

Review Article

## The Global Landscape of Counterfeit Pharmaceuticals: Modes, Hazards, and Detection Methods

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### ABSTRACT

The problem of drug counterfeiting has been known for decades. Falsified and counterfeit drugs pose continuously growing health and socioeconomic concerns worldwide. The global market of illegal medicines encompasses many essential and widely consumed therapeutic modalities such as antibiotics, steroids, hormones, anti-protozoals, analgesics, and therapies for erectile dysfunction. Because the illegal medicine business is rapidly changing and adapting, national and international health authorities are obliged to take necessary measures and bring together collaborative and organized efforts to protect public health and interests. The establishment and implementation of good distribution practice becomes more important than ever to ensure safe drug circulation and administration. Moreover, the adoption of robust and accurate analytical procedures is fundamental for the detection and evaluation of the legal standing of pharmaceutical products and the assessment of their potential threats to public life. Here, we review types of counterfeit drugs, modes of counterfeiting, health and socioeconomic hazards, and analytical methods for detection. The review places special emphasis on the problem of drug counterfeiting and efforts to combat it.

**Keywords:** Chromatography, Counterfeit drugs, Detection, Hazards, Spectroscopy

### 1. INTRODUCTION

The World Health Organization (WHO) has defined counterfeit drugs as those that are deliberately mislabelled with respect to identity and/or source. Pharmaceutical counterfeiting has serious consequences for consumers, health care suppliers, drug producers and governments. Counterfeiting can apply to both branded and generic products. Counterfeit preparations include those with altered dosages, wrong pharmaceutical active ingredients (APIs), without active ingredients, or with fake packaging. In such cases, the identity of the source is deliberately and fraudulently mislabelled in a way, to mimic the authentic product. The International Federation of Pharmaceutical Manufacturers Associations has estimated that 7% of all drugs sold around the world are counterfeits.<sup>[1]</sup> Recent monetary estimate for the global market of counterfeit drugs is huge, ranging between US\$75 and US\$200 billion.<sup>[2]</sup> The continued rise in the availability of counterfeit drugs signifies the importance of developing more sophisticated and sensitive methods for their analysis and or detection. Additionally, establishing firm guidelines for good distribution practice for drug circulation and administration becomes increasingly important.<sup>[3]</sup>

## 2. CLASSES AND EXAMPLES OF COUNTERFEIT DRUGS

The main classes of medicines that are vulnerable to counterfeiting are those with high consumption and high prices such as anti-protozoals, antibiotics, steroids, hormones,<sup>[4]</sup> paracetamol, atorvastatin,<sup>[5]</sup> and products for weight control and erectile dysfunction. Dangerous counterfeit, substandard, adulterated and contaminated herbal medicinal products have also been identified.<sup>[6,7]</sup>

There are numerous examples of "sub-standard products", which do not contain the exact dose of active ingredients, do not meet quality specifications, or are subject to poor manufacturing practices.<sup>[8]</sup> Supplementary Table S1 provides a list of some examples of counterfeited medicines, the country of origin, and the specific problem of counterfeiting encountered.

## 3. TYPES AND MODES OF COUNTERFEIT DRUGS

The first step for fighting fake drugs is to identify different types of counterfeit drugs. Counterfeit drugs are classified into drugs with (a) poor quality of APIs, (b) no active pharmaceutical ingredient, (c) undeclared or unapproved APIs, (d) mislabelled medications and (e) incorrect dose of APIs.

### 3.1. Drugs with poor-quality APIs

The term "poor quality" entails that APIs are not produced as instructed by the guidelines of Good Manufacturing Practice that are globally accepted. This type of counterfeit consists of either too few or too many APIs.<sup>[9]</sup> The presence of unstable chemical materials, particularly in developing countries and inadequate storage conditions, as well as poor-quality control during production are major reasons for inferior API quality.<sup>[10-12]</sup> Furthermore, decreasing the concentration of API may result from dilution of drugs with sugars and water.<sup>[13]</sup> The most important categories of poor-quality active pharmaceutical ingredients include antibiotics, anti-tuberculosis, antivirals, vaccines, and antimalarials.<sup>[14]</sup>

