REVIEW ARTICLE

Counterfeit Medicine in India: Are We Heading in the Right Direction at the Desired Pace?

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ABSTRACT

Counterfeit medicines pose a significant global health threat, with developing countries like India particularly vulnerable. This article examines India's efforts to combat pharmaceutical counterfeiting, evaluating the regulatory framework, technological interventions, and enforcement mechanisms against global best practices. While India has made notable strides through legislative reforms and technological innovations, challenges persist in implementation, coordination, and resource allocation. The paper provides a comparative analysis with successful anti-counterfeiting strategies from countries such as the United States, European Union, China, and Nigeria, highlighting lessons India can adopt. The research concludes that while India is moving in the right direction, the pace of progress remains insufficient to address the scale and complexity of the problem. Recommendations include strengthening regulatory capacity, enhancing stakeholder collaboration, investing in advanced detection technologies, improving public awareness campaigns, and accelerating the adoption of global best practices in pharmaceutical authentication and supply chain security.

Keywords: Counterfeit medicines, Artificial Intelligence, Regulatory Framework, Global Surveillance, Global Comparisons.

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INTRODUCTION

Counterfeit medicines represent one of the most pressing public health challenges globally (fig. 1), with an estimated 10-30% of drugs in developing countries being substandard or falsified.[2] India, as one of the world's largest pharmaceutical manufacturers, faces a dual challenge: protecting its domestic market and maintaining its reputation as a reliable global supplier of medicines. The World Health Organization (WHO) defines counterfeit medicines as products that are "deliberately and fraudulently mislabeled with respect to identity and/or source".[3] These products may contain incorrect ingredients, improper dosages, or no active ingredients at all, posing severe health risks to consumers.

India's pharmaceutical sector, valued at approximately $50 billion, accounts for about 20% of global exports of generic medicines.[4] This prominence makes India's approach to combating counterfeit medicines particularly significant. This article examines whether India is moving in the right direction at the desired pace in addressing this critical issue, analyzing the regulatory framework, technological interventions, and enforcement mechanisms currently in place, while contextualizing India's efforts within the global landscape of pharmaceutical counterfeiting.

Global Scope of the Problem

The counterfeit medicine problem extends far beyond India's borders, affecting countries at all economic levels. According to the WHO, the global market for counterfeit pharmaceuticals is estimated to be worth up to $200 billion annually (refer fig. 2). In some African countries, the prevalence of counterfeit medicines can reach as high as 30-40% of the market.[5] Even in highly regulated markets like the United States and European Union, counterfeit medicines have penetrated legitimate supply chains, though at significantly lower rates of 1% or less.[6]

The COVID-19 pandemic exacerbated the problem globally, with Interpol reporting a 18% increase in seizures of counterfeit pharmaceuticals in 2020 compared to the previous year.[8] Counterfeiters exploited supply chain disruptions, increased demand for certain medications, and the rise of online pharmacies during lockdowns. This global context is crucial for understanding the challenges India faces and evaluating its response in comparative perspective.

Regulatory Framework and Legal Measures in India

Evolution of Pharmaceutical Regulations in India

India's regulatory framework for pharmaceuticals has evolved significantly over the years. The Drugs and Cosmetics Act of 1940, amended multiple times, remains the primary legislation governing the manufacture, distribution, and sale of drugs.[9] The 2008 amendment of the Act significantly increased penalties for manufacturing and selling counterfeit medicines, including imprisonment terms of up to life.[10]

More recently, the New Drugs and Clinical Trials Rules (2019) have strengthened the regulatory oversight of new

