

NAVIGATING THE REGULATORY LANDSCAPE: ENSURING DRUG SAFETY IN THE FACE OF SPURIOUS DRUGS

Dr Dilip Bhaurao Timande, Research Scholar, Central Christian University

ABSTRACT

The proliferation of spurious drugs poses a grave threat to public health globally, necessitating robust regulatory frameworks to ensure drug safety. This paper navigates through the intricate regulatory landscape aimed at countering the menace of spurious drugs. Beginning with an exploration of the history and sources of spurious drugs, including the alarming rise of Substandard, Falsified, and Counterfeit (SFFC) medicines, the paper highlights the pandemic nature of this threat. The Indian scenario of spurious drugs is examined, shedding light on their detrimental effects on human health, including treatment failures and adverse reactions. Central to the discourse is the concept of drug safety, emphasizing the paramount importance of quality assurance measures in pharmaceutical regulation. Against this backdrop, the paper delves into the regulatory landscape designed to combat spurious drugs and ensure drug safety. Through a comprehensive analysis, various regulatory mechanisms and initiatives aimed at detecting, preventing, and mitigating the circulation of counterfeit medicines are elucidated. In conclusion, the paper underscores the critical need for collaborative efforts among regulatory agencies, industry stakeholders, and healthcare professionals to navigate the regulatory landscape effectively and safeguard public health. By embracing innovative counterfeit detection technologies and bolstering quality assurance measures, regulatory frameworks can evolve to meet the challenges posed by spurious drugs, thereby ensuring the integrity of pharmaceutical supply chains and the safety of patients.

Keywords: Spurious drugs, regulatory frameworks, drug safety, pharmaceutical regulation, counterfeit medicines, quality assurance, public health, counterfeit detection technologies, etc.

I. INTRODUCTION

The integrity of the pharmaceutical supply chain is indispensable for safeguarding public health and ensuring the efficacy and safety of medicinal products. However, amidst the complexity of global markets and the proliferation of counterfeit medicines, maintaining this integrity poses significant challenges. Spurious drugs, including counterfeit, falsified, substandard, and unregistered pharmaceuticals, represent a formidable threat to public health worldwide. These illicit products infiltrate legitimate supply chains, often with dire consequences for patients, healthcare systems, and regulatory authorities.

The historical evolution of spurious drugs reveals a persistent and evolving threat to drug safety. From rudimentary counterfeit operations to sophisticated global networks, the landscape of illicit pharmaceuticals has undergone a dramatic transformation. The emergence of Substandard, Falsified, and Counterfeit (SFFC) medicines as a pandemic threat underscores the urgency of addressing this multifaceted challenge. These products not only undermine the efficacy of legitimate treatments but also pose serious risks of adverse reactions, treatment failures, and antimicrobial resistance.

Nowhere is the impact of spurious drugs more pronounced than in countries like India, where regulatory oversight may be inadequate, and market dynamics foster the proliferation of counterfeit medicines. The Indian scenario provides a compelling case study of the human toll exacted by spurious drugs, with reports of treatment failures, adverse reactions, and public health crises. Against this backdrop, it becomes imperative to examine the regulatory frameworks designed to ensure drug safety and combat the menace of counterfeit medicines.

Central to the discourse on drug safety is the concept of regulatory oversight and quality assurance. Regulatory authorities play a pivotal role in establishing and enforcing standards for pharmaceutical products, from manufacturing to distribution and beyond. However, the effectiveness of these regulatory frameworks hinges on their ability to adapt to evolving threats and technologies. In the face of counterfeit detection technologies, regulatory agencies must continually innovate and collaborate to stay ahead of counterfeiters and protect public health.

This article navigates through the complex regulatory landscape aimed at ensuring drug safety in the face of spurious drugs. By critically examining the regulatory mechanisms and initiatives deployed to detect, prevent, and mitigate the circulation of counterfeit medicines, this paper seeks to shed light on both the challenges and opportunities inherent in combating the proliferation of spurious drugs. Through a comprehensive analysis of the Indian scenario and global regulatory frameworks, it aims to contribute to the discourse on enhancing drug safety and safeguarding public health in an increasingly interconnected world.

