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BANNED DRUG AND DRUG RECALL PROCEDURE: REGULATORY FRAME WORK AND CHALLENGES FACED

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ABSTRACT

The term "drug" originates from the Greek word *droughe*, meaning herb. Medicines are essential for preventing and treating diseases-life saving or supportive benefite, while others provide supportive benefits. However, despite their therapeutic value, drugs can cause adverse drug reactions, which may be short-term or long-term. In some cases, even drugs approved through clinical trials can lead to serious health issues when widely used. A notable example is Diclofenac, which caused a severe decline in Gyps vulture populations in South Asia. Due to its harmful environmental effects, the Indian government banned it in 2006. Additionally, 328 fixed-dose combination (FDC) drugs were later banned because they lacked sufficient therapeutic benefits and posed health risks. Drug safety is ensured through Pharmacovigilance, which involves monitoring adverse effects and evaluating the risk–benefit ratio of medicines. Sometimes, harmful effects arise only when drugs are combined, leading to bans on specific combinations rather than individual drugs. Despite regulations, some banned drugs continue to be available in India due to limited awareness and regulatory gaps. Therefore, strengthening drug laws, improving monitoring systems, and increasing public awareness are essential steps to ensure drug safety and protect public health.

KEYWORDS: Deviations, Compounded, Adhering, Recurrence, Disparity, Exacerbates, Statutory.

INTRODUCTION

Banned drugs are medicines that are prohibited because their risks and adverse effects outweigh their therapeutic benefits. Although drugs play a vital role in the diagnosis, treatment, and prevention of diseases, lack of public awareness often leads to the continued use of unsafe or banned medicines, resulting in serious health issues such as liver and kidney damage. Each country has its own list of banned drugs, yet some drugs restricted in other nations are still available in India. The decision to ban a drug is based on a careful risk–no benefit analysis, considering factors such as unexpected side effects, toxicity, harmful interactions, availability of safer alternatives, and failures in risk management. Developed regions, especially in Europe, respond more rapidly to such risks due to strong pharmacovigilance systems and effective adverse drug reaction (ADR) reporting. In contrast, India faces delays in regulatory actions and insufficient ADR reporting, allowing potentially harmful drugs to remain in the market.

Additionally, weak implementation of drug bans and recalls in developing countries, due to limited resources and enforcement gaps, further contributes to this issue. A drug recall refers to the withdrawal of a drug product from the market due to safety, quality, or efficacy concerns. It may involve a specific batch or the entire product line. Regulatory authorities like the Food and Drug Administration (FDA) can mandate recalls, while manufacturers may also initiate them voluntarily. Effective recall management is essential to ensure drug safety, protect public health, and reduce legal risk.

OVERVIEW OF BANNED DRUG

A. Reason for banning a drug

jyrDrugs are introduced into the market to improve patients' quality of life, but all medicines can have adverse effects. Before approval, drugs undergo rigorous testing and quality control to assess their safety and effectiveness. However, some toxic effects may only become apparent after widespread use. Factors such as

severe side effects, high toxicity, harmful interactions, irrational use, availability of safer alternatives, and failure of risk management determine whether a drug should be used cautiously or banned. When harmful effects are identified, the government can issue a ban and stop its manufacture and sale. In India, several single drugs and fixed-dose combinations (FDCs) have been banned, yet some remain available over the counter due to poor reporting of adverse drug reactions. Misuse of performance-enhancing drugs, especially anabolic steroids, has been linked to serious health issues like liver and kidney damage. Additionally, inappropriate use of antibiotic combinations can lead to toxicity and antimicrobial resistance, highlighting the need for strict regulation and public awareness.

B. Drug banned in other countries but available in india

In India that have been banned in many other countries remains a serious public health concern. Medicines such Nimesulide(above 100mg), Dextropropoxyphene, Terfenadine, Astemizole, as are examples often cited in this context. These drugs have been restricted or banned elsewhere due to significant safety concerns, including risks of liver damage, cardiovascular complications, and hemorrhagic stroke. However, they have at times remained accessible in India, either directly or in modified formulations. A key factor contributing to this issue is the common patient mindset that faster relief equates to better treatment. Many individuals rely on drugs that provide quick symptomatic relief for minor ailments such as colds, coughs, headaches, and fever, without understanding the potential long-term risks. This behavior is compounded by widespread self-medication, where people purchase medicines over the counter without consulting qualified healthcare professionals. Lack of awareness among both patients and physicians further exacerbates the problem. Not all healthcare providers stay updated on regulatory changes or banned drug lists, while patients often remain unaware of the harmful side effects associated with certain medications. Poverty and the high cost of safer alternatives also drive people toward cheaper, potentially unsafe drugs. In some cases, the non-availability of appropriate or safer medicines forces both doctors and patients to rely on these options.[11]

