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Drug counterfeiting is an issue in both industrialized and poor nations.

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ABSTRACT

The issue of phony or inferior medications is one that the entire world is dealing with. These inferior medications have led to potentially fatal problems, financial losses for both the producer and the consumer, and a decline in public confidence in the healthcare system. The issue is more serious in developing nations where people have easy access to these medications. This problem must be addressed immediately, and steps must be taken to limit its widespread access and use. In order to preserve and promote public health, India has adopted certain preventive measures to combat the issue of substandard/spurious pharmaceuticals, but much more work needs to be done.

Key Words: Generic medications, developing nations, and counterfeit drugs.

INTRODUCTION

One-third of people worldwide do not have access to necessary medications1. The general public finds it extremely difficult to afford the pricey prescriptions in developing nations like India, where almost 40% of the population makes less than $1 per day2. The market for inexpensive and accessible counterfeit medications is growing as a result of the criminals engaged in the illegal drug trade simply infiltrating the supply chain. The WHO initially recognized the problem of drug counterfeiting as a developing issue in 19853. However, since then, this issue has gotten much worse, with over 10% of pharmaceuticals worldwide being counterfeit, and in some nations, the situation is significantly worse, with over 50% of the drug supply being counterfeit3. In India, the issue of counterfeit medications is widespread. In addition to being the victims of the issue, emerging nations are also the suppliers of counterfeit medications, with China and India being the world's top offenders. According to a European Commission figure, 75% of counterfeit medications come from India, while a survey claims that the majority of counterfeit medications sold in Nigerian markets come from India. A pharmaceutical product that is manufactured and marketed with the intention of falsely representing its source, legitimacy, or efficacy is known as a counterfeit drug3. It could include offensive amounts of active substances, may be mishandled by the body or contain ingredients not listed on the label, and is frequently marketed with erroneous, false, or misleading packaging and labeling3. While almost all medications are counterfeit, new, high-priced lifestyle medications including hormones, steroids, erectile dysfunction pills, and antihistamines are the most often counterfeited in wealthy nations3,7,8. However, medications used to treat life-threatening illnesses like HIV/AIDS, cancer, TB, malaria, and various

antibiotics are the most frequently counterfeited in underdeveloped nations.

However, the Indian government has taken steps to give some patient groups free generic medications9. However, because of their low cost, ease of access, and market availability, consumers continue to tolerate, favor, and purchase fake or inferior goods over authentic or branded ones10. These gullible consumers don't know the manufacturer's location or the product's quality. Frequently, they don't even know that the product is outdated, deteriorated, or subpar, which leads to treatment failure and, in the case of antibiotics, an increase in antimicrobial resistance11,12. Once limited to rare and expensive medications like Viagra, the issue of drug counterfeiting has spread to cough syrups, vitamin

Painkillers and supplements 13. China, the United Arab Emirates, and India are the main nations from whom European customs authorities confiscate counterfeit goods. 14, 15. India, the biggest provider of generic medications worldwide, has turned into a hub for phony and counterfeit medications. In India, Bihar, West Bengal, Uttar Pradesh, and Gujarat13 accounted for the majority of local market cases involving counterfeit and fraudulent medications. Similar to certain areas of parasite resistance, sub-therapeutic doses from counterfeit and inferior medications have been linked to artemisinin-based medications16. Numerous investigations have documented the extensive distribution of subpar medications in certain regions of Asia and Africa. It has been demonstrated that the majority of them include hazardous compounds17–20, subtherapeutic levels of the active pharmaceutical ingredient (API), or no API at all. Inadequate infrastructure, unethical production methods, or a lack of experience result in inferior medications, while black marketers produce counterfeit goods12. Generally speaking, using spurious/falsely-labeled/falsified/counterfeit (SFFC) medications might result in treatment failure or even death. The definition of poor quality drugs differs by country21,22. SFFC medications are defined as "medicines which are deliberately and fraudulently mislabeled with respect to identity and/or source, and which may include the products with correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging" by the World Health Organization's (WHO) International Medical Products Anti-Counterfeiting Taskforce (IMPACT). 3. In India, poor quality pharmaceuticals are defined as mislabeled, counterfeit, and adulterated drugs under sections 17, 17A, and 17B of the Drug and Cosmetic (D and C) Act, 1940, respectively23. The Central Drugs Standard Control Organization (CDSCO), the Indian drug regulatory body, has classified not-of-standard quality (NSQ) products into three categories, A, B, and C, as a result of the 2008 amendment of the D and C Act. This classification is crucial and useful for classifying the products during quality evaluation3, 24.

