufacturer's production of these drugs following the alert. During the COVID-19 pandemic, the WHO and other agencies issued alerts about falsified remdesivir, citing its lack of efficacy and the potential harm from unknown or toxic ingredients (Shrivastava 2023, Venkatasubramanian 2022). WHO also highlighted supply chain issues during COVID-19 shortages and issued such alerts through its Medicinal Product Alert system.^{68, 105-109}

India: Indian health officials and health regulators inspected pharma facilities whose drugs were recalled and halted the production of cough syrup of Maiden Pharma and issued routine monitoring of NDMA levels in ranitidine, which was published in the news article and alert.^{110, 111, 112, 113} In 2023, Goa FDA seized the production of contaminated Diegene Gel, and CDSCO directed the state controller to monitor and seize the affected stocks.⁷²⁻⁷³ CDSCO also suspended the license of Delsam Pharma's eye drop after identification of a GMP violation in the manufacturing of contaminated artificial tears.⁶⁴ In 2020 and 2021, the Maharashtra and Bihar state governments also initiated recalls due to endotoxin contamination and falsified supplies of remdesivir.⁶⁶⁻⁶⁷

Indian regulators acted reactively after issuing alerts from other authorities or global alerts. Literature related to action taken by CDSCO and MoHFW is limited. In July 2025, Indian authorities created a website to provide information about NSQ drugs and falsified drugs; however, it is still in a preliminary stage, and not all information is available.^{95, 114} Therefore, policy formed by the Indian Govt. after the recall is not sufficient to draw conclusions about post-recall action by Indian authorities. CDSCO regularly issues NSQ drug alerts, but a centralized transparent recall database is still not available.

While the FDA and EMA established structured policies such as nitrosamine controls, India's post-recall regulatory frameworks remain reactive, fragmented, and underdeveloped.

6. Comparative Analysis: India vs EMA/USFDA

FDA classification of recall is based on the relative degree of health hazard of the product.

“Class 1 Recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Class II Recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III Recall: is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.”¹¹⁵

Once the firm identifies the violative product, it must immediately notify the FDA district office (typically within 24 hours of discovering the defect) and begin action based on the recall classification. Upon FDA's confirmation of recall classification, immediate action is required for Class I recall (US 21 CFR Part 7-enforcement policy, 2025, FDA 2024).¹¹⁶

FDA also has effectiveness checks such as site inspections, sample verification, and audit verification before the recall officially closes.¹¹⁷ The FDA spreads this communication and maintains transparency through an openly accessible online recall database. FDA also has multiple communication channels such as press releases, health alerts, social media, email, and phone hotlines. It also actively reaches out to consumers and healthcare professionals in case of urgent recalls. It periodically reviews recalls until completed or terminated. FDA provides transparent, real-time updates on ongoing recalls. During this period healthcare professionals and the public can also report adverse events if they occur due to a defective batch via the MedWatch program. FDA recalls are searchable by product, company, or reason in the database; this shows transparency in practice.²⁵

EMA: EMA follows the same three-class system and takes a risk-based approach for classification: serious, moderate, and low risk.¹¹⁸ EMA also mandates a “rapid alert system” for urgent and serious alerts of

defective products without any delay. Although EMA has given some flexibility to member states, they are required to report promptly after the discovery of a defect, with no delay in issuing alerts.¹¹⁸⁻¹¹⁹

The EU Rapid Alert Network and Eudravigilance connect with PIC/S and WHO for cross-border sharing of the information.¹¹⁸⁻¹²⁰ The European Risk Communication and Rapid Alert Network enables data sharing between member states related to recalls, which also links to WHO/PIC/S. The EU has linguistic diversity; therefore, multilingual communication channels exist to reach the diverse population; EMA also publishes safety updates and recall notices on its website. Transparency levels may differ between member states due to legal frameworks.¹²¹

CDSCO: India follows the FDA model to develop guidelines for recall.¹² Generally, as per CDSCO guidelines, recall can be done at three levels. The consumer or user level encompasses individual consumers, patients, physicians, and hospitals, while the retail level includes pharmacies, dispensing physicians, and institutions such as clinics and nursing homes, and the wholesale level refers to the distribution chain between manufacturer and retailer. The framework of depth of recall is almost the same across the FDA, EMA, and CDSCO.^{12, 115, 121}

All Class I recalls should extend to the wholesaler, retailer, and consumer; Class II recalls shall extend to the wholesaler and retailer level; and Class III recalls should extend to the wholesale level.^{12, 122}

‘The urgency of the recall procedure begins upon identification of the defective product/batch and is guided by the degree of health consequences/risk posed by the defect, with specific timelines for each class based on potential harm.

