



Mandatory Recall of Failed Medicines Explained

Comprehending the CDSO's Law

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Introduction

India is one of the world's leading producers of generic pharmaceuticals, accounting for roughly one-fifth of global generic pharmaceutical exports by volume.[1] Nonetheless, assuring the quality and safety of the country's drug supply and the drug market is a major concern. According to the World Health Organisation (WHO), roughly 10.5% of drugs globally are substandard drugs or counterfeit drugs, with approximately one in every ten medical items in nations with low or middle incomes being substandard or counterfeit.[2] This global problem endangers public health and safety. Substandard and counterfeit drugs are common throughout India.

Despite being a significant global player in the industry, the lack of a specific substandard drug recall law exposes patients to the dangers associated with defective or substandard drugs. The current regulatory framework relies primarily on provisions dispersed across numerous statutes and regulations, resulting in an ad hoc approach to drug recalls. Inadequate drug recall laws have repercussions that extend beyond compromising patient safety. The absence of a streamlined process harms the reputation of the pharmaceutical industry, erodes public trust, and raises international stakeholders' concerns. It also impedes the ability of drug manufacturers to promptly resolve safety concerns and protect their brand image.

The recent occurrence of Abbot, a multinational pharmaceutical company's notice regarding a mislabelled batch of medicine has further raised concerns regarding recall law in India. Considering these pressing concerns, India must implement a comprehensive drug recall law that includes clear procedures, defined responsibilities, and severe penalties for noncompliance. This article will analyse India's position on this in the following manner:

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Drug Regulations in India

India has several regulations in place concerning the pharmaceutical industry, which govern the manufacture, distribution, and sale of drugs. These regulations aim to safeguard public health, ensure drug quality, and maintain ethical standards within the pharmaceutical industry.

The Drug and Cosmetics Act, 1940

The Drug and Cosmetics Act of 1940[3] is the basis for drug regulation in India. It establishes the legal framework for the import, production, distribution, and sale of drugs. The act contains provisions regarding the licensing, labeling, advertising, and quality control of pharmaceuticals. It authorizes the CDSCO to implement regulatory measures and initiate action against manufacturers or distributors who do not comply.

Central Drugs Standard Control Organization (CDSCO)

The CDSCO, which is overseen by the Ministry of Health and Family Welfare, is India's major drug regulating authority. It is critical in the approval of new pharmaceuticals, the granting of licenses to manufacturers, and the oversight of clinical trials.

- **Formulation of Rules and Regulations:** The CDSCO has created an array of rules and standards to govern many parts of the pharmaceutical industry. The *Drugs and Cosmetics Rules of 1945* and *The New Drugs and Clinical Trial Rules of 2019*[4], for example, define the procedures for medication approval, licensing, and clinical trials. Furthermore, the CDSCO has given recommendations for acceptable laboratory and clinical practices, as well as post-marketing surveillance.
- **The Drug Approval Process:** A drug must go through a rigorous approval process before it can be sold in India. The CDSCO requires pharmaceutical businesses to disclose data on the safety, efficacy, and quality of their products. The review mechanism involves expert groups and regulatory authorities.[5]
- **Pharmacovigilance:** Pharmacovigilance, or the science and activities of monitoring and evaluating medication safety, is an essential component of India's drug legislation. The CDSCO established the *Pharmacovigilance Programme of India* (PvPI) to collect and investigate adverse drug reaction concerns. This technology speeds up the deployment of corrective measures by making it easier to identify and mitigate drug-related risks.
- **Quality Control Norms:** To ensure the efficacy and safety of pharmaceuticals, India has implemented severe quality control norms. The *Good Manufacturing Practices* (GMP)[6] and *Good Distribution Practices* criteria are enforced by

the CDSCO. Regular inspections are carried out to ensure that these requirements are followed and that pharmaceuticals meet established quality criteria.

The recent *New Drugs, Medical Devices, and Cosmetics Bill 2022*^[7] does provide for the recall of “*Ayurveda, Unani, Siddha, Sowa-Rigpa, Homoeopathy drugs*”, but does not deal with the recall of Allopathic drugs.

