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Challenges of Counterfeit Drugs in the Indian Market: A Comprehensive Review

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Abstract: *The proliferation of counterfeit, substandard, and falsified medicines represents a critical public health crisis in India, undermining decades of therapeutic advancement and threatening patient safety across all therapeutic categories. This review examines the epidemiology, regulatory landscape, supply chain vulnerabilities, health consequences, and proposed interventions for combating counterfeit pharmaceuticals in the Indian market. A comprehensive analysis of recent literature reveals that India ranks as the world's fourth largest market for counterfeit and substandard medicines, with prevalence estimates suggesting that one in five medicines sold in major Indian cities may be counterfeit. The global counterfeit drug market is valued at approximately $200 billion USD annually, with 67% of these medicines classified as dangerous to human health. Beyond direct patient harm, counterfeit antimicrobials—particularly antibiotics and antimalarials—are neglected drivers of antimicrobial resistance, contributing to an estimated 58,000 antibiotic-related deaths annually in India alone. This paper synthesizes current evidence on definitional frameworks, prevalence patterns, vulnerable drug categories, distribution channels, regulatory mechanisms, detection methodologies, and evidence-based interventions. The analysis identifies critical workforce shortages, supply chain opacity at the active pharmaceutical ingredient level, inadequate regulatory enforcement, and gaps in pharmacovigilance infrastructure as primary systemic barriers. Recommendations include strengthening the regulatory apparatus through technological innovation (serialization, blockchain-based tracking, portable analytical devices), expanding the pharmacovigilance network beyond current capacity, implementing workforce planning reforms, enhancing inter-state coordination, and establishing international cooperation mechanisms. The urgency of addressing this challenge is underscored by documented health consequences including acute renal failure, severe hypoglycaemia, toxic encephalopathy, and treatment failures in communicable disease programs, affecting both pediatric and adult populations*

Keywords: counterfeit medicines, pharmaceutical fraud, drug safety, India, antimicrobial resistance, regulatory framework, pharmacovigilance, public health

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