Class I recall: Within 24 hours up to a maximum up to 72 hours

Class II recall: maximum up to 10 days

Class III recall: maximum up to 30 days.¹²

Priority is given to authority-requested or external recall and internally initiated Class I recall. Class II and Class III recalls are voluntary, but reporting is mandatory within the defined timelines.^{12, 120, 118, 116} CDSCO employs a rapid alert system and uses media such as newsletters, circulars, and public notifications. There is no searchable central database, and transparency is limited; reliance is on circulars/notifications.^{12, 123}

The Indian Pharmacopoeia Commission (IPC) is an autonomous institution of MoHW, Government of India, which also publishes the National Formulary of India to promote rational use of generic drugs. It also acts as the National Coordination Centre for the Pharmacovigilance Program of India. India integrated recall with pharmacovigilance early, directly linking quality defects with safety monitoring, while the FDA and EMA have separate sites for recall and defective product quality and pharmacovigilance.^{124, 118, 125}

Although India has recall guidelines in place, it lacks enforcement of this law. After four years of new drug or manufacturing approval, oversight shifts to state drug controllers, leading to fragmented quality supervision. India lacks a central database, relying mainly on gazette notifications. Rapid alerts are limited to Class I, and post-recall monitoring remains informal, making India’s recall system weak.^{95, 13}

State resources and expertise vary, compounding fragmentation, resulting in irregular enforcement of recall guidelines across India.¹²⁶

A study of data on recalls from 2013 to 2023 showed that in FY2023, Class I and II recalls rose sharply. Common causes included labeling errors, non-sterility, particulate contamination, and cGMP lapses, which exposed consumers to serious hazards.¹²⁷

Like other low-income countries, the main challenges are inadequate knowledge of reporting procedures, limited availability of reporting forms, poor communication and low motivation, low recorded ADR volumes, poor data quality, inadequate PV tools, political pressure and insufficient stakeholder coordination, and limited financial and human resources.^{128, 129, 130} Overall, FDA communicates the recall in a real-time, transparent manner; EMA follows multilingual communication and cross-border communication. Although India has integrated PV with recall, it lags in enforcement and monitoring.

Table 2 describes the features of recall systems in a comparative analysis of the US FDA, EMA, and India. Please see **Table 2** for further details.

Table 2: Comparative Analysis of Drug Recall Systems: FDA, EMA, and India

Feature	US FDA	EMA	India
Recall classification	Class I, II, III (21 CFR Part 7)	Serious, Moderate, Low risk	Class I, II, III
Transparency	Central online recall database; weekly postings	EudraGMDP and EMA websites	No central portal; NSQ bulletins only, intermittent
Enforcement	Mandatory, strong oversight	Risk-based, harmonized	Weak enforcement; voluntary/fragmented state action
Reporting	Publicly accessible	Publicly accessible	Limited disclosure; not consumer-friendly
Timelines	Rapid notification (≤ 24 hrs for Class I)	Risk-based, prompt	Class I: up to 72 hours Class II: 10 Days Class III: 30 Days; often delayed
Integration with PV	Linked to MedWatch	Linked to EudraVigilance	PvPI exists but poorly integrated with recall process

Sources: Data from FDA (2018–2025)^{25, 125}; EMA (2018–2020)^{16,45, 101}; WHO Medical Product Alerts (2022–2024)^{23,69,107}; CDSCO annual reports (2019–2025)³³⁻⁴⁰, and published studies¹¹⁵⁻¹³⁰.