### 3.2. Drugs with no APIs

Drugs with no APIs are the most frequent scenario in drug counterfeit. APIs are commonly substituted by substances like flour, curcuma, or cassava in oral preparations, and water in drinkable or injectable prescribed forms.<sup>[15]</sup> According to the WHO, the elimination of APIs from these products causes dramatic cuts in the production costs.<sup>[16]</sup>

### 3.3. Mislabelled drugs

The label on a drug bottle, container or vial lets the patient know the identity and dose of the drug, the dose of the

medicine, the timing of taking the drug, and any interactions that may be harmful to the patient. The label of a counterfeit drug also contains batch number, manufacturing number and other details which might be also fake. The health risks of the counterfeit mislabelled drugs include: taking the incorrect medication, accidentally overdosing, drug interactions and experiencing toxicity manifestations.

### 3.4. Drugs manufactured with improper dose of APIs

Counterfeit drugs may be produced using wrong **doses** of the active ingredients. More than 19% of the counterfeit medicine cases investigated by WHO encompassed medications with incorrect API doses.<sup>[17]</sup>

## 4. HEALTH AND SOCIOECONOMIC IMPACT OF COUNTERFEIT DRUGS

Counterfeit medicines are a significant global problem, particularly in developing countries, where they constitute 10-30% of the market.<sup>[18,19]</sup>

### 4.1. Health hazards

Counterfeit drugs pose serious health risks, including increased mortality and morbidity. This can result from toxic ingredients, inert fillers, or sub-therapeutic concentrations of active ingredients.<sup>[20]</sup>

### 4.2. Drug resistance

The use of poor-quality or sub-therapeutic counterfeit drugs contributes to drug resistance, a major public health threat. Beyond criminal counterfeiting, poor manufacturing standards or improper storage can also lead to ineffective drugs.<sup>[21]</sup>

### 4.3. Disease prevalence

Ineffective counterfeit drugs fail to prevent, cure, or control infectious diseases, leading to increased disease prevalence. This creates a larger pool of infected individuals, facilitating wider transmission and the rapid spread of diseases to new areas.<sup>[22]</sup>

### 4.4. Socioeconomic impact

Counterfeit drugs also have significant socioeconomic consequences:<sup>[23]</sup>

**Intellectual Property:** They undermine the incentive for pharmaceutical companies to invest in research and development by cutting into their revenues. This loss of revenue, projected at \$75 billion in 2010, hampers innovation, job creation, and overall economic growth.

Health Systems Cost: Counterfeit drugs lead to wasted financial expenditure by patients and families on ineffective products. Furthermore, adverse effects, treatment failures, and resulting infections necessitate additional spending on healthcare services, including repeated treatments with quality-assured medicines, tests, more expensive drugs for resistant infections, and costs associated with increased disease prevalence and transmission.

## 5. DETECTION OF COUNTERFEIT DRUGS

With the introduction of a large number of novel chemically-synthesized drugs annually, it is not feasible to rely on reference standards of drugs for the detection of counterfeiting.<sup>[24]</sup> In such cases, efforts should continue to isolate and chemically identify these derivatives and include them in the inspection list of illegal substances. Many analytical testing methods are used to detect and identify counterfeit drugs.<sup>[25]</sup> A summary of chromatographic and spectroscopic techniques used for the analysis of counterfeited drugs is outlined in Supplementary Table S2 and Figure 1.

### 5.1. Chromatographic methods for the detection of drugs counterfeiting

Chromatographic methods are optimal choices for the identification of structurally related compounds as they are not target-oriented and have the potential to unveil new or unknown compounds.