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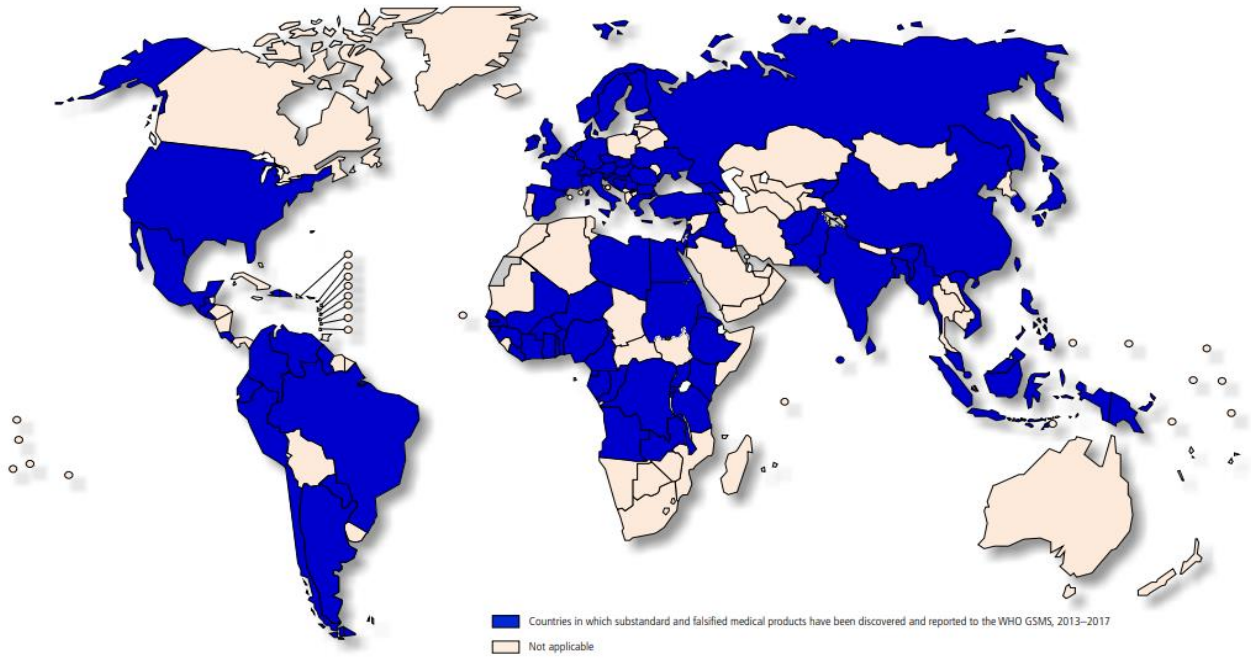

Figure 1: Countries in which Substandard and Falsified Medical Products have been Discovered and Reported to the WHO GSMS, 2013-2017[1]

drugs and clinical trials.[11] The proposed Drugs, Medical Devices, and Cosmetics Bill, 2022 aims to replace the existing Act and incorporate modern regulatory practices, including provisions specifically targeting counterfeit medicines.[12]

Central Drugs Standard Control Organization (CDSCO)

The Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare, serves as the national regulatory body for pharmaceuticals.[13] The CDSCO's role includes setting drug standards, approving new drugs, and coordinating with state drug regulatory authorities. The organization has established a dedicated cell to investigate cases of counterfeit medicines and has been working to enhance its regulatory capacity through training programs and infrastructure development.

State-Level Implementation

While the regulatory framework at the central level appears robust, implementation at the state level remains inconsistent. State drug regulatory authorities often lack the necessary resources, expertise, and personnel to effectively monitor and enforce regulations.[14] The variation in regulatory capacity across states creates vulnerabilities that counterfeiters can exploit. A 2021 audit found that drug testing laboratories in 10 states were operating with less than 30% of the required technical staff.[15], highlighting the resource constraints that hamper effective enforcement.

Global Regulatory Best Practices

United States Regulatory Framework

The United States maintains one of the world's most robust regulatory systems for pharmaceutical security. The Drug Supply Chain Security Act (DSCSA) of 2013 created a comprehensive track and trace system for prescription drugs.[16] The DSCSA mandates a standardized product identifier on each package, establishes requirements for wholesale distributors and third-party logistics providers, and requires electronic product tracing throughout the supply chain.