The Reasons Behind the Lack of a Drug Recall Law

Despite there being comprehensive regulations governing the pharmaceutical industry and the drug market, no rules or regulations provide for a drug recall law. There have been several discussions, such as by the Drugs Consultative Committee (DCC) and the CDSCO in 1976^[8], and even in recent years in the 2018-19 meetings, but no such law to recall substandard drugs has been enacted. The reasons behind the same are:

- **Regulatory Focus on Pre-Market Approval:** India's drugs regulatory system lays a strong emphasis on pre-market approval processes, which evaluate the safety, efficacy, and quality of pharmaceuticals before they are released to the public. This ensures a certain level of inspection during the early stages, but it lacks a comprehensive system for post-market surveillance and drug recall.
- **Inadequate Post-Market Surveillance:** Effective post-market surveillance is critical for identifying and addressing drug safety issues. India's post-market monitoring infrastructure and methods have historically been weak. Inadequate resources, manpower, and coordination among regulatory authorities are the reasons behind it.
- **Changing Regulatory Objectives:** The drug regulatory landscape in India has undergone major modifications throughout the years, with shifting regulatory goals and problems. Despite efforts to enhance drug regulations, a dedicated drug recall law has received little attention because of competing priorities, resource limits, and a dynamic regulatory environment.
- **Legal and Procedural Difficulties:** Creating and implementing a comprehensive drug recall law entails traversing complex legal and procedural stumbling blocks. Legislation that finds a balance between patient safety, industry interests, and regulatory enforcement necessitates thought and collaboration with relevant parties.
- **Concerns in the Industry and Stakeholder Involvement:** Industry participants may be concerned about the financial consequences and brand reputation damage connected with drug recalls. It is vital to find a balance between the interests of many stakeholders and participate in constructive communication for a drug recall law acceptable to all parties.

The Need For A Comprehensive Drug Recall Law

Given the recent and rare occurrence involving a mislabelled batch of medication supplied by Abbott, India is in dire need of a comprehensive drug recall law, as is quite common in the US. Such legislation would provide a systematic and standardized approach to comparable situations, ensuring that drug manufacturers take swift action to correct errors and safeguard the public's health and safety.

- **Protecting Public Health:** A comprehensive drug recall law protects public health by detecting and removing hazardous drugs from the market as soon as possible, reducing patient harm.
- **Enhancing Consumer Confidence:** A well-defined drug recall law boosts consumer trust by assuring them that regulatory authorities regularly monitor drug

quality and safety, resulting in improved health outcomes and higher consumer satisfaction.

- **Promoting Industry Accountability:** A drug recall law provides duties for pharmaceutical corporations, fostering an industry-wide accountability culture. Quality control methods are made more severe by reporting unfavorable events, conducting investigations, and applying penalties.
- **Strengthening Post-Market Surveillance:** A specialized drug recall law improves post-market surveillance, allowing for the early detection and mitigation of potential dangers. Proactive monitoring reduces the spread of harmful drugs and the risk of patient harm.
- **International Compliance and Reputation:** Having a thorough drug recall law connects India with worldwide standards, improving compliance and strengthening India's reputation as a reliable producer of high-quality pharmaceutical products.

By enacting a comprehensive drug recall law, India can strengthen its commitment to public health, improve industry accountability, and bolster its position as a global leader in the pharmaceutical industry.

Conclusion

Overall, the absence of a comprehensive drug recall law in India emphasizes the necessity for prompt action. Developing such laws is critical for protecting public health, increasing consumer confidence, encouraging industry accountability, improving post-market surveillance, and adhering to international norms. By establishing a thorough drug recall law, India can assure the quick and effective removal of hazardous drugs from the market, protecting citizens' health and enhancing the reputation of its pharmaceutical industry.

Frequently Asked Questions (FAQs)

What are the reasons behind India not having a dedicated drug recall law?

India lacks a comprehensive drug recall law due to a fragmented regulatory structure, insufficient post-market surveillance, shifting regulatory priorities, legal and procedural hurdles, and industry concerns.

What are the advantages of a comprehensive drug recall law?

A comprehensive drug recall law protects public health, boosts consumer confidence, promotes business accountability, improves post-market surveillance, and ensures the quick and efficient removal of hazardous drugs from the market.

How does drug recall occur in the US?

In the United States, the Food and Drug Administration (FDA) oversees a well-established drug recall system. The FDA can recall drugs and take the necessary precautions to protect public health. Notifying healthcare professionals and the general public, categorizing recalls based on risk, and working closely with pharmaceutical companies for proper recall execution are all included in the process.

[1]<https://www.ibef.org/industry/pharmaceutical-india>.

[2]<https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified>.

[3]https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf.

[4]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTg40A==.

[5]https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/New-Drug

[s/Process/NDD_APPL_Organogram.pdf](#).

[6]https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/import-registration/Import_guidance_doc.pdf.

[7]<https://main.mohfw.gov.in/newshighlights-97>.

[8]https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=0DUy.

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Tel: [+91 11 41032969](tel:+911141032969) | Email: info@ksandk.com