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COUNTERFEIT MEDICINES: A GLOBAL THREAT TO PUBLIC HEALTH

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ABSTRACT

The rise of counterfeit medicines poses a significant global public health challenge, jeopardizing patient safety and eroding confidence in healthcare systems. These counterfeit products may contain dangerous or incorrect ingredients, incorrect dosages, or no active substances, leading to increased health risks, preventable deaths, and higher healthcare costs. This issue affects both developing and developed countries, with commonly counterfeited medications including antibiotics, antimalarials, cancer treatments, and lifestyle drugs, further aggravated by the COVID-19 pandemic's introduction of fake vaccines and treatments. The World Health Organization estimates that 5-7% of pharmaceutical products globally are counterfeit, underscoring the critical need for effective detection and prevention measures. This review examines the extent of the counterfeit medicine crisis, assesses various analytical tools-such as handheld spectrometers-that enable quick field testing, and discusses regulatory strategies and public awareness efforts. By exploring these facets, the study aims to deepen our understanding of the risks associated with counterfeit medicines and to propose viable solutions for addressing this pressing issue worldwide.

INTRODUCTION

Counterfeit medicines have emerged as a critical global health challenge over the past few decades. Defined as medicines that are deliberately mislabeled in terms of their identity or source, these fake drugs are often produced in unregulated or clandestine facilities. The proliferation of counterfeit drugs erodes patient trust in healthcare systems, causes therapeutic failures, and contributes to an array of public health crises. It's a problem that spans both developed and developing countries, but it disproportionately affects lower-income nations with weaker regulatory controls [1-3]. Historically, counterfeit medicines were primarily associated with lifestyle drugs, such as those used for weight loss, erectile dysfunction, or cosmetic purposes. However, the spectrum of counterfeit drugs has expanded significantly in recent years, now including life-saving medications such as antimalarials, antibiotics, and cancer therapies. The COVID-19 pandemic has further complicated this issue, with an influx of fake vaccines and treatments circulating in the market, capitalizing on public fear and demand for unapproved or scarce therapies [4-6]. Governments, regulatory agencies, healthcare providers, and the pharmaceutical industry are working together to develop countermeasures, but the challenge remains immense. The spread of these counterfeit products in LMICs-where resources to combat the problem are often limited-creates a particularly difficult scenario [7, 8].

Definition and Scope: Counterfeit medicines are deliberately mislabeled concerning their identity, composition, or source. They may contain incorrect or no active ingredients, posing serious risks to patient safety. Substandard medicines, while problematic, are authorized but fail to meet quality standards. Falsified medicines, a subset of counterfeits, involve deliberate fraud. The presence of counterfeit drugs, especially in

developing countries with weak regulatory frameworks, is a growing problem that demands immediate attention. These medicines are estimated to make up 10% of the global market, with figures rising significantly in LMICs [9-11].

Impact on Public Health: The health risks associated with counterfeit medicines are wide-ranging and severe. Fake drugs can lead to treatment failures, prolong illnesses, and in some cases, directly cause death. In the context of infectious diseases, counterfeit antibiotics or antimalarials that contain insufficient active ingredients can result in subtherapeutic dosing, which not only fails to treat the infection but also encourages the development of resistant strains of pathogens. Drug resistance is now one of the greatest threats to global health, according to the World Health Organization (WHO), and counterfeit medicines contribute significantly to this problem [12, 13]. Moreover, patients suffering from chronic conditions such as hypertension, diabetes, or cardiovascular diseases may experience a worsening of their health conditions due to counterfeit drugs that either lack the required active ingredients or include harmful substances. The use of counterfeit cancer therapies, in particular, has been associated with a rising number of treatment failures and preventable deaths, especially in regions where access to legitimate medications is scarce [14-16]. The psychological impact is also significant. The existence of counterfeit medicines undermines public trust in health systems, creating a culture of fear and suspicion toward even legitimate medical products. This can lead to patients avoiding necessary treatments altogether or seeking alternative therapies outside of regulated medical channels [12,17].

Key Therapeutic Categories Affected: Antibiotics and antimalarials are the most frequently counterfeited, accounting for 28-36% of reported cases. Counterfeit antimalarials, in particular, have caused numerous preventable deaths, especially in regions like Southeast Asia and sub-Saharan Africa. Lifestyle medicines (e.g., erectile dysfunction drugs, weight loss medications) and expensive treatments like cancer therapies are also commonly counterfeited, particularly in developed countries [18,19].

