International Journal of Scientific Research and Engineering Development-– Volume 9 Issue 1, Jan-Feb 2026
Available at www.ijsred.com

RESEARCH ARTICLE OPEN ACCESS

A Review on Counterfeit Medicines

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Abstract
Counterfeit medicines are a growing global public health concern. These medicines may contain incorrect ingredients, no active pharmaceutical ingredient, or an improper amount of drug substance. They are often manufactured and distributed without regulatory approval and are designed to imitate genuine pharmaceutical products. This review discusses the definition, classification, challenges in detection, regulatory measures, and public health impact of counterfeit medicines, with special focus on developing countries such as India. The role of international organizations including the World Health Organization (WHO) and INTERPOL, particularly during the COVID-19 pandemic, is also reviewed. Various analytical techniques such as UV–Visible spectrophotometry, GC–MS/MS, HPLC, and LC–MS/MS used for detection of counterfeit medicines are described. Strengthening regulatory frameworks, improving public awareness, and adopting modern analytical techniques are essential to ensure patient safety and medicine quality.

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1. INTRODUCTION
The manufacture and distribution of counterfeit medicines is not a new phenomenon; however, its impact has become increasingly visible in recent decades. The issue gained global attention during the 1980s when the World Health Organization began reporting widespread circulation of falsified medicines. Counterfeit medicines are produced by unauthorized manufacturers and are intended to imitate genuine pharmaceutical products in order to deceive consumers. The circulation of such products leads to therapeutic failure, drug resistance, increased morbidity and mortality, and loss of public confidence in healthcare systems. The problem is particularly severe in developing countries due to weak regulatory systems, complex supply chains, and limited access to essential medicines.

2. DEFINITION AND CLASSIFICATION OF COUNTERFEIT MEDICINES
Definitions of counterfeit medicines vary across regulatory and legal frameworks. According to the World Health Organization, a counterfeit or falsified medicine is one that is deliberately misrepresented in terms of its identity, composition, or source. Such medicines may contain incorrect ingredients, insufficient quantities of active ingredients, or no active ingredient at all. The WHO categorizes these products under Substandard, Spurious, Falsely Labelled, Falsified, and Counterfeit (SSFFC) medical products. Both branded and generic medicines can be counterfeit.

3. CHALLENGES IN DETECTING COUNTERFEIT MEDICINES
Detection of counterfeit medicines is challenging due to the complexity of pharmaceutical supply chains and the increasing sophistication of counterfeiters. Counterfeit products may enter the market during manufacturing, transportation, or distribution. Although packaging features such as barcodes, holograms, and QR codes are used to identify genuine products, counterfeiters often reuse authentic packaging. The growth of online pharmacies has further increased the availability of counterfeit medicines. Effective detection

requires a combination of visual inspection, pharmacovigilance, regulatory surveillance, and laboratory-based analytical testing.

4. MEASURES AND REGULATORY ACTIONS

Several national and international initiatives have been undertaken to combat counterfeit medicines. The World Health Organization has issued guidelines and established surveillance systems to monitor substandard and falsified medicines. INTERPOL collaborates with law enforcement agencies globally to prevent illegal trade in counterfeit medicines, particularly through online platforms. Regulatory authorities such as the FDA and national drug control agencies also play a crucial role in monitoring, recalling, and preventing the circulation of counterfeit products.

5. IMPACT OF THE COVID-19 PANDEMIC

The COVID-19 pandemic significantly worsened the problem of counterfeit medicines due to global shortages of essential medicines and medical supplies. During this period, counterfeit antivirals, antimalarials, antibiotics, vitamins, personal protective equipment, and diagnostic kits were widely reported. Disruptions in manufacturing and international trade created opportunities for criminal networks to exploit supply chain weaknesses. Increased reliance on online purchasing further facilitated the spread of falsified medical products.

6. ANALYTICAL TECHNIQUES FOR DETECTION

Various analytical techniques are employed to detect counterfeit medicines. UV–Visible spectrophotometry is commonly used for preliminary screening due to its simplicity and low cost. Chromatographic techniques such as High-Performance Liquid Chromatography (HPLC) enable accurate quantification of active ingredients. Advanced methods including Gas Chromatography–Mass Spectrometry (GC–MS/MS) and Liquid Chromatography–Tandem Mass Spectrometry(LC–MS/MS) provide high sensitivity and specificity, allowing precise identification of counterfeit compounds.

7. CONSEQUENCES OF COUNTERFEIT MEDICINES

Counterfeit medicines can result in treatment failure, toxicity, drug resistance, organ damage, and death. They also lead to economic losses for patients, healthcare systems, and pharmaceutical manufacturers. The use of counterfeit medicines undermines trust in healthcare professionals and regulatory authorities, ultimately affecting public health outcomes.

8. CONCLUSION

Counterfeit medicines pose a serious threat to global public health and patient safety. Combating this problem requires coordinated efforts involving regulatory authorities, pharmaceutical manufacturers, healthcare professionals, and the public. Strengthening regulatory frameworks, enhancing analytical capabilities, and increasing awareness can significantly reduce the circulation of counterfeit medicines and protect public health.