Antimalarial medication counterfeits are common in underdeveloped nations, especially in Southeast Asia and Africa25,26. There have also been reports of counterfeit antiretroviral medications in Africa. 27. At one point, there were over 35 fake versions of the Panacea Biotech medication Nimulid (Nimesulide) available on the market. According to a survey, 8% of pharmaceuticals imported into the Philippines were discovered to be counterfeit. 24. It was discovered in 2006 that the medication Lipitor did not include enough API in the UK. According to a 1999 nationwide survey conducted in Cambodia, 60% of the antimalarial Mefloquine tablets contained the considerably less expensive but useless sulphadoxine-pyrimethamine, which was either a fake or came from stocks that ought to have been destroyed28,29. In 2007, Xenical, an obesity medication, was offered in the US through websites run outside the country without an API. According to a survey, 38% of the antimalarial Artesunate tablets sold in five mainland South East Asian countries were fraudulent. 23. In 2008, an unidentified source imported erectile dysfunction medications Cialis and Viagra into Thailand. The literature also provides examples of how aspirin is used in Africa to make counterfeit chloroquine (30). There are additional instances from China where, in 2009, a traditional antidiabetic medication used to decrease blood sugar that included six times the recommended dosage of Glibenclamide resulted in two fatalities and nine hospitalizations. Between 1984 and 1993, 78% of the 771 reports of counterfeit medications came from developing nations (31). 30 child deaths in India in 199832 and 89 deaths in Haiti in 1995 were caused by the use of Paracetamol cough medicine, which contains diethylene glycol, a hazardous substance used in antifreeze. Twenty countries submitted 46 reports of counterfeit medications between January 1999 and October 2000, with 60% coming from developing countries and 40% from industrialized ones3,33. From an average of five cases annually in the 1990s to roughly 20 cases annually in 2001 and 200234, the US Food and Drug Administration (FDA) is now investigating four times as many cases of counterfeit

medications. According to estimates from the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), counterfeit medications make up 7% of all medications supplied globally3. Additionally, they have proposed that the this deal is worth over $30 billion USD. The number has been estimated to be 12% in Russia and up to 40% in Ukraine. 3, 34. The US Food and Drug Administration (FDA) warned of fake flu cures, including fake prescription Oseltamivir (Tamiflu) medication3,33 in late January 2006. In addition to the poor world, a growing number of cases are now occurring in wealthy nations35–37.

What are the options? One of the main causes of sickness, mortality, and a decline in public trust in medications and healthcare systems is counterfeit medication. There are numerous instances from around the globe. Compared to the public health sector, around half of the medications used by patients are bought from private establishments (pharmacies, patent medicine stores, and street vendors), where regulation is challenging. As a result, it is anticipated that drug counterfeiters will have an easier time breaking in. The frequency of counterfeit medications seems to be increasing 1,4 despite tight collaboration between pharmaceutical companies, governments, or international organizations involved in commerce, health, customs and excise, and counterfeiting. Guidelines for the creation of countermeasures against counterfeit medications were provided by the World Health Organization39. Coordination between the stakeholders at all levels—from the policy maker to the regulator to the consumer—as well as suitable regulatory procedures and laws that are strictly enforced are the solutions to this worldwide issue. The issue is enormous and calls for drastic measures. Law enforcement plays a crucial role, and anyone engaged in such corrupt activities ought to be detained and punished accordingly. By doing this, more individuals will abstain from engaging in such activities since fear will be present in the thoughts of those who engage in them. Additionally, the government ought to expand the number of regulatory officer positions. Strict monitoring was advised by the Mashelkar Committee (1993), with frequent surprise checks at pharmacies and for the cause checks (suspicious checks)4,40. There will be more supervision and less manufacturing opportunities the more controlling officers there are marketing of fake medications. The public should be urged to check pharmaceuticals before purchasing, and the drugs should have complex, one-of-a-kind processes, although these are typically costly. 41, 42. Additionally, more recent methods such as Raman spectroscopy, tensiography, chromatographic and mass spectrometric radio-frequency identification (RFID), near-infrared spectroscopy, electronic pedigree (E-Pedigree) system, isotopic characterization, and handheld refractometer can be used to detect the fake medications. 4, 43. Recent advancements in this area include the creation of intricate labels that are challenging to counterfeit and the use of SMS text messages to verify the legitimacy of a specific pharmaceutical product. Other Asian and African nations are increasingly implementing this SMS technology, which was created in the United States in Ghana and Dia. 8,44. Since these products are frequently sold outside of any authorized distribution system, pharmacy stores should exercise caution when it comes to the products they sell. Everyone should have access to generic medications, and initiatives to promote their wider usage should be supported. For the purpose of controlling the market for counterfeit pharmaceuticals, the involvement of politicians, doctors, community leaders, and drug controllers is crucial. Drug surveillance must be conducted on a regular basis. Information about standard quality, counterfeit, adulterated, and misbranded medications should be made public by the government. The over-the-counter customers will benefit from this. At least one free drug quality testing center should be established in each area, if not laboratories with quick and affordable equipment are available. Before entering the Indian market, imported medications must to be examined. These are a few of the laws that will significantly aid in regulating the market for counterfeit pharmaceuticals.

RECOMMENDATIONS

The issue of low-quality medications is already a major one, is only getting worse, and is probably going to get worse soon. The citizens' general health is impacted by the subpar medications. The issue of fake or bogus pharmaceuticals has developed significantly and has origins across the nation. Combating corruption in the pharmaceutical systems at different levels is essential to the fight against counterfeit medications' success 8. One crucial aspect of medical care22 is the preservation of drug quality. The general public should be made aware of this issue. For this, health education and health information play a critical role. To raise awareness, large-scale public awareness initiatives are required. The generic medications ought to be widely advertised and promoted. In this context, the function of drug inspectors and supervision is crucial. In order to reduce the number of fake, mislabeled, falsified, or counterfeit medications that are not of standard quality, there is a need Governments and policymakers have a crucial role in addressing the issue by enforcing stricter regulations and taking legal action. Nonetheless, drug counterfeiting is a global issue that necessitates global action to address [46].

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DISPUTE OF INTEREST:

The writers affirm that they have no competing interests.

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