II. SPURIOUS DRUGS

Spurious drugs refer to pharmaceutical products that are either counterfeit, falsified, substandard, or unregistered. These drugs may not meet the quality, safety, and efficacy standards required for their intended use. Here's a breakdown of each category:

- **Counterfeit Drugs:** Counterfeit drugs are medications that are deliberately and fraudulently mislabelled with respect to identity or source. They may contain incorrect ingredients, improper dosages, or no active ingredients at all. Counterfeit drugs are often produced and distributed with the intent to deceive consumers, leading them to believe they are purchasing authentic pharmaceuticals.
- **Falsified Drugs:** Falsified drugs are similar to counterfeit drugs but may include genuine ingredients that have been manipulated, improperly handled, or stored under substandard conditions. These drugs pose serious risks to patients as they may lack the expected efficacy or may be contaminated with harmful substances due to poor manufacturing practices.
- **Substandard Drugs:** Substandard drugs are legitimate pharmaceutical products that do not meet quality standards or specifications established by regulatory authorities. These drugs may be produced by licensed manufacturers but fail to meet quality control measures, resulting in variations in potency, purity, stability, or bioavailability. Substandard drugs can arise from inadequate manufacturing processes, poor quality raw materials, or improper storage and transportation conditions.

- **Unregistered Drugs:** Unregistered drugs are pharmaceutical products that have not undergone the necessary regulatory review and approval processes required for market authorization. These drugs may be produced and distributed without proper oversight, making it difficult to verify their safety, efficacy, and quality. Unregistered drugs are often associated with informal or illicit markets where regulatory oversight is lacking or insufficient.

Overall, spurious drugs pose significant risks to public health by compromising the effectiveness of medical treatment, contributing to the development of antimicrobial resistance, and undermining patient trust in healthcare systems. Regulatory authorities and healthcare stakeholders must remain vigilant in detecting and preventing the circulation of spurious drugs to protect the safety and well-being of patients worldwide.

History of Spurious Drugs:

The history of spurious drugs dates back centuries, with instances of counterfeit and adulterated medicines documented across different civilizations. In ancient times, the practice of counterfeiting drugs was often driven by economic motives, as unscrupulous individuals sought to profit by selling fake remedies or substituting cheaper ingredients for genuine ones. Historical accounts reveal instances of counterfeit drugs being traded in markets and apothecaries, posing serious risks to unsuspecting consumers.

The advent of modern pharmaceuticals in the 19th and 20th centuries brought new challenges in combating spurious drugs. The industrialization of drug manufacturing and the globalization of pharmaceutical markets created opportunities for counterfeiters to exploit regulatory loopholes and technological limitations. Counterfeit drugs became more sophisticated, mimicking the appearance of genuine products and evading detection through improved manufacturing techniques.

The 21st century has witnessed a dramatic escalation in the prevalence and complexity of spurious drugs, fuelled by factors such as globalization, e-commerce, and the proliferation of online pharmacies. With advancements in technology and the rise of digital platforms, counterfeiters have found new avenues to produce, distribute, and market spurious drugs on a global scale. The emergence of Substandard, Falsified, and Counterfeit (SFFC) medicines as a pervasive threat has heightened concerns among regulatory authorities and public health experts, underscoring the need for concerted action to combat this multifaceted challenge.

- **Sources of Spurious Drugs:** Spurious drugs originate from diverse sources, ranging from illicit manufacturing operations to legitimate supply chains compromised by counterfeiters. The primary sources of spurious drugs include:
- **Illicit Laboratories:** Criminal organizations and clandestine manufacturers operate illicit laboratories to produce counterfeit drugs using substandard ingredients and unregulated manufacturing processes. These illicit operations often operate in hidden locations, making it challenging for authorities to detect and dismantle them.
- **Online Pharmacies:** The proliferation of online pharmacies has provided counterfeiters with a convenient platform to market and distribute spurious drugs to unsuspecting consumers.

Rogue online pharmacies may operate without proper regulatory oversight, allowing them to sell counterfeit or unregistered medications with impunity.

- **Parallel Trade:** Parallel trade involves the legal importation and distribution of pharmaceutical products across different countries within the same geographic region. However, counterfeiters may exploit parallel trade channels to introduce spurious drugs into legitimate supply chains, posing risks to patient safety and public health.
- **Supply Chain Vulnerabilities:** Legitimate supply chains can be vulnerable to infiltration by counterfeiters at various stages of the distribution process. Weaknesses in supply chain management, such as inadequate quality control, poor traceability, and lack of authentication measures, can facilitate the entry of spurious drugs into the market.
- **Recycling and Repackaging:** Counterfeiters may engage in recycling and repackaging of expired or discarded medications to create counterfeit products. By relabelling or repackaging expired drugs, counterfeiters seek to disguise the true nature of the products and extend their shelf life, deceiving consumers and healthcare professionals.