The US Food and Drug Administration (FDA) also conducts the BeSafeRx campaign to educate consumers about the risks of counterfeit medicines purchased online.[17] Additionally, the FDA's Office of Criminal Investigations works closely with other law enforcement agencies to investigate and prosecute pharmaceutical crimes.

European Union's Falsified Medicines Directive

The European Union implemented the Falsified Medicines Directive (FMD) in 2019, establishing a comprehensive framework to prevent counterfeit medicines from entering the legal supply chain.[18] The FMD requires safety features on medicine packaging, including a unique identifier and an anti-tampering device. It also established a pan-European verification system that allows pharmacies and hospitals to verify the authenticity of medicines before dispensing them to patients.

The European Medicines Agency coordinates a network of national regulatory authorities, facilitating information sharing and coordinated action against pharmaceutical counterfeiting.[19] This multilevel governance approach could offer valuable lessons for India's federal system.

China's Regulatory Response

China, previously identified as a major source of counterfeit medicines, has made significant strides in strengthening its regulatory framework. The country reformed its drug regulatory system following several high-profile scandals, establishing the National Medical Products Administration (NMPA) in 2018.[20] The NMPA implemented a comprehensive electronic tracking system for pharmaceuticals and significantly increased penalties for counterfeiting under the revised Drug Administration Law of 2019.[21]

China's approach included centralizing regulatory authority, investing heavily in laboratory and inspection capacities, and implementing severe criminal penalties for violators. These measures have reportedly reduced the prevalence of counterfeit medicines in the domestic market and diminished China's role as an exporter of counterfeit pharmaceuticals.[22]

Technological Interventions in India

Track and Trace Systems

India has made significant strides in implementing track and trace systems for pharmaceutical products. The Directorate General of Foreign Trade (DGFT) mandated the implementation of barcoding for all pharmaceutical exports in 2011.[23] This system enables the tracking of products throughout the supply chain, from manufacturer to end-user (indicated in fig. 3).

In 2015, the government launched the Pharma Sahi Daam (right price for pharmaceuticals) mobile application, which allows consumers to verify the authenticity and price of medicines.[24] While these initiatives represent positive steps, their implementation has faced challenges due to the complexity of the supply chain, the need for substantial investment in infrastructure, and resistance from some stakeholders.

Unlike the EU's FMD or the US DSCSA, India has not yet implemented a comprehensive domestic track and trace system that covers the entire pharmaceutical supply chain. The focus has primarily been on exports, leaving the domestic market more vulnerable to infiltration by counterfeit products.

Innovative Authentication Technologies

Several innovative technologies are being deployed and some are on developing stage to combat counterfeit medicines in India. These include:

- Already used - Holographic labels and security seals
- Under development
- Radio Frequency Identification (RFID) tags- used in USA
- Blockchain technology for supply chain transparency
- Artificial Intelligence (AI) and Machine Learning (ML) for detecting counterfeit patterns
- Mobile authentication services that allow consumers to verify product authenticity via SMS-Used in Nigeria

The Indian pharmaceutical industry has been increasingly adopting these technologies, with major companies implementing multi-layered security features on their products.[25] However, the adoption of these technologies remains fragmented, with smaller manufacturers often unable to afford the necessary investments.

Global Technological Innovations

Advanced Track and Trace in Turkey

Turkey implemented one of the world's first comprehensive pharmaceutical track and trace systems in 2010. The Turkish Pharmaceutical Track and Trace System (İTS) assigns a unique serial number to each pharmaceutical package and tracks it through the entire supply chain.[26] The system has been highly successful, reducing counterfeit medicines in the Turkish market to nearly zero and serving as a model for other countries.

Turkey's system demonstrates the potential impact of a well-implemented national track and trace system, offering valuable lessons for India as it works to expand its own tracking capabilities beyond exports to include the domestic market.

