



A Comparative Study on the Review and Evaluation of the Regulatory Process of Spurious and not Standard Quality Drugs in Different Countries

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ABSTRACT

To protect the public's health, the pharmaceutical business must first ensure the efficacy and safety of its products. In this comparative study, the regulatory frameworks for fake and inferior-quality medicines in India and the United States are analysed and contrasted. The study uses a mixed-approaches methodology, combining qualitative and quantitative research methods. Interviews with important figures from pharmaceutical corporations, healthcare organisations, and regulatory authorities are used to collect primary data. These interviews are combined with a thorough analysis of the literature, laws, and case studies that have already been published. We evaluate the efficacy of corrective measures implemented by regulatory bodies to reduce the dangers associated with fake and subpar medications. The comparative research identifies the regulatory frameworks of each nation's strong and weak points, revealing possible areas for development. Suggestions are made for improving inter-agency communication, streamlining inspection processes, and implementing cutting-edge technologies for improved surveillance. In the end, this study contributes to the global conversation on drug regulation and public health by illuminating the obstacles and opportunities that India and the USA must overcome in their fight against fake and subpar medications. Policy makers, regulatory bodies, and stakeholders in both nations are likely to benefit from the research's findings, which will help create a more effective and flexible regulatory framework for pharmaceuticals.



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INTRODUCTION

India, as a developing country, faces significant challenges, with over 40% of its population living on less than \$1 a day. Those in need of opioid treatment often find it financially burdensome, paying over half their income. To address this, the Indian government has introduced various initiatives to provide generic pharmaceuticals to different patient groups. However, due to low-cost tariffs and easy access, individuals sometimes choose counterfeit drugs over authentic ones, leading to opioid overdose and antibiotic failure, contributing to bacterial resistance [1]. The right to well-being is recognized as a fundamental right in India, enshrined in the national constitution and supported by legal

and international guidelines. While over 1.24 billion Indian citizen's benefit from this right, around 2 billion people worldwide, a third of whom belong to the world's poor, lack access to basic medical care. Drugs are vital for their survival, but the cost burden falls heavily on the infected individuals, particularly in low and middle-income countries, where they pay 20-60% of care costs and more than 50-90% for drugs. The issue of drug quality is a growing concern, with counterfeit drugs posing a significant threat. Different terms like spurious, falsified, and counterfeit (SFCC) drugs are used to describe these illegal products. The World Health Organization's (WHO) International Medical Product Anticounterfeiting Task Force (IMPACT) defines SFCC drugs as intentionally and fraudulently identified or misbranded products, which may not contain the right ingredients or may have incorrect packaging [1].

In India, poor-quality drugs are categorized under the Drug and Cosmetic (D and C) Act of 1940, which includes misbranded, spurious, and adulterated drugs. The Central Drugs Standard Control Organization (CDSCO), the Indian drug regulatory authority, further categorizes not-of-standard quality (NSQ) products into three categories: A, B, and C. Category A comprises spurious and adulterated drugs that may imitate well-known brands and may or may not contain active ingredients. Category B includes grossly substandard drugs that fail disintegration or dissolution tests, with active ingredient assays below 70% or 5% of permitted limits for thermolabile and thermo-stable products, respectively. Category C involves products with minor defects or variations in formulation, labelling, or content. This issue of lower-quality drugs poses a serious and increasing risk, warranting urgent attention and regulatory actions [2].

METHODOLOGY

Comparative Analysis

Similarities and Differences in the Regulatory Processes of Both Countries

It provides a comprehensive comparison of the regulatory processes for spurious and not standard quality drugs in India and the USA. Identify the similarities and differences in their drug approval timelines, requirements, and post-marketing surveillance mechanisms. Discuss the organizational structures and roles of the respective regulatory agencies, CDSCO in India and FDA in the USA.

