

Counterfeit Drugs: A Threat to the Healthcare System

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ABSTRACT

This article is to review the implications that are globally affiliated with inferior/counterfeit drugs in advancing countries. Counterfeiting of the drug has become an immense issue worldwide. This issue is rapidly rising and has reached a significant level to get attention among all. The World Health Organization [WHO] has publicized that counterfeit drugs can make up to 50% of the global pharmaceutical market. Counterfeit drugs can be seen in every category of medicines, be it Anti-Malarial, Anti-Bacterial, or Anti-Infective drugs. In this review, counterfeit drugs in economically developing countries such as India, the laws against counterfeiting drugs, and the counterfeit drugs in various categories are being discussed.

Keywords: Counterfeiting, Drugs, Medicines, Developing Countries, Global Threat, COVID-19, WHO,

I. INTRODUCTION

Counterfeit drugs are medicines produced by using the wrong ingredients or ingredients with no therapeutic value. They are often designed to look identical to genuine medicines and can cause adverse effects. However, these drugs fail to cure

the disease or to give the desired therapeutic effect that is intended. Such medicines mostly exist in industrially advanced and economically developing countries. The expanse of the issues and various other elements concerning counterfeited drugs anyhow conflict note-worthily between industrialized and developing nations. The issue of counterfeit drugs came up in 1980 when more members of the WHO revealed that counterfeit medicines were being used. The Black's Law Dictionary states that counterfeit drugs are the medicines manufactured by a person other than the actual genuine manufacturer, by duplicating or imitating the initial standard product without any legal rights. Such drugs are inferior in quality and are manufactured in the vision of fraud intended to result in financial gain. Counterfeit medicine is the one that is illegal and unethical, which is incorrectly labeled concerning the specification and origin. The term counterfeiting the medicines can be applied to both the Branded and Generic Medicines. The WHO has given a few names for counterfeit medicines concerning their qualities i.e. substandard drugs, spurious drugs, falsely labeled drugs, and falsified medicines².

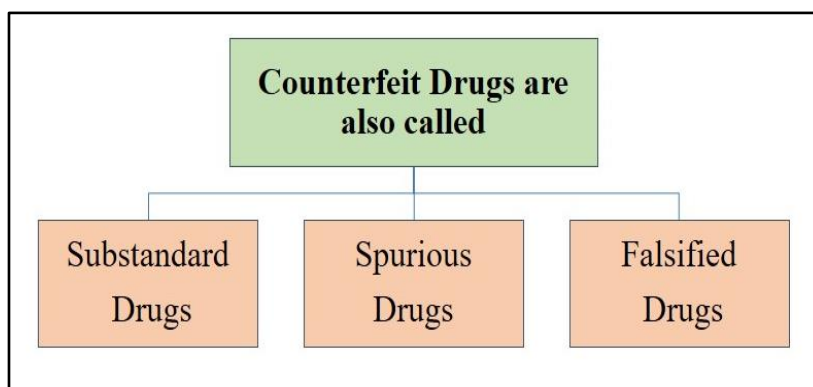


Figure. 01 Counterfeit Drugs

effective, moreover, they can have several adverse effects. It has been reported that the contamination of Heparin by Chinese counterfeiters in 2007 and 2008, killed 149 patients in the United States of America. This is gradually being more of a concern in the developing regions (i.e. mostly Africa and Asia), where the regulatory and the enforcement systems are weak. Most studies indicate that all forms of counterfeit drugs are in terms of middle-income markets of underdeveloped countries³. In high-income countries, counterfeit versions of lifestyle drugs like Viagra and cancer medications are highly dominant over anti-infective drugs. It has been stated by WHO that “Counterfeited drugs may erode public confidence in healthcare systems, healthcare professionals, the suppliers of genuine drugs, pharmaceutical industries, and National drug regulatory authorities”³. The consequences of counterfeit drugs are as diverse as their solutions. The enactment and enforcement of new laws for prohibiting counterfeit drugs are vital. The counterfeiting of drugs has reached global proportions and unraveling those needs a global approach. The fight against counterfeit drugs must be reinforced without further delay.