Nigeria's Mobile Authentication Service

Nigeria faced a severe counterfeit medicine problem, with some estimates suggesting that up to 70% of pharmaceuticals in the country were substandard or falsified in the early 2000s.[27] In response, Nigeria implemented the Mobile Authentication Service (MAS), which allows consumers to verify the authenticity of their medications through a free SMS service.[28]

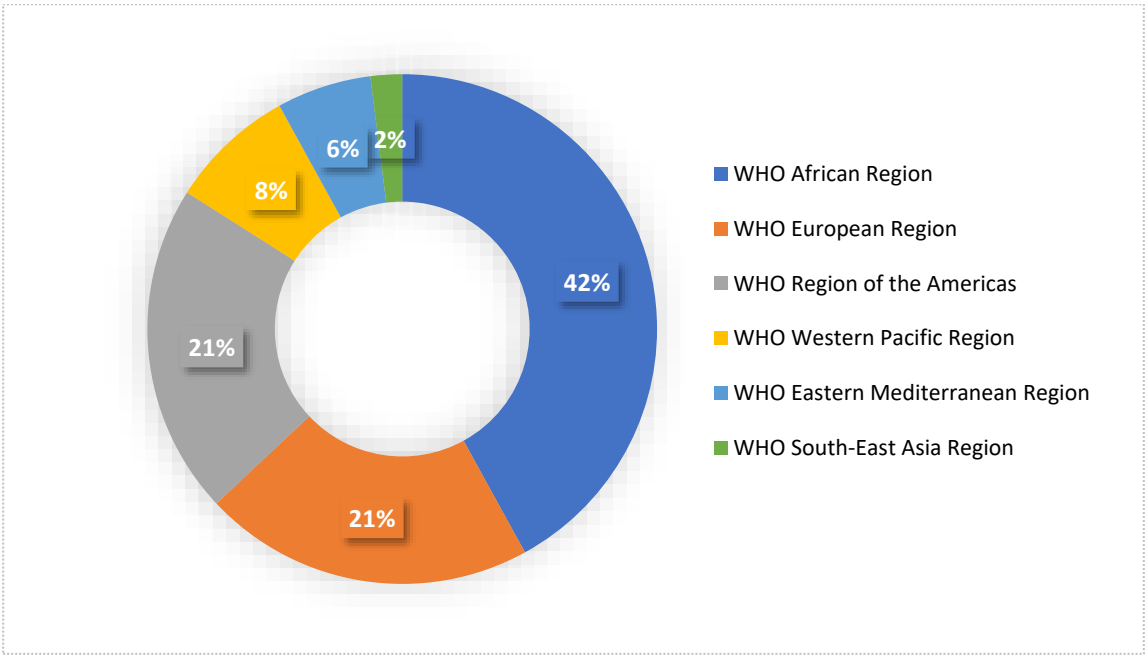

Figure 2: Percentage of Reports from Each WHO Region to the GSMS: Global System for Mobile Health (mHealth) Survey (2013-2017)[7]

The MAS system places a scratch-off panel on medicine packaging, revealing a unique code that consumers can text to a designated number for immediate verification. This simple yet effective solution has significantly reduced the prevalence of counterfeit medicines in Nigeria and increased consumer confidence in pharmaceuticals.

Blockchain Technology in the Pharmaceutical Supply Chain

Several countries, including the United States, Switzerland, and Singapore, have piloted blockchain-based systems for pharmaceutical supply chain security.[29] Blockchain technology creates an immutable record of transactions throughout the supply chain, making it nearly impossible for counterfeiters to introduce fake products without detection.

MediLedger, a blockchain-based system developed in the United States, connects manufacturers, wholesalers, and pharmacies in a secure network that ensures product authenticity and compliance with regulatory requirements.[30] Such systems represent the cutting edge of pharmaceutical security and could offer a model for India's future technological developments.