Addressing the sources of spurious drugs requires a multifaceted approach that encompasses regulatory enforcement, international collaboration, public awareness campaigns, and technological innovations. By targeting illicit manufacturing operations, strengthening supply chain security, and enhancing regulatory oversight, stakeholders can mitigate the risks posed by spurious drugs and safeguard the integrity of pharmaceutical supply chains.

SFFC drugs: A pandemic threat:

Substandard, Falsified, and Counterfeit (SFFC) drugs represent a pervasive and escalating threat to public health on a global scale. This category of spurious drugs encompasses a spectrum of illicit pharmaceutical products that deviate from quality, safety, and efficacy standards. Their proliferation poses significant risks to patients, healthcare systems, and regulatory authorities, constituting a veritable pandemic threat in the modern era.

The emergence of SFFC drugs as a pandemic threat is driven by various interconnected factors. Globalization has facilitated the rapid expansion of pharmaceutical markets, enabling counterfeiters to exploit regulatory gaps and supply chain vulnerabilities across borders. Technological advancements have empowered counterfeiters to produce increasingly sophisticated counterfeit medicines, replicating the appearance and packaging of genuine products with alarming accuracy. Moreover, the rise of e-commerce and online pharmacies has provided counterfeiters with virtual platforms to market and distribute spurious drugs with ease and anonymity.

The consequences of SFFC drugs extend far beyond mere economic losses or breaches of intellectual property rights. These illicit products jeopardize patient safety by exposing individuals to potentially harmful substances, incorrect dosages, or ineffective treatments. Moreover, the use of counterfeit and substandard medicines contributes to the spread of antimicrobial resistance, exacerbating global health challenges and undermining the efficacy of essential medicines.

The impact of SFFC drugs is particularly pronounced in low- and middle-income countries, where regulatory oversight may be limited, and access to quality-assured medicines is constrained. In these settings, patients are vulnerable to exploitation by unscrupulous counterfeiters, often unable to distinguish between genuine and counterfeit products. As a result, they may unwittingly purchase and consume spurious drugs, placing their health and well-being at grave risk.

Addressing the pandemic threat posed by SFFC drugs requires a multifaceted and collaborative approach. Regulatory authorities must enhance surveillance and enforcement efforts to detect and disrupt the production and distribution of counterfeit medicines. International cooperation and information sharing are essential to combat cross-border counterfeit networks and supply chain infiltrations. Additionally, public awareness campaigns and education initiatives are crucial to empower consumers with the knowledge and tools to identify and report suspicious medicines.

In conclusion, the proliferation of SFFC drugs represents a complex and evolving challenge that demands urgent action from governments, regulatory agencies, healthcare providers, industry stakeholders, and civil society. By strengthening regulatory frameworks, enhancing supply chain security, and fostering international collaboration, stakeholders can mitigate the pandemic threat posed by spurious drugs and safeguard public health for generations to come.

III. INDIAN SCENARIO OF SPURIOUS DRUGS

Effects of Spurious Drugs on Human Being:

The Indian scenario of spurious drugs presents a complex and multifaceted challenge, characterized by a combination of regulatory gaps, market dynamics, and socioeconomic factors. Despite significant strides in pharmaceutical regulation and healthcare infrastructure, India continues to grapple with the proliferation of counterfeit, falsified, substandard, and unregistered medicines, posing grave risks to public health and patient safety.

One of the primary contributing factors to the prevalence of spurious drugs in India is the fragmented regulatory landscape and enforcement challenges. While India boasts a robust regulatory framework overseen by agencies such as the Central Drugs Standard Control Organization (CDSCO) and state drug control authorities, regulatory oversight may be unevenly implemented across different regions. Weak enforcement mechanisms, limited resources, and corruption within regulatory agencies have created opportunities for counterfeiters to operate with impunity, exploiting loopholes in the system.

The vast and diverse pharmaceutical market in India, coupled with the proliferation of informal and unregulated sectors, further exacerbates the problem of spurious drugs. With thousands of pharmaceutical manufacturers, wholesalers, and retailers operating across the country, ensuring the integrity of the supply chain presents a formidable challenge. Counterfeiters often exploit the complexities of the Indian pharmaceutical market, infiltrating legitimate supply chains and distributing spurious drugs alongside genuine products.

