RESEARCH PAPER

Counterfeit Pharmaceuticals in India: An Analysis of Prevalence Across Major Drug Categories and Strategies to Mitigate Diversion

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Abstract
Counterfeit pharmaceuticals represent a significant and evolving threat to public health and pharmaceutical governance in India. This comprehensive narrative review examines the prevalence of counterfeit medicines across major therapeutic drug categories and analyzes the structural vulnerabilities that enable diversion within the Indian pharmaceutical supply chain. Drawing on peer-reviewed literature, policy documents, and international research, the study identifies uneven distribution of counterfeit risks, with heightened exposure observed in anti-infectives, oncology drugs, and central nervous system medicines. These high-risk categories are influenced by strong market demand, high economic value, and misuse potential. The review further highlights systemic weaknesses within India's multi-tier distribution network, including manufacturing compliance gaps, wholesale opacity, informal retail practices, and digital marketplace expansion. Diversion mechanisms-such as warehouse theft, prescription manipulation, and parallel trade-emerge as critical pathways that blur the distinction between legitimate and illicit pharmaceutical circulation. The findings indicate that counterfeit activity in India is strategically driven by market incentives, supply chain fragmentation, and regulatory coordination challenges rather than isolated criminal acts. Emerging trends reveal increasing digitalization of counterfeit trade and convergence between diversion networks and substance misuse markets. Addressing these risks requires an integrated approach combining strengthened regulatory oversight, technological traceability systems, and improved inter-agency governance. This review underscores the need for coordinated national strategies to safeguard pharmaceutical integrity, protect patient safety, and preserve India's global credibility as a leading supplier of generic medicines.

Keywords: Counterfeit pharmaceuticals, Drug diversion, Pharmaceutical supply chain, India, Public health governance

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1. Introduction

Counterfeit pharmaceuticals are an emerging and a growing menace to the health of the people of the world, which has been amplified by globalization, growing trade in pharmaceuticals, and more intricate supply chains. With the transnationalization of the medicine production and distribution systems, chances of counterfeit penetration have increased, and fake and low-quality products are now able to be transmitted across the boundaries with more advanced techniques (Barnett, 2021). The fast urbanization, rise in population, and the growing access to healthcare services in developing economies have only added pressure on affordable medicines, which in turn has led to structural weak points, which illegitimate actors capitalize on (Amico et al., 2015). Simultaneously, the expansion of the digital market and online pharmacy sales has changed the magnitude and rate of the introduction of counterfeit pharmacology into both legal and illegal spheres (Mackey, Nayyar, 2017).

Across the world, the impact of fake medicines is negative, as they reduce the efficacy of treatment, jeopardize patient lives and undermine trust in healthcare systems. These products can be filled with wrong active ingredients, wrong dosage, or harmful contaminants, resulting in morbidity that can be prevented and failure of therapy (Lima & Yonamine, 2023). The fact that counterfeits have not been eradicated indicates that single-agent methods are insufficient, and system-level interventions are required on a holistic and multi-level level (El-Jardali et al., 2015; Fadlallah et al., 2016). As it has been pointed out in the study, the most important ways of its prevention are connected with enhancing the efficiency of regulatory systems, enhancing cross-border collaboration, and enhancing transparency throughout pharmaceutical supply chains (Lima et al., 2018). The technological solutions proposed as necessary to mitigate the issue of the integrity of the supply chain are serialization, track-and-trace, and digital authentication platforms, yet their implementation depends on the capacity and coherence of the government (Blais, 2022; Mackey and Nayyar, 2017).India excels in this world scenario. As one of the largest generic pharmaceutical manufacturers in the world, India offers low cost pharmaceutical products to the local market as well as the global customer count.