Enforcement Mechanisms and Challenges in India

Enforcement Challenges

Despite strengthened legal provisions, enforcement remains a significant challenge. The 2018 report by the Office of the United States Trade Representative (USTR) highlighted India as one of the countries with high levels of counterfeit pharmaceutical production and distribution.[31] Factors contributing to enforcement challenges include:

- Limited resources and capacity of regulatory authorities
- Inadequate coordination between central and state agencies
- Corruption and bureaucratic inefficiencies
- Lack of specialized training for enforcement personnel
- Insufficient penalties for repeat offenders

A 2019 study found that drug inspectors in India are responsible for monitoring an average of 197 retail outlets and 64 manufacturing facilities each, compared to the WHO recommended ratio of 10 outlets per inspector.[32] This severe understaffing makes comprehensive monitoring virtually impossible.

Figure 3: Retail Barcodes for India

Recent Enforcement Initiatives

In response to these challenges, India has implemented several initiatives to enhance enforcement:

- Establishment of specialized units within the CDSCO to address counterfeit medicines
- Implementation of risk-based inspection systems
- Increased frequency of inspections at manufacturing facilities and distribution channels
- Collaboration with international organizations such as WHO and Interpol
- Public-private partnerships for information sharing and joint enforcement actions

The effectiveness of these initiatives, however, remains limited by resource constraints and coordination issues. The budget allocation for drug regulatory activities at both central and state levels remains inadequate relative to the scale of the pharmaceutical sector and the counterfeit medicine problem.

Global Enforcement Success Stories

Operation Pangea

Interpol's Operation Pangea represents one of the most successful international enforcement efforts against counterfeit medicines.[33] This annual operation targets the online sale of counterfeit and illicit pharmaceuticals, involving police, customs, and health regulatory authorities from countries worldwide, including India.

The 2021 iteration of Operation Pangea resulted in the seizure of more than 9 million units of counterfeit pharmaceuticals globally and the shutdown of 113,000 websites selling illegal medicines.[34] This collaborative approach demonstrates the potential impact of coordinated international enforcement efforts.

South Korea's Pharmaceutical Crime Investigation Unit

South Korea established a specialized Pharmaceutical Crime Investigation Unit within its Ministry of Food and Drug Safety in 2013.[35] This dedicated unit consists of investigators with specialized training in pharmaceutical crimes and has the authority to conduct criminal investigations independently.

The unit has successfully reduced the prevalence of counterfeit medicines in South Korea to one of the lowest levels globally. Its success demonstrates the value of dedicated, specialized enforcement units with sufficient resources and authority.

United States' Import Alert System

The US FDA maintains an Import Alert system that allows for the detention without physical examination of drugs from manufacturers or countries with a history of violations.[36] This proactive approach has effectively prevented many counterfeit pharmaceuticals from entering the US market.

The system is supported by a network of international offices and collaborations with foreign regulatory authorities. This global perspective allows for more effective enforcement against transnational counterfeiting operations.

International Cooperation and Harmonization

India's Global Partnerships

India has been actively participating in international efforts to combat counterfeit medicines. The country is a member of the WHO's Member State Mechanism on substandard and falsified medical products and has collaborated with Interpol in operations targeting counterfeit medicines.[37]

In 2019, India joined the Pharmaceutical Inspection Co-operation Scheme (PIC/S) as an observer, demonstrating its commitment to harmonizing its regulatory practices with international standards.[38] Additionally, bilateral agreements with countries like the United States and the European Union have facilitated information sharing and joint enforcement actions.

Harmonization Efforts

India has made efforts to harmonize its regulatory standards with international norms, including the WHO's Good Manufacturing Practices (GMP) and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines.[39] These harmonization efforts contribute to the overall quality and safety of pharmaceutical products.

However, full compliance with international standards remains a work in progress, with gaps in implementation and enforcement. A 2022 assessment found that only about 60% of Indian pharmaceutical manufacturers were fully compliant with WHO GMP standards, highlighting the need for continued improvement.[40]

Global Cooperation Models

The MEDICRIME Convention

The Council of Europe's MEDICRIME Convention, which came into force in 2016, is the first international criminal law instrument to criminalize the production and distribution of counterfeit medicines.[41] The convention establishes a framework for international cooperation in investigating and prosecuting pharmaceutical crimes.