Assessment of the Effectiveness of Each Regulatory System in Combating Spurious and Not Stan-

ard Quality Drugs

Assess the effectiveness of each country's regulatory system in combating spurious and not standard quality drugs. Analyse the regulatory agencies' track records in detecting and preventing the entry of such drugs into the market. Evaluate the frequency and scale of incidents related to spurious drugs in each country and how effectively the regulatory bodies respond to such incidents. Discuss the impact of the regulatory processes on public health, patient safety, and the pharmaceutical industries in India and the USA. Use qualitative and quantitative data to support your assessment.

Identification of Best Practices and Potential Areas for Improvement in Each Country

To identify and discuss the best practices observed in the regulatory processes of both countries concerning spurious and not standard quality drugs. Highlight any specific strategies, technologies, or policies that have been successful in one country and could be adopted by the other. Emphasize the importance of cross-country learning and collaboration in strengthening drug regulation and combating counterfeit drugs. Additionally, identify potential areas for improvement in each country's regulatory framework, addressing the weaknesses and challenges identified.

Select Case Studies of Spurious and Not Standard Quality Drugs in India and the USA

Specific case studies of incidents involving spurious and not standard quality drugs in both India and the USA. Choose representative cases that highlight different aspects of the issue, such as counterfeit drugs, substandard medications, or illegal manufacturing and distribution. Ensure that the cases have sufficient information available in the public domain to facilitate a detailed analysis.

For example, select a case in India where a counterfeit drug entered the market and caused harm to patients, and a similar case in the USA where a substandard drug resulted in adverse effects. Include information about the drugs involved, the affected patients, the healthcare facilities impacted, and any relevant legal actions taken against the perpetrators. Use credible sources such as official reports, news articles, and academic publications for the case studies.

Analysis of How Each Country's Regulatory Process Handled These Cases

In this analyse how each country's regulatory process handled the selected case studies of spurious and not standard quality drugs. Evaluate the responsiveness of the regulatory agencies (CDSCO in

India and FDA in the USA) in detecting and responding to these incidents. Discuss the investigation procedures, communication with the public, and measures taken to mitigate the impact. Compare the effectiveness of the regulatory actions and the outcomes of each case study. Consider the coordination between regulatory bodies, law enforcement, and other stakeholders in addressing these drug quality issues.

Lessons Learned and Implications for Future Improvements

The key lessons learned from the case studies and their implications for future improvements in the regulatory processes of both countries. Discuss the strengths and weaknesses of the regulatory response to each case and draw broader insights on what worked well and what could have been handled better. Analyse the impact of each incident on public health, patient safety, and the pharmaceutical industry. Consider the economic implications of such incidents, including healthcare costs and loss of public trust in medications [3].

Based on the analysis, propose actionable recommendations and strategies for strengthening the regulatory processes in both India and the USA. These recommendations should be informed by the insights gained from the case studies and align with the best practices identified. Consider the challenges faced by regulatory agencies and the potential areas for improvement to prevent and respond to future cases of spurious and not standard quality drugs effectively. Discuss the need for enhanced surveillance, collaboration with international partners, and the use of advanced technologies to combat counterfeit and substandard drugs.

Ensure that the lessons learned and implications for future improvements are supported by evidence from the case studies and relevant research. You may also draw on expert opinions or interviews with regulatory officials and stakeholders to provide a well-rounded perspective on the potential improvements. By providing detailed case studies, analysing the regulatory responses, and drawing valuable lessons and implications for future improvements, this chapter contributes significantly to the practical implications of your research. It demonstrates the real-world impact of the regulatory processes and offers evidence-based recommendations for enhancing drug regulation in India and the USA.