REGULATORY AUTHORETIES OF BANNED DRUG

Regulatory authorities are responsible for ensuring that drugs available in the market are safe, effective, and of good quality. They play a crucial role in banning or restricting harmful drugs to protect public health. Both international and national organizations work together to regulate drugs and take necessary actions against unsafe substances.

At the global level, the World Health Organization (WHO) provides guidelines on drug safety and promotes rational use of medicines. It collaborates with countries to monitor adverse drug reactions and supports decisions on banning harmful drugs. Another important international body is the United Nations Office on Drugs and Crime (UNODC), which focuses on controlling illicit drug trade and supports international drug control conventions.[12]

In India, the primary regulatory authority is the Central Drugs Standard Control Organization (CDSCO), which operates under the Ministry of Health and Family Welfare. It is headed by the Drug Controller General of India (DCGI). CDSCO is responsible for approving new drugs, regulating clinical trials, and banning drugs that are found to be unsafe. It also coordinates with State Drug Control Authorities to ensure proper enforcement of drug laws across the country.

Another key Indian authority is the Indian Pharmacopoeia Commission (IPC), which plays a major role in monitoring drug safety through the Pharmacovigilance Programme of India (PvPI). It collects data on adverse drug reactions and helps in identifying harmful drugs that may need to be restricted or banned.

At the regional level in Europe, the European Medicines Agency (EMA) is responsible for evaluating and supervising medicinal products. It provides scientific recommendations and supports member countries in taking regulatory actions against unsafe drugs. Additionally, the European Monitoring Centre for Drugs and Drug Addiction monitors new psychoactive substances and provides early warnings about potentially harmful drugs entering the market.

The document highlights that regulatory authorities are increasingly using alternative legal frameworks such as consumer protection laws, food safety regulations, and medicines legislation to control new drugs. These approaches allow faster action compared to traditional criminal laws. Authorities can withdraw unsafe products, restrict sales, or classify substances as medicinal products requiring approval.

Furthermore, many regulatory bodies implement rapid response systems such as temporary bans and emergency control measures. These are based on the precautionary principle, which allows action to be taken even when full scientific evidence is not available. This helps prevent widespread harm from newly emerging substance.[10]

EXAMPLE OF BANNED DRUG NATURE OF PHARMACOLOGICAL ACTION

Pharmaceutical Class	Description / Use	Examples of Banned Drugs	Reason for Ban
NSAIDs (Non- Steroidal Anti-Inflammatory Drugs)	Pain relief, anti-inflammator y	Rofecoxib, Valdecoxib, Nimesulide (in combinations)	Cardiovascular risk, liver toxicity
Antihistamines (H1 blockers)	Allergy treatment	Terfenadine, Astemizole	Cardiac arrhythmias (QT prolongation)
Analgesics (Opioid/Non-opioid)	Pain management	Dextropropoxyphene, Phenacetin, Metamizole	Toxicity, overdose risk, kidney damage
Antidiabetic Drugs	Blood sugar control	Rosiglitazone, Phenformin	Cardiovascular risk, lactic acidosis
Appetite Suppressants / Anti-obesity Drugs	Weight loss	Rimonabant, Sibutramine	Psychiatric effects, cardiovascular risk
Antimicrobial Agents (Antibiotics combinations)	Treat infections	Cefixime + Azithromycin, Ofloxacin + Metronidazole	Irrational combinations, resistance
Gastrointestinal Drugs	Treat GI disorders	Cisapride (implied), some FDCs with ranitidine/famotidine	Cardiac toxicity, interactions
Central Nervous System (CNS) Drugs	Psychiatric/ neurological use	Imipramine combinations, Diazepam combinations	Sedation, dependency, toxicity
Hormonal / Metabolic Drugs	Endocrine disorders	Pioglitazone combinations	Increased risk of adverse metabolic effects
Antispasmodics / GI combinations	Abdominal pain relief	Diphenoxylate + Atropine + Furazolidone	Toxicity, misuse

FIG: Dextropropoxyphene hydrochloride capsule.