While India is not a signatory to the MEDICRIME Convention, its framework offers valuable lessons for enhancing international cooperation against counterfeit medicines. The convention's emphasis on specialized investigative units, cross-border cooperation, and victim protection could inform India's approach to international collaboration.

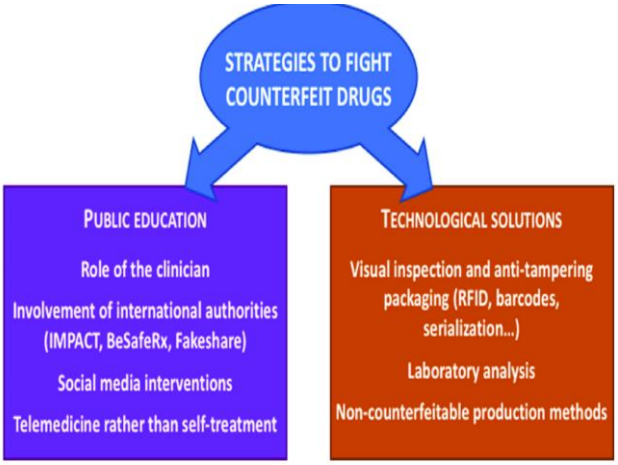

Figure 4: Strategies to fight counterfeit medications

WHO Global Surveillance and Monitoring System

The WHO established the Global Surveillance and Monitoring System for substandard and falsified medical products in 2013.[42] This system collects data on counterfeit medicines from member states, facilitates information sharing, and provides technical support for investigations.

India participates in this system, but reporting remains inconsistent. Enhanced engagement with the WHO surveillance system could improve India's capacity to detect and respond to counterfeit medicines.

Regional Harmonization Initiatives

Regional regulatory harmonization initiatives, such as the African Medicines Regulatory Harmonization (AMRH) program, have demonstrated success in strengthening pharmaceutical regulation across multiple countries.[43]

These initiatives involve sharing resources, coordinating inspections, and standardizing regulatory requirements.

India could benefit from similar regional cooperation within South Asia, potentially through the South Asian Association for Regional Cooperation (SAARC) framework. Such regional harmonization could address cross-border trafficking of counterfeit medicines more effectively.

Public Awareness and Education in India

Consumer Education Initiatives

Public awareness is crucial in combating counterfeit medicines. The Indian government, in collaboration with industry associations and NGOs, has conducted awareness campaigns to educate consumers about the risks of counterfeit medicines and how to identify them.[44] These initiatives include:

- Public service announcements in various media
- Educational materials distributed through healthcare facilities
- Mobile applications for verifying medicine authenticity
- Workshops and seminars for healthcare professionals

While these efforts are commendable, their reach and impact remain limited, particularly in rural and remote areas where counterfeit medicines often proliferate. A 2020 survey found that only 37% of Indian consumers were aware of the existence of counterfeit medicines, and even fewer knew how to identify them.[45]

Whistleblower Protection

In 2014, India introduced whistleblower protection legislation to encourage reporting of illegal activities, including the production and distribution of counterfeit medicines.[46] However, the implementation of this legislation has been inconsistent, with whistleblowers often facing retaliation despite legal protections.

Global Awareness Best Practices

Australia's Be Medicinewise Campaign

Australia's National Prescribing Service (NPS) MedicineWise runs the comprehensive "Be Medicinewise" campaign, which educates consumers about all aspects of medicine safety, including how to avoid counterfeit products.[47] The campaign uses multiple channels, including television, social media, and community workshops, to reach different demographic groups.

The campaign's success is regularly evaluated through consumer surveys, which show increasing awareness of

medicine safety issues. This evidence-based approach to public education could serve as a model for India's awareness efforts.