Drug Counterfeiting in India

The Indian pharmaceutical industry is highly knowledge-based and is growing steadily. It

plays an important role in the Indian economy². The Indian pharma industry is ranked 4th in the world, in terms of production volumes and not less than 55% of production is exported to highly regulated markets. India is an authentic example of a developing country with a powerful pharmaceutical industry that holds an effective drug regulatory system. A report in the Times of India was given by Rama Lakshmi, that an approximate 12 to 25 % of all drugs sold within India are found to be counterfeit. India is one of the countries with the biggest producers of counterfeit drugs as well as it also has an immense market for spurious drugs². The ministry of health estimated that 5% of drugs in the Indian market are counterfeit and 0.3% are spurious. Bhagirathi Palace Chandni Chowk, New Delhi, India is found to be a pivot of counterfeiters². Almost 20% of 40,000 crores is formed from fake medicines in the Indian Pharma market. It was once confined to exotic and highly expensive pills like Viagra which is now escalated to cough syrups, vitamin supplements, and antibiotics. The list of countries in which counterfeit drugs were seized by the European Customs Organization [ECO] included countries like India, China, The United Arabian Emirates, and many more. Figure. 02 shows the approx. percentage of counterfeits globally. in comparison with other countries globally.

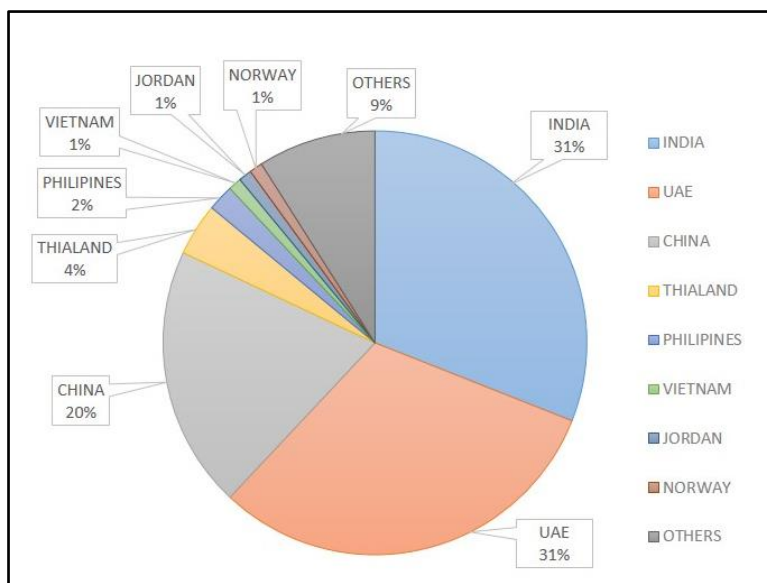


Figure .02 Approximate % of Counterfeits Seized by ECO in 2006

Indian Civil and Criminal Laws against Counterfeit Drugs

The Indian pharmaceutical field has shown immense growth in past decades, which has led India to be an uprising exporter in the pharmaceutical world. While the business of drugs has expanded the standards of formulation have been a crucial concern. The global pandemic of the Covid-19 allowed the counterfeiters to boost their production and distribution of illegal productions. The WHO's Global Surveillance and Monitoring System report for the falsified and substandard medications in 2017, has claimed that nearly about 10.5% of medicines sold in the Indian market were found to be counterfeit. The Indian Penal Code [IPC], 1860 states that any person who tries to adulterate any drug or medicinal preparation in any manner would be imprisoned for an extent of six months and is payable of a fine up to a thousand rupees. Drugs and Cosmetic Act, 1940 includes the procedure to oppose adulterated, spurious, or misbranded drugs and their export in India. This act states that any drug that is likely to lead to a patient's death or cause severe harm to health, is punishable with the imprisonment of seven to ten years⁷. This may also extend to life-long imprisonment and a liable fine of not less than ten lakh or 3 times the cost of counterfeited drugs. The Bureau of Indian Standards Act, 2016 exhibits the penalties regarding the offenses of those manufacturers that use the Indian Standards Institute [ISI] mark without any certified license. This bureau investigates such cases of misuse of ISI marks and serious actions are taken wherever desired.