Proposed Recommendations for Strengthening the Regulatory Process in Both India and the USA

A set of proposed recommendations aimed at strengthening the regulatory processes in both India

and the USA concerning spurious and not standard quality drugs. These recommendations should be based on the findings from the comparative analysis in Chapter 6 and the insights gained.

a. **Enhancing Post-Marketing Surveillance:** Propose strategies for improving post-marketing surveillance to detect and respond quickly to incidents involving spurious and not standard quality drugs. This may include the use of advanced data analytics, pharmacovigilance systems, and collaboration with healthcare professionals and patients to report adverse events.

b. **Strengthening Inspection and Enforcement:** Recommend measures to enhance the inspection and enforcement activities of the regulatory agencies. This could involve increasing the frequency and scope of inspections, implementing risk-based approaches to target high-risk facilities, and imposing stricter penalties for non-compliance [4].

c. **Promoting Public Awareness and Education:** Suggest initiatives to educate the public and healthcare professionals about the risks associated with spurious and not standard quality drugs. This may include awareness campaigns, information dissemination through digital platforms, and promoting responsible use of medications.

d. **Emphasizing International Collaboration:** Advocate for stronger collaboration between regulatory agencies in India and the USA. Encourage information sharing, joint training programs, and mutual recognition of inspections to enhance the exchange of best practices and resources.

e. **Implementing Track and Trace Technologies:** Recommend the implementation of track and trace technologies to improve the traceability and authentication of drugs throughout the supply chain. This can help prevent counterfeit drugs from entering the market and ensure the integrity of the pharmaceutical supply [5].

Suggestions for Collaboration and Mutual Learning between the Two Countries

Elaborate on specific suggestions for collaboration and mutual learning between India and the USA to address the issue of spurious and not standard quality drugs.

a. **Bilateral Workshops and Seminars:** Propose organizing joint workshops, seminars, and conferences where regulatory officials, industry representatives, and experts from both countries can share experiences, challenges, and best practices in drug regulation.

b. **Exchange Programs and Secondments:** Recommend the establishment of exchange programs and

secondments between regulatory agencies to foster mutual learning and knowledge transfer. This can facilitate a deeper understanding of each other's regulatory frameworks and operations.

c. **Data Sharing and Information Exchange:** Suggest mechanisms for sharing relevant data, information, and intelligence related to drug safety and quality. This could include creating a secure platform for confidential information exchange [6].

d. **Harmonization of Standards:** Advocate for harmonizing certain aspects of the regulatory standards and requirements between the two countries to reduce redundancies and streamline the drug approval process.

Policy Implications for Global Efforts to Combat Spurious and Not Standard Quality Drugs

The broader policy implications of the research for global efforts to combat spurious and not standard quality drugs. Consider how the experiences and recommendations from India and the USA can be applied to other countries facing similar challenges.

Strengthening International Cooperation: Emphasize the importance of international cooperation and collaboration among regulatory agencies, law enforcement, and intergovernmental organizations to tackle the global issue of counterfeit and substandard drugs.

Standardizing Good Manufacturing Practices: Propose the adoption of standardized Good Manufacturing Practices (GMP) and quality control measures globally to ensure the production of safe and effective medications [7].

Technology-Driven Solutions: Highlight the role of technology-driven solutions, such as block chain and data analytics, in preventing drug counterfeiting and ensuring the integrity of the pharmaceutical supply chain at a global level.

Supporting Developing Nations: Discuss ways to support developing nations in strengthening their regulatory capacity and combating the menace of spurious and not standard quality drugs. It serves as a critical component of the thesis, offering valuable insights for policymakers, regulatory agencies, and stakeholders involved in drug regulation and public health efforts.

DISCUSSION

The pharmaceutical market in India has experienced rapid growth, becoming increasingly important for vaccines, generic medicines, and various other pharmaceutical products. Ensuring global health coverage requires not only increasing access to medical products but also ensuring their safety and quality. Indian drug regulators have become

more vigilant in enforcing drug quality standards and regulations among manufacturers. However, manufacturers of not-of-standard quality (NSQ) and spurious drugs often go unpunished due to certain loopholes. India has become a prominent destination for medicine exports, with many Indian pharma companies obtaining approvals from international regulators like USFDA, MHRA, and others. Nevertheless, concerns have been raised by the USFDA about the quality and efficacy of medicines sold in India.