The impact of spurious drugs on the Indian population is profound, with reports of treatment failures, adverse reactions, and public health crises making headlines on a regular basis. Patients, particularly those from marginalized communities, are disproportionately affected by the risks associated with counterfeit and substandard medicines. Lack of access to quality-assured medications, coupled with

limited awareness of the dangers posed by spurious drugs, further compounds the problem, leaving vulnerable populations susceptible to exploitation.

Efforts to address the Indian scenario of spurious drugs require a concerted and multifaceted approach. Strengthening regulatory oversight and enforcement mechanisms, enhancing pharmacovigilance systems, and promoting transparency and accountability within the pharmaceutical industry are essential steps towards combating the proliferation of counterfeit medicines. Additionally, raising public awareness about the risks associated with spurious drugs, empowering healthcare professionals to identify and report suspicious medicines, and fostering collaboration between government agencies, industry stakeholders, and civil society organizations are critical components of a comprehensive strategy to safeguard public health and ensure the integrity of India's pharmaceutical supply chain.

IV. DRUG SAFETY

Drug safety refers to the measures taken to ensure that pharmaceutical products are safe for use by patients. It encompasses various aspects of the pharmaceutical industry, including drug development, manufacturing, distribution, prescribing, and usage. The primary goal of drug safety is to minimize the risks associated with medication use while maximizing its therapeutic benefits.

Key components of drug safety include:

Clinical Trials: Before a new drug is approved for use, it undergoes rigorous testing in clinical trials to assess its safety and efficacy. These trials involve carefully controlled studies in human volunteers to evaluate the drug's effects, side effects, and potential interactions with other medications.

Regulatory Oversight: Regulatory agencies, such as the Food and Drug Administration (FDA) in the United States or the European Medicines Agency (EMA) in Europe, play a crucial role in ensuring drug safety. These agencies review data from clinical trials and other sources to evaluate the risks and benefits of new drugs before granting approval for marketing and distribution.

Pharmacovigilance: Pharmacovigilance is the ongoing monitoring of drugs after they have been approved for use. It involves collecting, assessing, and reporting adverse drug reactions (ADRs) and other drug-related problems to regulatory authorities. Pharmacovigilance helps identify previously unrecognized safety concerns and allows for timely interventions to minimize risks to patients.

Post-Marketing Surveillance: Once a drug is on the market, regulatory agencies continue to monitor its safety through post-marketing surveillance programs. These programs collect data on real-world drug use and monitor for adverse events or safety signals that may not have been detected during clinical trials.

Labeling and Packaging: Clear and accurate labeling and packaging are essential for ensuring the safe use of medications. Drug labels provide important information about dosing, administration, side effects, contraindications, and precautions. Packaging design can also influence medication adherence and reduce the risk of medication errors.

Quality Assurance: Quality assurance measures ensure that pharmaceutical products are manufactured to meet high standards of quality, purity, and potency. Good Manufacturing Practices (GMP) govern manufacturing processes to minimize the risk of contamination, adulteration, or other manufacturing defects that could compromise drug safety.

Education and Awareness: Healthcare professionals and patients play a critical role in drug safety through education and awareness initiatives. Healthcare providers need to stay informed about the latest safety information and communicate potential risks and benefits to patients. Patients, in turn, should be empowered to ask questions, report adverse events, and adhere to medication instructions.

Overall, drug safety is a multifaceted endeavour that requires collaboration among regulatory agencies, pharmaceutical companies, healthcare professionals, patients, and other stakeholders. By implementing robust safety measures throughout the drug development and distribution process, stakeholders can minimize the risks associated with medication use and ensure the well-being of patients.

V. REGULATORY LANDSCAPE FOR ENSURING DRUG SAFETY IN THE FACE OF SPURIOUS DRUGS

The regulatory landscape for ensuring drug safety in the face of spurious drugs is multifaceted and dynamic, involving various stakeholders, mechanisms, and initiatives aimed at detecting, preventing, and mitigating the circulation of counterfeit medicines. This regulatory framework encompasses several key elements:

Regulatory Frameworks: Regulatory authorities establish and enforce legal and institutional frameworks for pharmaceutical regulation. These frameworks define standards, guidelines, and requirements for the quality, safety, efficacy, and labeling of pharmaceutical products. Regulatory agencies, such as the FDA in the United States or the EMA in Europe, oversee the approval, licensing, registration, inspection, and enforcement activities related to pharmaceutical products.

