CDSO’s Recall Mechanisms for Failed Drugs in India

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Introduction:

A drug recall is a pivotal intervention within the pharmaceutical sector, activated when a prescription or a medication is recognized as presenting potential threats or hazards to consumers. This course of action is set in motion upon the identification of a drug product that contravenes the laws and regulations overseeing its safety, effectiveness, or quality. Quality-related issues leading to recalls encompass the identification of products as not of standard quality, adulterated, or spurious drugs, signifying departures from established standards that could jeopardize the well-being of patients. Furthermore, recalls are instigated by safety and efficacy concerns, particularly when severe adverse reactions or fatalities are linked to a specific drug.

The absence of a national Drug Recall Law in India is a critical gap in the regulatory framework that urgently needs attention. The lack of a centralized and uniform mechanism inhibits the swift and coordinated response required to address nationwide concerns about drug quality and safety. To ensure the prompt and comprehensive removal of substandard drugs from the market, it is imperative for India to establish a national Drug Recall Law. Such legislation would empower authorities at the national level to swiftly and efficiently order the withdrawal of an entire batch identified as Not of

Standard Quality, thereby enhancing the country's capacity to safeguard public health and maintain the integrity of its pharmaceutical market.

Significance of Drug Recall:

The principal objective of a drug recall is to promptly eliminate the implicated product from the market, thereby safeguarding the public from potential harm. Moreover, the recall procedure is designed to offer redress or reimbursement to consumers who have previously acquired the product, ensuring their protection from associated risks. This recall protocol is applicable to drugs proscribed under the Provisions of Drugs & Cosmetics Act**[1]**, accentuating the imperative of upholding regulatory benchmarks. Furthermore, recalls encompass items for which product licenses are either suspended or revoked, underscoring the rigorous measures implemented to uphold the integrity and safety of pharmaceuticals and, by extension, to preserve public health.

Challenges:

The drug regulatory landscape in India faces several challenges due to a fragmented regulatory structure. This decentralized approach creates loopholes, as a drug banned in one state can potentially be sold in another, highlighting jurisdictional issues and inconsistent law enforcement. Additionally, the current system lacks a focus on processes, predominantly concentrating on end products rather than the underlying manufacturing processes. Transparency is also a concern, with no mandatory disclosures or transparency requirements regarding medicinal needs in the existing legislation.

The complexity of the drug regulation process further hampers effective oversight by the Union Health Ministry, which faces a lack of expertise in this critical area. Moreover, there is a perceived imbalance, as the government appears more inclined towards fostering the growth of the pharmaceutical industry than prioritizing public health protection. Notably, the absence of a specific law on drug recall, despite discussions since 1976, leaves the regulatory framework reliant on guidelines rather than a binding legislative mandate, raising questions about the efficacy of the current regulatory mechanisms. Addressing these challenges is crucial to ensuring a robust and comprehensive regulatory framework that prioritizes public health and safety.

Need of the hour:

India's prolonged struggle to institute a mandatory recall law for substandard drugs or drugs not of standard quality has been marked by a series of discussions and deliberations dating back to 1976. The Drugs Consultative Committee, comprising state drug controllers, bureaucrats from the Ministry of Health, and the national drug regulator, the Central Drug Standard Control Organisation (CDSCO), has engaged in multiple dialogues on the critical issue of drug recalls over the years. Despite these discussions, there has been a notable absence of concrete legislative amendments to the Drugs & Cosmetics Act that would establish a robust recall mechanism. The persistent lack of progress raises concerns about the regulatory framework's effectiveness in addressing public health risks associated with substandard drugs, highlighting the need for decisive action to safeguard the well-being of the populace.

The Drugs & Cosmetics Act & Rules do incorporate references to product recalls, complaints, and adverse reactions in Para 27 & 28 of Schedule M, as well as conditions for defective product recall in Rule 74(j) and Rule 78(i)[2]. However, there is a pressing need for a well-defined and uniform recall procedure, complete with clear timelines at every stage of the supply chain. The current framework lacks effective auditing and accountability mechanisms. This deficiency becomes evident in instances involving drugs declared as not of standard quality by Government Analysts, cases of serious adverse effects or deaths, incidents related to banned drugs under Section 26A, and situations where manufacturers voluntarily withdraw drugs from the market due to defects. The absence of a systematic and time-bound recall procedure raises concerns about public health and underscores the urgency for comprehensive regulatory measures to address these critical issues in the pharmaceutical industry.

Way Ahead:

Drug regulations in India place significant emphasis on pre-market approval processes, meticulously assessing the safety, efficacy, and quality of pharmaceuticals before their introduction to the public. While this approach ensures a thorough inspection at the initial stages, it falls short in establishing a comprehensive system for post-market surveillance and drug recall. The inadequacy in post-market monitoring is attributed to historical weaknesses in infrastructure, insufficient resources, manpower, and coordination among regulatory authorities. The dynamic nature of the drug regulatory landscape in India has seen evolving objectives and challenges over the years.

Despite efforts to strengthen drug regulations, the establishment of a dedicated drug recall law has received minimal attention due to competing priorities, resource constraints, and the continually evolving regulatory environment. The creation and implementation of such a law face intricate legal and procedural difficulties, requiring careful consideration and collaboration with relevant stakeholders to strike a balance between patient safety, industry interests, and effective regulatory enforcement. Industry

concerns about financial implications and brand reputation damage associated with drug recalls add another layer of complexity, emphasizing the importance of constructive communication and stakeholder involvement to devise a drug recall law acceptable to all parties involved.

Guidelines On Recall and Rapid Alert System For Drugs:

The guidelines[3] on recall and rapid alert system for drugs are designed to be universally applicable, encompassing all reports of quality-defective products and incidents related to the safety and efficacy of drugs, including vaccines and biologicals. It is imperative for licensees, including manufacturers, importers, stockists, distributors, and retailers, to adhere to these guidelines, irrespective of whether the recall is voluntary or statutory in nature. The comprehensive procedure outlined in these guidelines is not only intended for industry stakeholders but can also be employed by the Drugs Control Authorities at both the Central and State levels when urgent actions are needed to safeguard public or animal health.

Conclusion:

The guidelines by providing a systematic and stepwise approach, offer a structured framework for the recall strategy, ensuring that evaluation takes place at every level of the supply chain. Such a systematic approach is instrumental in achieving compliance within stipulated time frames, promoting efficiency, and enhancing overall drug safety and quality assurance measures.

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

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

[3]https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/biologicals/6GuidelinesnRecallanRapidAlert.pdf

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