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The fact that its pharmaceutical ecosystem is large, diverse and decentralized is however a problem with regulatory and logistical implications (Chandrakala et al., 2023). The multi-level distribution systems, the regional discrepancies on the implementation and availability of the informal retail markets, all have weaknesses that can crack the door open to counterfeit to penetrate into the market. Furthermore, the fact that the problems of intellectual property can be mixed with the importance of public health complicates the policy reaction process, particularly in the international trade (Barnett, 2021). The issue of pharmaceutical integrity in India is therefore not only a health issue in India but the world over. In addition to counterfeiting, drug diversion is also another aspect of pharmaceutical crime that is equally important. Diversion is redirecting rightfully produced drugs into illegal markets most commonly through taking advantage of loopholes in monitoring and prescription and export regulations. These practices make it difficult to tell the difference between a legal production and illegal distribution making it hard to detect and punish. New methods of investigation demonstrate that sophisticated data analysis and forensic solutions must be used to detect anomalies in complicated supply systems (Kruger, 2025). Diversion is often associated with counterfeit circulation especially in high-demand or high value medicines and therefore increasing systemic risks.There are large health and economic impacts of the counterfeit and diverted pharmaceuticals to the general population. Poor or counterfeit medicines may increase the burden of disease, promote antimicrobial resistance, and the lack of trust in patients towards healthcare providers (Lima & Yonamine, 2023). The economic aspects of counterfeit trade pervert fair competition in the market, creates losses of money to pharmaceutical companies, and makes healthcare services more expensive because of treatment failure and associated chronic disease (Amico et al., 2015). The resilience of supply chains has in turn become a strategic focus, and to enhance it, there has to be a concerted regulatory, technological and institutional reaction (Lima et al., 2018).Since the prevalence of counterfeit activity varies by the type of product, considering prevalence by the larger therapeutic categories provides a more accurate picture of risk-taking. Some drug classes, especially high demand essential drugs and high value specialty drugs experience disproportionate exposure as a result of pricing mechanisms, use levels and intensity of regulation. A category-specific policy permits policy intervention, which would be more effective in reducing risks. Herein therefore, the review intends to review the level of counterfeit drugs circulating within the therapeutic drugs of the major categories in India, as well as look at the diversion methods and structural vulnerabilities within the supply chain that facilitates the circulation of counterfeit drugs. The study aims to integrate regulatory, public health as well as supply chain approaches to synthesize strategic interventions to improve pharmaceutical integrity and resilience in the context of the changing India healthcare system.

2. Methodology

The authors employ a thorough narrative review to examine the prevalence of fake drugs in India with particular attention to how significant drugs are classified, and how the diversion programs work. Systematic search of peer-reviewed journals and credible conference proceedings was done. The search of databases such as Google scholar, science direct, DOAJ and other approved academic databases was done using the keywords counterfeit medicines, substandard pharmaceuticals, drug diversion, pharmaceutical supply chain India and falsified drugs. The sources were chosen according to the relevance to the prevalence information, analysis of therapeutic categories, the susceptibility in the supply chains, and regulatory systems. The gathered studies were then tabulated into thematic categories which then guided the structured synthesis and analytical discussion that was carried out in the Results section. The general review process is presented in figure 1, and it includes the following stages: literature identification, screening, thematic classification and synthesis.

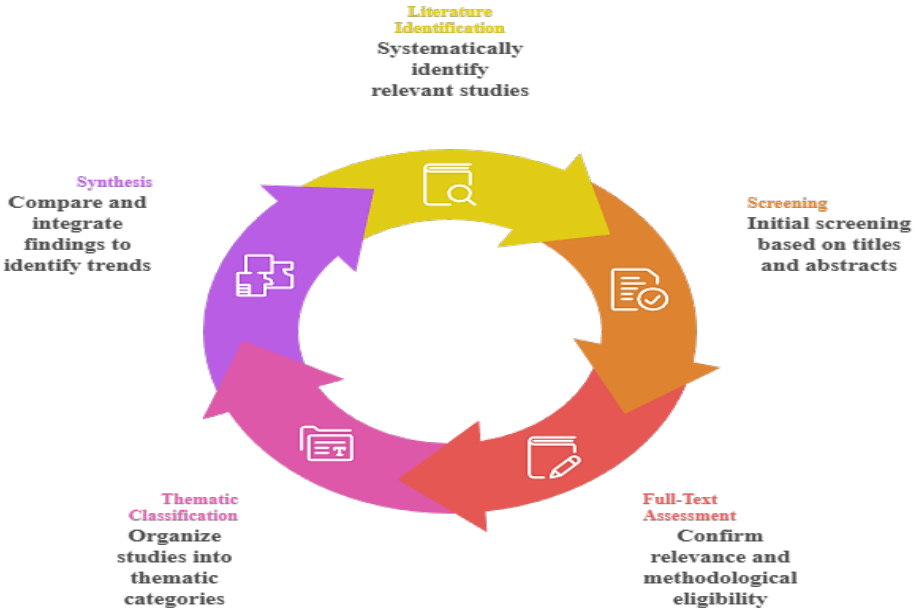

Figure 1. Overview of the Comprehensive Review Process

3. Results

3.1 Prevalence of Counterfeit Pharmaceuticals in India

The distribution of counterfeit drugs differs according to classes and distribution of drugs in India. It has been observed that counterfeit risks are not distributed evenly but rather they are concentrated in high-demand and high-value drug segments. The informal markets and the retail environments with weak control are especially prone. Moreover, supply chain interruptions and the increasing level of digital trade have also negatively impacted the changing levels of counterfeit across regions. Table 1 provides estimated relative risk levels of major categories of drugs.