Canada's Buying Safe Medicines Program

Health Canada's Buying Safe Medicines program focuses specifically on educating consumers about the risks of counterfeit medicines and how to purchase medications safely, particularly from online sources.[48] The program provides clear guidelines for identifying legitimate pharmacies and recognizing warning signs of counterfeit products.

The program has been particularly effective in addressing the growing trend of online medicine purchases, which present unique challenges for regulatory oversight. Given India's rapidly expanding e-pharmacy sector, similar targeted awareness campaigns could be valuable.

Philippines' Oplan Katharos Campaign

The Philippines' Food and Drug Administration launched the Oplan Katharos campaign, which combines public education with enforcement activities.[49] The campaign includes a reporting system that allows consumers to report suspected counterfeit medicines via SMS or online platforms, creating a direct link between awareness and enforcement.

This integrated approach has increased public participation in combating counterfeit medicines and provided valuable intelligence for enforcement efforts. A similar system in India could leverage the country's high mobile phone penetration to enhance both awareness and reporting.

Private Sector Involvement

Industry Initiatives in India

The Indian pharmaceutical industry, through organizations such as the Indian Pharmaceutical Alliance (IPA) and the Federation of Indian Chambers of Commerce and Industry (FICCI), has implemented several initiatives to combat counterfeit medicines.[50] These include:

- Development of authentication technologies
- Training programs for stakeholders in the supply chain
- Advocacy for stronger regulatory measures
- Public awareness campaigns

In 2020, FICCI launched the CASCADE (Committee Against Smuggling and Counterfeiting Activities Destroying the Economy) initiative, which focuses specifically on counterfeit products, including pharmaceuticals.[44] While these industry-led efforts are valuable, their impact could be enhanced through better coordination with government initiatives.

Public-Private Partnerships

Public-private partnerships have emerged as a promising approach to address the counterfeit medicine problem. The Partnership for Safe Medicines India (PSM India), established in 2010, brings together pharmaceutical companies, healthcare professionals, patient organizations, and regulatory authorities to combat counterfeit medicines through education and advocacy.[51]

Similarly, the Authentication Solution Providers' Association (ASPA) works with both government agencies and private companies to develop and implement anti-counterfeiting technologies.[52] These collaborative approaches leverage the strengths of both sectors but require stronger institutional support and resources to maximize their impact.

Global Industry Collaboration Models

The Pharmaceutical Security Institute (PSI), a global organization of pharmaceutical companies, coordinates intelligence-sharing and enforcement actions against counterfeit medicines across borders.[53] PSI's collaborative model has been effective in identifying and disrupting major counterfeiting operations.

The Alliance for Safe Online Pharmacies (ASOP Global) brings together industry stakeholders, government agencies, and non-profit organizations to address the challenges of illegal online pharmacies and counterfeit medicines sold through digital channels.[54] Given the growing importance of e-commerce in the pharmaceutical sector, similar focused collaborations could be valuable for India.

Impact on Public Health and Economy

Health Consequences

The health consequences of counterfeit medicines in India are severe and far-reaching. A 2023 study estimated that substandard and falsified antimicrobials contribute to approximately 72,000 deaths annually from childhood pneumonia and malaria in India.[55] Counterfeit medicines also contribute to antimicrobial resistance, treatment failures, and increased healthcare costs.

Particularly vulnerable populations, including those in rural areas with limited access to regulated pharmacies, bear a disproportionate burden of these health consequences. The COVID-19 pandemic highlighted these vulnerabilities, with counterfeit vaccines and treatments emerging in various parts of the country.[56]

Economic Impact

The economic impact of counterfeit medicines extends beyond direct health costs. The Indian pharmaceutical industry loses an estimated $4.3 billion annually due to counterfeiting, reducing tax revenues, employment opportunities, and investment in research and development.[57] The reputational damage to India's pharmaceutical exports, valued at over $24 billion annually, could have long-term economic consequences.[58]

A 2024 analysis by FICCI estimated that counterfeiting across sectors, including pharmaceuticals, costs the Indian economy approximately $30 billion annually.[44] Addressing this issue effectively could yield significant economic benefits alongside the more important public health improvements.