FIG: Astemizole tablet.

FIG: Terfenadine.

DRUG RECALL PROCESS

A drug recall is a systematic process of removing or correcting defective, unsafe, or substandard pharmaceutical products from the market to protect public health. It is an essential component of pharmacovigilance and quality assurance systems, ensuring that medicines available to patients meet safety, efficacy, and quality standards.

The process begins with the identification of a problem. This may arise from various sources such as consumer complaints, adverse drug reaction (ADR) reports, routine quality control testing, post-marketing surveillance, or inspections by regulatory authorities. According to the study, the most common causes of drug recalls include microbiological contamination**,** composition errors **(**such as incorrect or undeclared ingredients**),** and packaging

defects. Other issues may involve lack of sterility assurance, presence of particulate matter, or marketing of unapproved drugs.

Once a defect is identified, a risk evaluation is conducted to determine the severity and potential impact on public health. Based on this assessment, recalls are generally classified into different categories depending on the level of risk (for example, life-threatening, temporary health risk, or minimal risk). This classification helps prioritize the urgency and extent of recall actions.

Following risk assessment, the manufacturer or regulatory authority initiates the recall decision and strategy development. This includes defining the scope of the recall (specific batch, lot, or entire product), identifying distribution channels, and planning communication strategies. Effective communication is critical and involves notifying distributors, healthcare professionals, pharmacies, and sometimes the public. Clear instructions are provided regarding the handling, return, or disposal of the affected product.

The next step is the execution of the recall, where the product is physically removed from the market. This involves coordination across the supply chain, including wholesalers, retailers, and healthcare facilities. Proper documentation and tracking systems are used to ensure that all affected units are accounted for and retrieved efficiently.

Simultaneously, a root cause analysis is performed to identify the underlying reason for the defect. The study highlights that many recalls are linked to failures in Good Manufacturing Practices (GMP), inadequate quality control, or poor packaging systems. Identifying the root cause is essential to prevent recurrenc.

PHASES OF RECALL IMPLEMENTATION

A. Detection and Identification of Defect

The recall process begins when a defect is identified in a drug product. This may arise from quality control failures, customer complaints, adverse drug reactions, or post-marketing surveillance. Issues such as contamination, labeling errors, stability failures, or serious safety concerns trigger further investigation. Early detection is crucial to minimize risk to patients and ensure timely action.

B. Initial Evaluation and Risk Assessment

Once a defect is reported, the manufacturer or quality assurance team evaluates the severity and potential impact of the issue. This involves assessing whether the defect affects the product's safety, efficacy, or quality. Based on this evaluation, the recall is classified (e.g., Class I, II, or III) depending on the level of health hazard. The extent of distribution and urgency of recall are also determined at this stage.

C. Decision to Recall

After risk assessment, a formal decision is made to initiate a recall. This decision may be voluntary (by the manufacturer) or statutory (mandated by regulatory authorities). The responsible authority records the recall details in a recall log and assigns a unique recall reference number.

D. Communication and Notification

Effective communication is a key phase of recall implementation. The manufacturer notifies distributors, retailers, and relevant stakeholders using rapid communication methods such as email, phone, or official notices.

Regulatory authorities are also informed about the recall. In serious cases, public announcements through media may be required to alert consumers and healthcare professionals.

E. Distribution Freeze and Product Retrieval

At this stage, the distribution of the defective product is immediately stopped. Distributors and retailers are instructed to "freeze" the stock, meaning they must halt sales and isolate the affected batches. The recall then proceeds to retrieve products from various levels of the supply chain—wholesale, retail, and consumer levels depending on the severity of the recall.

F. Monitoring and Documentation

All parties involved must maintain proper records of the recall process. This includes tracking the quantity of product distributed, returned, and remaining in stock. Distributors and retailers document recall notifications, stock status, and returned goods. Regulatory authorities and drug inspectors verify the effectiveness of the recall and ensure compliance with guidelines.

G. Corrective and Preventive Actions (CAPA)

After retrieval, the manufacturer investigates the root cause of the defect. Corrective actions are taken to resolve the issue, while preventive measures are implemented to avoid recurrence. This may involve changes in manufacturing processes, quality control systems, or supplier management.

H. Final Review and Closure

The final phase involves evaluating the effectiveness of the recall. Authorities assess whether all affected products have been successfully removed from the market. A final report is prepared, and the recall is officially closed once all regulatory requirements are fulfilled.