Quality Assurance Measures: Quality assurance measures are essential to maintain the quality, purity, and potency of pharmaceutical products throughout the supply chain. Regulatory authorities set standards and requirements for manufacturing practices, product testing, quality control, and documentation to ensure compliance with Good Manufacturing Practices (GMP) and other quality standards. By adhering to GMP standards, manufacturers can minimize the risk of contamination, adulteration, or other manufacturing defects that could compromise drug safety.

Surveillance and Monitoring: Surveillance and monitoring systems are critical for detecting and monitoring the circulation of spurious drugs in the market. Regulatory authorities utilize surveillance mechanisms, such as inspections, sampling, testing, and adverse event reporting, to identify counterfeit, falsified, substandard, and unregistered medicines. Monitoring systems track the movement of pharmaceutical products throughout the supply chain to identify potential vulnerabilities and risks.

Enforcement Actions: Enforcement actions are necessary to deter and combat the production, distribution, and sale of counterfeit and substandard medicines. Regulatory authorities have the authority to conduct inspections, seize illicit products, impose sanctions, and prosecute offenders to

enforce compliance with regulatory requirements. Enforcement actions may target illicit manufacturing operations, rogue distributors, unauthorized online pharmacies, and other actors involved in the trade of spurious drugs.

International Collaboration: International collaboration is essential for addressing the global nature of the spurious drugs trade and coordinating efforts to combat counterfeit and substandard medicines. Regulatory authorities, law enforcement agencies, and intergovernmental organizations collaborate on initiatives to share information, harmonize standards, strengthen enforcement mechanisms, and build capacity to address common challenges. International cooperation facilitates the exchange of best practices, technical assistance, and resources to enhance regulatory oversight and enforcement capabilities across borders.

Overall, navigating the regulatory landscape for ensuring drug safety in the face of spurious drugs requires a coordinated and collaborative approach among regulatory agencies, industry stakeholders, healthcare professionals, and international partners. By embracing innovative technologies, strengthening quality assurance measures, enhancing surveillance and enforcement efforts, and fostering international cooperation, stakeholders can mitigate the risks posed by counterfeit and substandard medicines and uphold the integrity of pharmaceutical supply chains to protect public health.

Several acts and regulations are implemented by governments to ensure drug safety and combat the circulation of spurious drugs. Here are some key acts and regulations from various countries:

United States:

Federal Food, Drug, and Cosmetic Act (FD&C Act): This act is the primary statute governing the safety, efficacy, and labeling of drugs in the United States. It grants the FDA authority to regulate the manufacturing, distribution, and marketing of pharmaceutical products and enforce compliance with regulatory requirements.

Drug Quality and Security Act (DQSA): Enacted in 2013, this act aims to improve the safety and security of the pharmaceutical supply chain by establishing new requirements for drug compounding, tracking, and tracing.

Drug Supply Chain Security Act (DSCSA): This act, part of the DQSA, requires manufacturers, wholesalers, and dispensers to implement systems for tracing the distribution of prescription drugs throughout the supply chain to prevent the distribution of counterfeit or adulterated drugs.

European Union:

Directive 2001/83/EC: This directive lays down the legislative framework for the regulation of medicinal products for human use in the European Union (EU). It establishes requirements for drug authorization, manufacturing standards, pharmacovigilance, labeling, and advertising.

Regulation (EC) No 726/2004: This regulation provides for the centralized authorization procedure for medicinal products in the EU, allowing for the harmonized assessment and approval of drugs by the European Medicines Agency (EMA) for use in all EU member states.

Falsified Medicines Directive (Directive 2011/62/EU): This directive aims to prevent the entry of counterfeit medicines into the legal supply chain by implementing measures such as mandatory safety features, verification systems, and penalties for falsification.

India:

Drugs and Cosmetics Act, 1940: This act regulates the import, manufacture, distribution, and sale of drugs and cosmetics in India. It establishes standards for drug safety, quality, and efficacy, as well as provisions for licensing, inspections, and enforcement by the Central Drugs Standard Control Organization (CDSCO) and state drug control authorities.

Drugs and Cosmetics Rules, 1945: These rules provide detailed provisions for the implementation of the Drugs and Cosmetics Act, including requirements for drug registration, manufacturing practices, labeling, and pharmacovigilance.