7. Impact on Public and Pharma

Drugs are meant to give health benefits to the public. However, many times, issues with substandard drugs or falsified products have posed serious risks as well as death to the patients. Recall of these drugs resulted in increased risk of adverse health outcomes, heightened patient anxiety, and treatment disruptions. For example, pantoprazole and valsartan recalls resulted in a change of medications, a temporary gap in the medications, and temporarily potential drug-drug interactions, which were further managed by alternative therapies. In some cases, there was a measurable increase in acute care visits.^{131- 133}

Recalls disrupt the supply chains and can cause drug shortages, especially of widely used drugs such as metformin and valsartan, and eventually lead to reputation and trust damage in pharmaceutical companies as well as healthcare systems. This can also lead to financial losses, legal liabilities, and increased regulatory scrutiny.^{5, 134-136} Recalls have brought attention to stricter manufacturing standards and better coordination between stakeholders.

Out-of-pocket expenditure on health care is one of the major concerns worldwide. Generic drugs provide a solution to decrease this burden; they are replicas of approved brand drugs in dosage form, safety, strength, route of administration, performance, and characteristics. The generic drug implementation policy was implemented first in the USA; as a result, its medical insurance expenditure reduced by US \$67.7 billion. There is a worldwide demand for generic drugs to help reduce healthcare burdens. For India, the availability of generic drugs is more crucial, as 70% of the Indian population lives in rural areas, and they require affordable health care solutions. With the objective of making quality generic products, in November 2008 the Government of India initiated the Jan Arushadi Scheme, which was relaunched by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, as the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) in 2015 to provide affordable medicine. Several functional outlets were opened to sell the generic drugs, but these numbers are just 1% of pharmacies spread across the country.¹³⁷

8. Recommendations

Recall can be minimized using the following principle:

Risk-based GMP audits and routine auditing of risk assessment frameworks, dynamic scheduling of audits, integration of digital technology such as artificial intelligence, standardized procedures and instruments, and continuous monitoring and feedback. ¹³⁸⁻¹⁴¹

Follow ICH Q7, Q9, and Q10 guidelines for GMP and risk management practices. Mandatory testing for impurities, especially nitrosamine impurities, using routine and sensitivity laboratory methods in both API and finished product. Stress and stability testing is especially important for drugs like ranitidine that are prone to degradation or nitrosamine formation, as instability can lead to increased impurity levels during storage or under certain conditions. ¹⁴²⁻¹⁴⁷

Not all NSQ drugs automatically trigger recalls; the decision is often based on risk assessment. Challenges related to reaching the recall information to stakeholders and the public create confusion regarding the status and urgency of product withdrawal. There is also ambiguity about when a product should be recalled versus when the other actions (such as warnings or market surveillance) are sufficient. An effective strategy to utilize PvPI alongside recalls can be helpful for early detection of adverse events and defective or falsified drugs. Limited transparency and regulatory ambiguity create confusion between NSQ and recalls. Awareness can be increased by providing training. Introduction of a recall portal similar to the FDA's. Stringent action against falsified product manufacturers and enforcement of the law. Improvement in India's recall system will not only safeguard Indian public health, but it will also protect global public health. This can also improve the reputation of the Indian pharmaceutical sector, supporting sustainable global market growth and financial growth by strengthening their international reputation.

Conclusion:

Drug recalls remain a global concern affecting patient safety, public trust, and the pharmaceutical industry. Nitrosamine impurities led to major recalls of valsartan, metformin, and ranitidine, prompting regulatory policy responses. Other major recalls (cough syrup, eye drops, remdesivir, Digene) exposed serious GMP lapses and weak oversight by regulators. The FDA and EMA have structured and transparent systems; however, in India recall processes are still at the premature stage, causing weak enforcement, poor transparency, and fragmented oversight. Recalls can lead to temporary shortages of drugs, therapy disruption, heightened anxiety in patients, and financial/reputational damage. Prevention can be done by strict GMP compliance, risk-based and routine audits, and stability testing of the drug with a low shelf life, such as ranitidine. Development of a transparent recall database, portal, and global harmonization of regulatory action are required. In India the recall framework can be strengthened by training, creating awareness in healthcare professionals and the public, and strict enforcement. Global collaboration and regulatory strengthening can prevent future tragedies.

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