IMPACT OF BANNED DRUG AND RECALL

Banned drugs and drug recalls have a major impact on public health, the pharmaceutical industry, and healthcare systems. According to the uploaded review article, drug recalls are carried out to protect patients from harmful, contaminated, falsified, or low-quality medicines.

Common reasons include nitrosamine impurities, microbial contamination, labeling errors, and poor manufacturing practices.

The most important impact is on patient safety. Defective drugs such as contaminated cough syrups, eye drops, and impure medicines have caused severe illness, organ damage, blindness, and even deaths. For example, cough syrups contaminated with diethylene glycol (DEG) and ethylene glycol (EG) were linked to the deaths of many children in countries like Gambia and Uzbekistan.

Drug recalls also create treatment disruptions and medicine shortages. Widely used drugs such as valsartan, ranitidine, and metformin were recalled globally because of cancer-causing nitrosamine impurities. These recalls forced patients to switch medicines, caused temporary shortages, and increased anxiety among users.

Another major impact is on the pharmaceutical industry and economy. Companies face financial losses, legal action, stricter regulatory inspections, and damage to reputation after recalls. Recalls of products like Digene Gel and remdesivir raised concerns about manufacturing quality and weakened public trust in pharmaceutical companies.

The review also highlights the impact on regulatory systems and pharmacovigilance. Agencies such as the FDA, EMA, WHO, and CDSCO introduced stricter safety rules, better impurity testing, and stronger monitoring systems after major recalls. However, India still faces challenges such as weak enforcement, fragmented recall systems, lack of a central recall portal, and underreporting of adverse drug reactions.[13]

CASE STUDIES

Case Study: Regulatory Challenges and the Impact of Banned Drugs and Recalls.

1. Executive Summary

This case study explores the complexities of drug safety management, focusing on why certain medications are banned and the systematic processes used to remove them from the market. It highlights the disparity between global regulatory standards and the Indian pharmaceutical landscape, emphasizing the risks of Fixed-Dose Combinations (FDCs) and the critical role of Pharmacovigilance in protecting public health.

2. The Problem: Therapeutic Risks vs. Benefits

Drugs are designed to improve quality of life, but clinical trials do not always capture long-term or widespread toxic effects.

- Environmental Impact: Diclofenac, once common, caused a catastrophic decline in the South Asian Gyps vulture population, leading to a 2006 ban in India.[1]
- Irrational Combinations: 328 FDCs were banned because they lacked therapeutic justification and posed unnecessary health risks.
- The Global Disparity: Medicines like Nimesulide and Rofecoxib are banned in many developed nations due to liver and cardiovascular risks but have remained available in India due to regulatory gaps and public demand for "fast relief".

3. Key Regulatory Players

The safety of the drug supply chain is managed by several national and international bodies.

Authority	Scope	Key Responsibility
WHO	Global	Provides safety guidelines and promotes rational drug use.
CDSCO	India	Approves new drugs and mandates bans/recalls (headed by the DCGI).
IPC	India	Monitors safety through the Pharmacovigilance Programme of India (PvPI).
FDA / EMA	US / Europe	Rapidly identifies and responds to Adverse Drug Reactions (ADRs).

4. The Drug Recall Process

When a drug is found to be defective—whether due to nitrosamine impurities, microbiological contamination, or packaging errors—a systematic recall is triggered.

Phases of Implementation

1. Detection: Identification of defects via consumer complaints or routine testing.
2. Risk Assessment: Classifying the hazard.
3. Decision: Formalizing the recall (voluntary by manufacturer or mandated by state).
4. Communication: Notifying distributors, healthcare providers, and the public.
5. Retrieval: Freezing stock and physically removing products from the supply chain.
6. Monitoring: Tracking the quantity of returned goods to ensure effectiveness.
7. CAPA: Implementing Corrective and Preventive Actions to fix root causes.
8. Closure: Final review by regulatory authorities.

5. Impact Assessment

The consequences of failing to regulate or recall drugs effectively are severe:

- Public Health: Contaminated syrups (e.g., DEG/EG contamination) have led to mass fatalities and organ damage in children globally.
- Healthcare Disruptions: Recalls of common medications like Metformin or Ranitidine due to carcinogens cause shortages and patient anxiety.
- Industry Damage: Pharmaceutical companies face massive financial losses, legal repercussions, and a loss of public trust (e.g., the Digene Gel recall).