International:

World Health Organization (WHO) Good Manufacturing Practices (GMP): These guidelines set international standards for the quality assurance of pharmaceutical products, including manufacturing practices, quality control, and documentation, to ensure compliance with safety and efficacy requirements.

WHO International Pharmacovigilance Guidelines: These guidelines provide recommendations for establishing and operating pharmacovigilance systems to monitor and assess the safety of medicinal products and detect adverse drug reactions at national and international levels.

These acts and regulations, along with others implemented by governments and regulatory agencies worldwide, aim to establish comprehensive frameworks for ensuring drug safety, protecting public health, and combating the circulation of spurious drugs. They define standards, requirements, and enforcement mechanisms to regulate the pharmaceutical industry and uphold the integrity of pharmaceutical supply chains.

VI. CONCLUSION

In conclusion, the proliferation of spurious drugs poses a significant threat to public health globally, necessitating robust regulatory frameworks to ensure drug safety. From counterfeit and falsified medicines to substandard and unregistered products, spurious drugs undermine the integrity of pharmaceutical supply chains and jeopardize patient safety. Addressing this multifaceted challenge requires a comprehensive and collaborative approach that encompasses regulatory oversight, quality assurance, surveillance, enforcement, and international cooperation. Regulatory authorities play a central role in navigating the complex regulatory landscape and combating the proliferation of spurious drugs.

By implementing robust regulatory frameworks, quality assurance measures, surveillance mechanisms, and enforcement actions, regulatory agencies can detect, prevent, and mitigate the circulation of counterfeit and substandard medicines. Collaboration among regulatory agencies,

industry stakeholders, healthcare professionals, and international partners is essential to effectively address the global nature of the spurious drugs trade and protect public health.

In conclusion, safeguarding drug safety in the face of spurious drugs requires collective efforts and sustained commitment from all stakeholders. By embracing innovation, strengthening regulatory oversight, and fostering collaboration, stakeholders can mitigate the risks posed by counterfeit and substandard medicines and ensure the integrity of pharmaceutical supply chains to safeguard public health for generations to come.

REFERENCES

- [1]. KD T. Essentials of medical pharmacology. JP Medical Ltd, India. 2013.
- [2]. Bate R, Zhe Jin G, Mathur A. Does price reveal poor-quality drugs? Evidence from 17 countries. *J Health Econ.* 2011; 30:1150–63.
- [3]. Taylor RB, Shakoor O, Behrens RH. Drug quality, a contributor to drug resistance? *Lancet.* 1995; 346:122.
- [4]. Furnham A, Valgeirsson H. The effect of life values and materialism on buying counterfeit products. *J Socio Econ.* 2007; 36:677–85.
- [5]. Thomas PA. The tragedy caused by fake antimalarial drugs. *Mediterranean journal of hematology and infectious diseases.* 2012; 4(1): 1-7.
- [6]. Khan A and Khar R. Current scenario of spurious and substandard medicines in India: A systematic review. *Indian journal of pharmaceutical sciences.* 2015; 77:2.
- [7]. Verma S, Kumar R and Philip P. The Business of Counterfeit Drugs in India: A Critical Evaluation. *International Journal of Management and International Business Studies.* 2014; 4:141-8.
- [8]. Jeong T, Lee SH, Mishra NK, De U, Park J, Dey P, Kwak JH, Jung YH, Kim HS and Kim IS. Synthesis and Cytotoxic Evaluation of N-Aroylureas through Rhodium (III)-Catalyzed C–H Functionalization of Indolines with Isocyanates. *Advanced Synthesis and Catalysis.* 2017; 359:2329-36.
- [9]. Blackstone EA, Fuhr Jr JP and Pociask S. The health and economic effects of counterfeit drugs. *American health and drug benefits.* 2014;7:216.
- [10]. Chika A, Bello S, Jimoh A and Umar M. The menace of fake drugs: consequences, causes and possible solutions. *Research Journal Medical Sciences.* 2011;5:257-61.
- [11]. Malik V. *Drugs and cosmetics act, 1940*, Eastern Book, India. 2006.
- [12]. Sundaram G. Cost estimation of drug abuse. In: Sundaram P.M. S. JK, editor. *International Conference on Exploring Linkages between Drug Usage and Criminal Victimization.* Tamil Nadu, India 2012. 85-90.