Global Comparisons

Studies comparing the economic impact of counterfeit medicines across countries highlight the relatively higher burden on developing economies like India. While developed countries typically lose 1-3% of pharmaceutical sales to counterfeiting, the figure for developing countries can reach 20-30%.[59] This discrepancy reflects the varying effectiveness of regulatory and enforcement measures.

The World Economic Forum has identified counterfeit medicines as one of the key challenges to achieving sustainable development goals related to health and economic growth, particularly in middle-income countries

like India.[60] Addressing this challenge effectively requires not only national action but also global cooperation.

CONCLUSION AND RECOMMENDATIONS

Assessment of India's Progress

India has made significant progress in addressing the counterfeit medicine problem through regulatory reforms, technological innovations, and international cooperation. The legal framework has been strengthened, with severe penalties for counterfeiting and increased regulatory oversight of pharmaceutical manufacturing and distribution. Technological initiatives, particularly for exported pharmaceuticals, have improved traceability and authentication.

However, the pace of progress remains insufficient relative to the scale and complexity of the problem. Implementation gaps, resource constraints, coordination challenges, and limited public awareness continue to hamper effective action against counterfeit medicines. The focus on exports rather than the domestic market has left significant vulnerabilities that counterfeiters continue to exploit.

While India is moving in the right direction, accelerated and more comprehensive action is needed to protect public health and maintain the country's position as a trusted global supplier of pharmaceuticals.

Key Recommendations

Based on the analysis presented in this article, the following recommendations emerge for strengthening India's efforts to combat counterfeit medicines:

Strengthen Regulatory Capacity

- Increase financial and human resources for regulatory authorities at both central and state levels
- Establish specialized training programs for regulatory personnel
- Implement uniform standards and procedures across all states
- Strengthen laboratory infrastructure for testing and analysis

Enhance Stakeholder Collaboration

- Formalize collaboration mechanisms between central and state regulatory authorities
- Strengthen public-private partnerships for information sharing and joint action
- Engage healthcare professionals, patient organizations, and consumer groups in anti-counterfeiting efforts
- Establish a national coordination center for counterfeit medicine intelligence and response

Invest in Advanced Detection Technologies

- Implement a comprehensive domestic track and trace system covering the entire supply chain
- Support the adoption of authentication technologies by smaller manufacturers
- Leverage emerging technologies such as AI, blockchain, and IoT for supply chain security
- Develop mobile authentication services accessible to consumers across the country

Improve Public Awareness and Education

- Launch comprehensive nationwide awareness campaigns using multiple channels
- Develop targeted education programs for vulnerable populations
- Strengthen whistleblower protections and reporting mechanisms
- Include counterfeit medicine awareness in healthcare professional training

Accelerate International Harmonization and Cooperation

- Pursue full membership in international regulatory networks such as PIC/S
- Consider joining the MEDICRIME Convention or adopting its principles
- Enhance participation in the WHO Global Surveillance and Monitoring System
- Lead regional harmonization efforts within South Asia

Focus on E-Pharmacy Regulation

- Develop specific regulatory frameworks for online pharmacies
- Implement digital authentication mechanisms for online medicine purchases
- Conduct targeted enforcement operations against illegal online pharmacies
- Launch awareness campaigns specifically addressing online medicine purchases

By implementing these recommendations, India can accelerate its progress in combating counterfeit medicines, protecting public health, and maintaining its position as a trusted global pharmaceutical supplier. The experiences of other countries demonstrate that significant improvements are possible with sustained, comprehensive efforts involving all stakeholders.

The counterfeit medicine problem represents not only a public health challenge but also an opportunity for India to demonstrate leadership in pharmaceutical quality and safety. With its significant scientific and technological capabilities, strong pharmaceutical industry, and increasing global influence, India has the potential to transform from a country of concern to a model of best practice in ensuring the integrity of the pharmaceutgical supply chain.

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