PREVENTIVE AND SAFETY MEASURE

The Foundation: Quality Management Systems (QMS)

A robust QMS serves as the primary defense against

manufacturing defects. By adhering strictly to Good Manufacturing Practices (GMP) and Standard Operating Procedures (SOPs), companies ensure consistency across all production stages. Key operational pillars include.

- Documentation & Audits: Comprehensive record-keeping and regular internal audits identify deviations before products reach the market.
- Asset Management: Continuous equipment calibration and process validation minimize mechanical variability.
- Supplier Integrity: Rigorous oversight and testing of raw materials prevent the introduction of contaminants.
- CAPA Protocols: Corrective and Preventive Actions (CAPA) ensure that once a root cause is identified, systemic changes are made to prevent recurrence.

9. Technological Integration & Risk Management

Modern pharmaceutical safety relies heavily on "Quality by Design" and data-driven oversight.

- Automation & Monitoring: Utilizing Process Analytical Technology (PAT) allows for real-time monitoring of drug formulations, reducing human error.
- Traceability: Serialization and track-and-trace technologies enable the rapid isolation of specific batches during a crisis, preventing wide-scale exposure.
- Predictive Analytics: AI analyzes historical data to forecast potential quality shifts. • Analytical Risk Tools: Methods like Failure Mode and Effects Analysis (FMEA) pinpoint critical failure points in the supply chain.
- Simulation: "Mock recalls" test the agility of internal systems, ensuring readiness for actual emergencies.

10. Regulatory Frameworks & Monitoring

National authorities, such as the CDSCO and the Ministry of Health, provide the legal and investigative infrastructure for safety.

- Pharmacovigilance: Continuous post-marketing surveillance is vital for detecting adverse effects that only appear in large, diverse populations.
- Standard Quality Testing: Authorities conduct "Not of Standard Quality" (NSQ) tests to identify and blacklist sub-par batches.
- Expert Oversight: Specialized committees evaluate the efficacy of drug combinations, leading to bans on irrational or unsafe formulations.
- Notification Systems: Efficient communication between the Drug Controller General and state authorities ensures that banned substances are removed from shelves immediately.

11. Professional Responsibility & Patient Safety

- Safety is a shared responsibility between healthcare providers, regulators, and the public.
- Mandatory ADR Reporting: Encouraging healthcare professionals and patients to report Adverse Drug Reactions (ADRs) creates an early-warning system for regulators.
- Educational Initiatives: Awareness campaigns and Drug Information Centers provide unbiased data to combat the use of internationally banned drugs. Furthermore, integrating safety training into medical curricula prevents the prescription of contentious medications.
- Prescription Adherence: Strict adherence to drug schedules—such as Schedule H (prescription only) and Schedule X (narcotics/psychotropics)—is mandatory to prevent drug abuse and toxicity.
- Provider Accountability: Doctors must prioritize "therapeutic benefit vs. risk," selecting medications that offer the highest efficacy with the lowest potential for side effects.

CONCLUSION

The safety and efficacy of the pharmaceutical supply chain are not merely regulatory requirements but fundamental pillars of public health. As evidenced by the historical impact of drugs like Diclofenac and the widespread recall of Fixed-Dose Combinations (FDCs), the journey of a medicine from clinical approval to mass consumption is fraught with potential risks that may only emerge through long-term use.

The findings of this report highlight a critical disparity between global safety standards and local implementation. While international bodies like the WHO and EMA maintain rigorous pharmacovigilance, countries like India face unique challenges, including a public preference for "fast relief" and the continued availability of medications banned elsewhere (e.g., Nimesulide). Bridging this gap requires a multifaceted strategy.

- Manufacturing Excellence: Implementation of Quality Management Systems (QMS) and Corrective and Preventive Actions (CAPA) is essential to eliminate defects at the source.
- Technological Vigilance: Transitioning toward Process Analytical Technology (PAT) and AI-driven predictive analytics can shift the industry from a reactive "recall" model to a proactive "prevention" model.
- Regulatory Rigor: Strengthening the CDSCO and PvPI frameworks is necessary to ensure that "Not of Standard Quality" (NSQ) drugs are identified and removed with surgical precision via efficient notification systems.
- Shared Responsibility: Safety is a collective effort. It demands active Adverse Drug Reaction (ADR) reporting from healthcare professionals, ethical prescription practices by doctors, and increased awareness among patients to avoid self-medication and irrational drug use.

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