Counterfeiting of Drugs in Different Categories

1) Counterfeit in Anti-Malarial Drugs

The counterfeit or inferior antimalarial drugs lead to drug resistance and insufficient treatment which leads to an instant threat to the population and investment in fighting malaria. Over 33 million people in the population are at a risk due to malaria. That is endemic in 106 countries⁸. And around 655 thousand to 1.2 million people die per year due to the Plasmodium Falciparum Infection. Plenty of this morbidity and mortality could have been prevented if the drugs given to the patients were efficacious, pure and of standard quality. Children in Southeast Asia have the highest risk of getting infected by Malaria. The global threat of malaria has reduced in the past decade. In the endemic region, antimalarial drugs are often distributed in the self-prescribed method, either correctly or incorrectly. The poor consumers and health workers get attracted to

such counterfeit drugs due to a lack of knowledge about drugs and the low costs of drugs.

2) Counterfeit in Cardiac Drugs

The substandard antihypertensive medication possesses great potential for serious health hazards and results in significant morbidity and mortality. The drug quality assessment has mainly focused on the anti-infective drugs and has a notable proportion of drugs that are counterfeited or of poor quality. The appropriate drug therapy makes a stronger pillar of cardiovascular risk reduction, and the use of standard medication should be done to avoid further risks. Availability, affordability, accessibility, acceptability, and quality are said to be the 5 described dimensions of access to medication. The substandard drugs used in cardiology can be a dangerous factor and can lead to failure of treatment. Counterfeit cardiovascular medicines are often reported and have tragic consequences. Furthermore, the potential of the variability of drugs may cause immense risk to patient health. Additionally, there can be a loss of confidence in the healthcare system, and drug regulatory authorities can recognize it to be mediocre.

3) Counterfeit in Antibiotic Drugs

The acquired bacterial resistance is common in developing countries and the resistance in the first line broad-spectrum agents is seen to be increasing simultaneously. It can be observed that these agents are quite inexpensive and have budgetary limits. Hence, antibiotics are a more affordable medication in comparison with any other. The affordability of these antibiotics has led to the misuse of drugs by physicians and unqualified practitioners. The antibiotics are being counterfeited in the aspect of poor-quality ingredients, including lack of adherence and degradation of crude materials. As an indication of the major issue of counterfeited antibiotics, it has been reported that the 15% of antibiotic medications sold worldwide are counterfeited or falsified¹³.

4) Counterfeit in Anti-Retroviral and Anti-Tuberculosis Drugs

Counterfeit drugs have the power and ability to surge in pandemic situations. The Trade of counterfeit drugs is liable for the increase in drug resistance among infectious diseases including Tuberculosis, HIV (Human Immunodeficiency Virus), and AIDS (Acquired Immune Deficiency Syndrome). A study in Botswana reported that 315 types of drugs used in the treatment of Tuberculosis were counterfeit or contained no API (Active

Pharmaceutical Ingredient)¹³.

Counterfeit Drugs during Covid-19 in India

The Covid-19 pandemic gave rise to worldwide awareness and brought huge changes in lifestyle. When India was immersed in perilous waves of Coronavirus infection, that hit large cities immensely and resulted in a lack of availability of medicines, oxygen cylinders, masks, PPE kits, and other life-saving essentials. Few families had gone through an additional economic burden due to the high demand for electronic self-diagnosis devices during Covid-19. Unfortunately, this crisis and the sudden urge to make these life-saving essentials available to every patient boosted the trade of counterfeits. It has been reported by 'The Times of India' on June 9, 2021, that "The Pharma employees and the owner of 'Max Relief Healthcare (Noida)' have been arrested by the police for manufacturing counterfeit drugs used in the treatment of Covid-19. A stash of fake medicines including Azithromycin and Favipiravir including other packaging machines worth around Rs.50 Lakhs were seized. The tablets worth Rs.25 Lakhs have been recovered." While the nation was struggling with human tragedy and loss of life, there was a huge rise in counterfeiters. It was reported by the Indian Media that "The Bengaluru police arrested a counterfeiter that tried to sell counterfeit Remdesivir Injection in the black market for a huge amount of Rs.14,000/- per vial". In addition to such acts of counterfeiting, the reports have also found that there were attempts to try and sell off saline water as Remdesivir Injection.

II. CONCLUSION

Drugs play a vital role in the quality of life and human dignity. In this article, we have highlighted a few issues regarding the counterfeit medicines that are been manufactured in India and Worldwide. We, as a responsible citizen of the country, must be aware and exercise caution and vigilance against such counterfeiting activities. Counterfeit medicines are found to be in almost every category of medicine i.e., Anti-malarial, Anti-retroviral, Anti-biotics, etc. The sudden outbreak of Covid-19 privileged the counterfeiters to spread their business rapidly.

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