Spurious and NSQ drugs pose significant risks to public health worldwide, affecting both generic and branded products. Various factors, including drug prices, competition, employment, and market transparency, influence the standard quality requirements. In response to the growing public health concern, global regulatory efforts have been established. India is focused on improving drug regulations to combat the spread of spurious and NSQ drugs. It has taken various initiatives and adopted protective measures to safeguard public health. The government's focus on healthcare as a top priority has led to the implementation of novel policies and programs to improve access to affordable, quality, and safe healthcare. Budget allocations have been increased to support the pharmaceutical segment, and efforts have been made to make generic drugs more accessible and affordable.

The public believes that the updated quality and regulatory systems adopted by state and central drug control offices will effectively minimize the availability of NSQ and spurious drugs in the market. Regular surveillance programs implemented by regulatory authorities will instil confidence and ensure the quality, safety, and efficacy of drugs and formulations for the Indian public in comparison to global regulatory standards.

In conclusion, continuous efforts by Indian regulatory authorities and the government's commitment to public health are crucial in ensuring access to high-quality pharmaceuticals and protecting the well-being of the vast patient population. Strengthening the drug regulatory process is essential to address the challenges posed by spurious and NSQ drugs effectively.

CONCLUSION

India needs further strong regulatory policy for curbing or preventing the sale of spurious drugs. For control of medical examination Good clinical practice (GCP) is adopted for examination that involve the participation of human subjects during clinical evaluation. To provide various methods for registration, advertising, and marketing with cer-

tain timelines. Pharmacovigilance program should be launched on drugs, vaccines, and blood products to detect the benefit/risk ratio. This will in turn provide information on quality of medicines. By the comparison of drugs with US and Europe markets, Indian market needs more awareness amongst the health care providers and public about the safety of medicine. Looking at developed countries regulatory framework on Spurious and not of standard quality drugs, Indian Regulatory must move forward in establishing one system across the nation for Quality evaluation, product registration and product supply chain tracking system. This will enable medical fraternity and public for better access to information about the safety of Drug formulation in India. Development of Technology (RFID – Radio Frequency Identification) with respect to Information about licensing/Permission for manufacture and sale will curb any spurious and NSQ Drugs availability in the Indian Market. (For better reconciliation of products manufactured) Track and Trace will enable the regulators to monitor more closely with the supply chain. The policy on Spurious Drugs and NSQ must include the technology utilization for better surveillance in the marketplace. A common web-based or cloud computing across all the Drugs Control Departments (State and central) so that information is not varied and easily accessible in turn it will help to curb the menace of not standard quality Drugs. This system of cloud computing will enable all the regulators to get the information about product permission issued/granted at various states for the manufacture of Drug substances and Drug Products. This uniform approach will resolve the quality, safety and efficacy issues about Drugs Products. A detailed information availability on a common website under CDSCO or State Drugs Control with a different domain if made available on par with Europe and USA will help the regulators. A central portal is the need of the hour to ensure the Not of Standard Quality Drugs is not available in the market and for human consumption. Effective withdrawal from, Policy must include mandates like Overt (Human Visible) and Covert (Machine Visible) features which should be available on all the unit packs sold at retailer level. Moreover, regulators must not permit any manufacturer who does not comply with this requirement. There must be periodic review on quality and safety by the regulators about Drugs products which are sold at very high volumes to curb the menace of Spurious Drugs. Periodic change in Pack size and shape of the container including label design change must be mandated to manufacturer by Regulators, this will in turn curb the menace of spurious Drugs. The policy

must include post marketing surveillance for quality safety and efficacy, and manufacturers to conduct periodic evaluation on fast-moving products and high-value small volume product. Import Permission granted to importers must include evaluation in the near future it is essential for Indian Regulatory Agency to have a strong policy on NSQ and Spurious Drugs.

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