Table 1. Estimated Risk Level of Counterfeit Medicines by Drug Category

Drug Category	Risk Level	Key Reference
Anti-infectives	High	Ozawa et al. (2018)
Cardiovascular & Antidiabetics	Moderate	Wahab et al. (2024)
Oncology Drugs	High	Venhuis et al. (2018)
CNS Drugs	Very High	Humphreys et al. (2022)
Pediatric Medicines	Moderate–High	Dewan et al. (2025)

3.2 Drug Category–Wise Analysis

The vulnerability of counterfeit also varies widely based on therapeutic classes because of demand, pricing and regulatory supervision. The use of anti-infectives is very specific, owing to a high level of consumption, and oncology drugs are sought by the criminal networks owing to the high profit levels. There is the increased exposure of chronic disease drugs with the increasing burden of non-communicable disease in India. The relationships between pharmaceutical diversion and substance misuse markets are proved to be effective in the case of central nervous system drugs. With the procurement systems whose quality is not highly controlled, pediatric medicines are at risk. Table 2 lists the category-specific drivers

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Table 2. Major Drug Categories and Associated Counterfeiting Risks

Therapeutic Category	Primary Risk Driver	Key Reference
Anti-infectives	High consumption demand	Ozawa et al. (2018)
Cardiovascular	Expanding chronic disease market	Rajora (2022)
Oncology	High unit price	Venhuis et al. (2018)
CNS Drugs	Abuse and diversion markets	Smith et al. (2016)
Pediatric Medicines	Weak regulatory oversight	Dewan et al. (2025)

3.3 Supply Chain Vulnerabilities in India

The pharmaceutical supply chain in India is multi-layered and it includes manufacturers, distributors, wholesalers, retailers and digital platforms. This complexity in structure lowers the traceability and creates more chances of infiltration by counterfeits. There are systemic vulnerabilities caused by manufacturing compliance lapses, wholesale level opacities, informal dispensing of retailing and the growth of online pharmacies. Transnational trade

channels also make enforcement mechanisms challenging. Table 3 presents the main supply chain weaknesses.

Table 3. Supply Chain Vulnerabilities

Supply Chain Stage	Key Vulnerability	Key Reference
Manufacturing	Quality compliance gaps	Bhushan (2017)
Wholesale	Multi-tier distribution complexity	Alfaouri et al. (2025)
Retail Pharmacies	Monitoring deficiencies	Pathak et al. (2023)
Online Pharmacies	Digital anonymity	Lavorgna (2015)
Cross-Border Trade	Smuggling networks	OECD (2020)

3.4 Mechanisms of Drug Diversion

Drug diversion is a very essential process through which fake and illicit drugs are distributed. Diversion happens when the legitimate medicines are diverted into an unauthorized channel by being stolen, damaged, misprescribed, misappropriated in hospitals, or by the parallel trade. Controlled substances are also easily vulnerable owing to limitations placed on regulatory monitoring. These side streets disorient the law and criminal distribution operations, and make it harder to enforce the law. Significant diversion mechanisms are summarised in Table 4.

Table 4. Common Diversion Pathways

Diversion Mechanism	Leakage Point	Key Reference
Warehouse Theft	Storage/transit	Bird et al. (2024)
Parallel Trade	Export channels	Yang & Mishra (2025)
Hospital Diversion	Institutional pharmacies	Yakubu (2020)
Prescription Manipulation	Retail level	Smith et al. (2016)

3.5 Emerging Trends and Patterns

In India, fake drug business is becoming more technological and trans-nationalized. Digital markets have increased the size and anonymity of illegal pharmaceutical business. Medicines of high value, especially cancer and specialty drugs are being targeted because of their profitability. The diversion networks and substance misuse markets are also becoming increasingly converged. Secondly, governance weaknesses and the pandemic-related supply chains disruptions have augmented the systemic vulnerabilities. Table 5 shows the important emerging patterns.

Table 5. Emerging Trends in Counterfeit Pharmaceuticals

Emerging Trend	System-Level Impact	Key Reference
Digital Expansion	Greater enforcement complexity	Lavorgna (2015)
High-Value Targeting	Organized crime incentives	Venhuis et al. (2018)
Diversion Convergence	Public health crisis overlap	Humphreys et al. (2022)
Pandemic-Related Disruption	Supply chain instability	Ziavrou et al. (2022)
Governance Gaps	Structural vulnerability	Haider et al. (2024)

4. Discussion

The results of this study point to the fact that the counterfeit pharmaceutical activity in India is not evenly spread but is concentrated in certain areas of therapeutic activity and in supply chains stages which are structurally susceptible. There is a higher risk profile of anti-infectives, oncology medicines, and central nervous system (CNS) drugs because of the high demand, price incentive, and regulatory sensitivity. The high-demand medicines provide volume-based returns whereas the high-value specialty drugs can be targeted by the organized criminal networks that aim at gaining the financial benefits. These risk patterns of differentiation indicate that exposure to counterfeits is not random but a strategic behavior of the criminals as it is adaptive to the pharmaceutical market.