Detection and Analytical Techniques: The detection of counterfeit medicines is a complex and evolving science. While visual inspection methods, such as checking packaging for unusual markings or errors, were once the first line of defense, the increasing sophistication of counterfeit drugs has necessitated more advanced, scientific methods of detection. Today, analytical techniques like high-performance liquid chromatography (HPLC), near-infrared spectroscopy (NIRS), and Raman spectroscopy are some of the most effective tools in identifying counterfeit drugs. High-Performance Liquid Chromatography (HPLC): This technique separates, identifies, and quantifies components in a mixture. HPLC is highly effective at determining the presence of correct active pharmaceutical ingredients (APIs) in a drug sample, but it requires specialized equipment and is typically used in laboratory settings rather than in the field. Raman and Near-Infrared Spectroscopy: Both Raman and NIRS are non-destructive techniques that can quickly and accurately assess the chemical composition of a drug. They have become valuable tools for regulators and field inspectors, as they allow for rapid screening of large volumes of pharmaceuticals. These technologies are also being integrated into portable devices that can be used in the field, enabling faster detection of counterfeit products without the need to send samples to laboratories for analysis. Handheld Devices: Recent advancements in portable technology have led to the development of handheld spectrometers that can provide real-time analysis of drug composition. These devices are increasingly being used in resource-poor settings, such as rural areas in Africa and Southeast Asia, where laboratory infrastructure is limited. Colorimetric and Thin-Layer Chromatography (TLC) Tests: In many LMICs, low-cost methods like colorimetric tests and TLC are gaining traction. These simple techniques allow for the preliminary identification of counterfeit medicines by visualizing differences in chemical composition, though they are less precise than advanced spectroscopic methods [20-24].

Role of Healthcare Professionals: Healthcare professionals, especially pharmacists, are the first line of defense against counterfeit medicines. They can use their expertise to identify suspicious drugs by examining packaging, verifying authenticity, and reporting doubtful products to regulatory authorities. Training healthcare providers and raising awareness among patients are critical steps in preventing the spread of counterfeit drugs [25,26].

Regulatory Measures and Global Collaboration: To combat the proliferation of counterfeit medicines, regulatory authorities around the world are intensifying their efforts. International agencies such as the WHO, the International Criminal Police Organization (INTERPOL), and national governments are working together to develop stronger surveillance and law enforcement measures. The WHO's Global Surveillance and Monitoring System (GSMS) is a critical initiative aimed at identifying and eliminating counterfeit medicines from supply chains by reporting suspicious products in real-time [27-29]. Countries are also enacting stricter regulations and penalties for the production, distribution, and sale of counterfeit medicines. For instance, the European Union has implemented the Falsified Medicines Directive (FMD), which mandates stringent supply chain monitoring and the serialization of pharmaceutical products to ensure authenticity from manufacturer to consumer. Similar efforts are being made in the United States under the Drug Supply Chain Security Act (DSCSA), which requires pharmaceutical companies to establish electronic systems to trace products throughout the supply chain. Public-private partnerships, such as the Fight the Fakes campaign, are also playing a key role in raising awareness about the dangers of counterfeit medicines. Pharmaceutical companies, healthcare organizations, and advocacy groups are collaborating to inform both healthcare professionals and the general public about how to identify counterfeit products and report them to the authorities [30-33].

Counterfeit Drug Detection Protocols: Formal protocols for detecting counterfeit medicines involve multi-tiered approaches that integrate visual, chemical, and physical tests. These protocols are designed to efficiently detect and isolate fake drugs before they reach patients. Visual Inspection: The first step in many counterfeit drug detection protocols is a careful examination of the drug's packaging. Regulators and healthcare professionals look for inconsistencies in labels, spelling errors, poor-quality printing, and unusual logos. They also examine the product itself for differences in size, shape, color, and texture. While this step is useful, it is often insufficient because counterfeiters are becoming more adept at mimicking the appearance of authentic products. Chemical Analysis: Following visual inspection, suspected counterfeit drugs are often subjected to chemical analysis. Methods such as HPLC and mass spectrometry can be used to verify the chemical composition and potency of a drug. These tests ensure that the active ingredients are present in the correct quantities and that no harmful contaminants are included. Spectroscopic Screening: Techniques such as Fourier-transform infrared spectroscopy (FTIR) and Raman spectroscopy are employed for rapid screening. These non-destructive methods can provide spectral fingerprints of authentic drugs, which are compared to those of suspected counterfeit samples [34-38].

CONCLUSION

The fight against counterfeit medicines requires a multi-faceted approach, involving stricter regulations, better detection tools, and increased awareness among healthcare providers and the public. International cooperation, robust regulatory frameworks, and improved pharmaceutical supply chain monitoring are crucial in combating this global threat. Ongoing advancements in analytical techniques provide hope for more effective detection and prevention of counterfeit medicines, but the challenge remains immense, particularly in LMICs where resources are limited.

Conflicts of interest: None

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