The analysis in terms of categories also shows that CNS drugs are one of the most complicated areas of weakness. Deviating controlled substances to the illicit markets is one of the examples of the legal pharmaceutical products that are misused without necessarily being falsified. This is where the diversion market intersects the misuse market; hence, it is difficult to identify and implement. The findings suggest that pharmaceutical crime is increasingly becoming peripheral to the larger social health concern of substance abuse as well as prescription abuse and posing a broader regulatory challenge compared to the traditional counterfeit production. Structural weaknesses of Indian pharmaceutical supply chain increase the counterfeit risks. This distribution system is multi-layered, i.e. it consists of manufacturers, wholesalers, retailers and online platforms and this non-transparency makes it even more opaque. The nodes that bind the supply chain participants are quite prone especially, and the functions of supervision are diffused.

The spaces of infiltration are created through the creation of compliance lapses, non-uniform auditing, and unofficial dispensing of retailers. Such systemic characteristics indicate that complexity of supply chain is a risk multiplier on its own in the event of lack of coordination of regulations.This weakness is also grounded on governance issues. The effect of the presence of enforcement roles of the various regulatory levels may lead to creation of loop holes, and differences in degree of monitoring, and variation in deterrence. Where there are few resources and decentralization of regulation, the counterfeit activity is likely to thrive. Additionally, the application of intellectual property and the management of the condition of the state of health are typically regulated by the other institutional requirements, which makes it even harder to treat them in an integrative manner. Improvement of the inter-agency response and harmonization of the regulatory roles hence becomes a critical structure agenda. One of the most significant overlaps that were identified in this course of the review is the one between counterfeiting and diversion. The diversion mechanisms such as theft of medicine in a warehouse, manipulation of prescriptions, and parallel trade allow the legal medicines to get into illegal markets, having a blurry line on the difference between legal and illegal circulation. Such a combination makes it hard to enforce since products can be original but distributed illegally. Overcoming counterfeit risks in India hence means paying attention to both fraudulent production and illegal redistribution.The tendencies in India are easy to find in the world trends in pharmaceutical crimes when compared with the previous international studies. Research has also indicated that trademark enforcement systems are generally unable to balance the protection of intellectual property and fair access to health services available to the population, which is also a tussle like in the Indian case (Magdun, 2021). Similarly, a global study of online pharmaceutical trades notes that online markets augment anonymity, as well as complexity in enforcement, and this trend is becoming more apparent in the emerging digital health market in India (O'Hagan and Garlington, 2018). The studies of diversion and misuse by other jurisdictions prove that the CNS drug markets often overlap with illegal redistribution networks, which supports similarities with the situation in India (Marland et al., 2024). Moreover, according to the global rating of the protection of the pharmaceutical supply chain, it is necessary to introduce technologies and institutional changes to exclude the leakage of counterfeits, and the central issue is strategic measures to increase system resilience (Mosby, 2025).

In general, it can be inspected that the problem of counterfeit pharmaceuticals in India can be viewed as a multi-dimensional governance problem created by commercial incentives, supply chain intricacy, fragmentation of regulation, and criminal adaptation. Risky therapeutic groups, the digital development, and convergence at diversion all bring about an even greater level of vulnerability to the system. The mitigation therefore ought to be sustainable by instituting institutional measures, improvements in the traceability measures and elastic regulatory measures capable of addressing the traditional counterfeiting as well as the new diversion schemes.

5. Conclusion

The scope of this paper is the counterfeit pharmaceuticals in India, and this is reduced to particular categories of high-risk therapeutics and structurally vulnerable aspects of the supply chain. Anti-infectives, drugs, used in oncology, and central nervous system drugs also portray the highest exposure since they are highly demanded, market value, and have a high diversion potential. Based on the results, market incentives, the absence of transparency in the supply chain, and regulatory fragmentation are not occurring instead, they are strategic in promoting the motion of counterfeits. Better still, counterfeiting and diversion intersect with each other particularly with controlled and high-value medicines that simulate the systemic risk to be greater and the enforcement more difficult. There is also a need to strengthen the ability to govern through institutional reforms, increased auditing systems and data based surveillance systems. The cooperation between the government, pharmaceutical, distributors and digital technologies is the association of regulation, technology and reforms in the field of governance and the efficient response to it. The need to trouble the integrity of medications should not be considered as a national health security issue but as an economic need to the policymakers and the health officials of the country. The commitment to systemic resilience in the long term will be highly basic in enhancing the security of the patients and in accordance with elevated medication credibility on the international platform in India.

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