### 5.2. Gas chromatography (GC)

It is a chromatographic technique with high efficiency for the separation of drugs that are thermostable and can be volatilized. Especially when coupled to mass spectrometry (GC-MS), it provides a sensitive, accurate, reproducible, and quantitative approach for drug analysis, especially when present in complex mixtures.<sup>[26]</sup> Nevertheless, such technology is rather costly and necessitates extensive optimization for

qualitative and/or quantitative determination of drugs. The technique is widely employed for drug analysis assuming that they can be volatilized at running temperature as such or post derivatization.<sup>[27,28]</sup>

### 5.3. Static headspace analysis combined with GC-MS

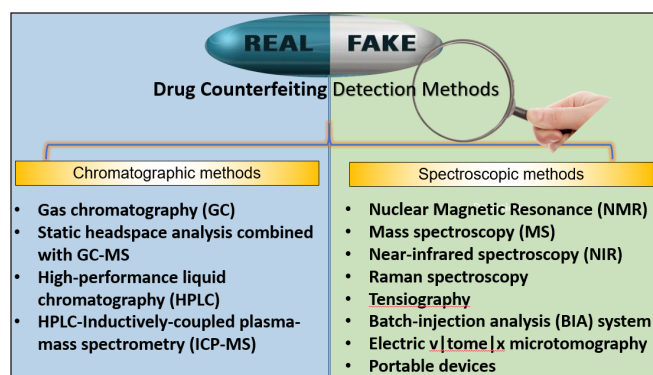
Headspace volatiles collection coupled to GC-MS was employed to discriminate and identify volatile impurities especially when present in non-volatile matrices, allowing for the detection of counterfeit drugs as well as tracking their source.<sup>[29,30]</sup> This method was utilized to differentiate between the manufacturers of a product based on impurity volatile profiles.<sup>[31]</sup>

### 5.4. High-performance liquid chromatography (HPLC)

HPLC is the most popular analytical technique used for qualitative and quantitative analyses of pharmaceuticals. One advantage of HPLC over GC is that it can be used for the analysis of non-volatile polar drugs. Moreover, HPLC can be coupled to several types of detectors such as electrochemical, evaporative light scattering, ultraviolet, and MS detectors, which offer better options for detecting a wide variety of chemical constituents.<sup>[32,33]</sup> Researchers from Glaxo SmithKline developed an LC/MS method for differentiating betamethasone from its cheaper alternative dexamethasone and similar compounds and to assign drug epimers in counterfeit drugs.<sup>[34]</sup> A sensitive LC-MS/MS method was established for the differentiation of genuine tramadol tablets from counterfeit ones without prior separation.<sup>[35]</sup> Compared to HPLC, ultra-high performance liquid chromatography (UHPLC) provides higher separation efficiency and better sensitivity suiting it more for drug analysis purposes, though is difficult to be implemented in the developing countries for drugs counterfeited detection.<sup>[36]</sup> Hyphenated techniques such as UHPLC-MS have been used to assess drug quality.<sup>[37]</sup> Among several analytical platforms to choose from for profiling authentic and counterfeit Viagra and Cialis, UHPLC along with ATR-FTIR that provided the most pertinent information for differentiation between authentic and fake drugs.<sup>[38]</sup>

### 5.5. Inductively-coupled plasma-mass spectrometry (ICP-MS)

ICP-MS is commonly applied for elemental analysis and detection of counterfeit drugs. Waddell and coworkers<sup>[39]</sup> reported on the use of ICP-MS to analyse trace metals in Ecstasy tablets aided by chemometric tools. ICP-MS is a reliable and sensitive method for the determination of trace elements in illicit heroin seizures.<sup>[40]</sup> Nonetheless, the use of ICP-MS is limited by expensive instrumentation and high maintenance costs.



**Figure 1:** A summary of chromatographic and spectroscopic methods used for the detection of drug counterfeiting.

## 6. SPECTROSCOPIC TECHNIQUES FOR COUNTERFEITED DRUGS DETECTION

Compared to chromatographic techniques employed for drug analysis which rely on prior separation of drug components prior to its detection, direct spectroscopic measurement offers the advantage of being robust as well as more reproducible providing the valuable metabolite signature of a drug.

### 6.1. Nuclear magnetic resonance (NMR)

NMR was one of the top techniques used to reveal counterfeited drugs and adulterated dietary preparations such as heparin, antimalarial medicines, drugs for erectile dysfunction, slimming, anti-inflammatory and cosmetic creams.<sup>[41]</sup> Since <sup>1</sup>H NMR can detect all proton-containing molecules, it is considered a universal method for structural elucidation of unknown compounds. Furthermore, quantification can be performed by simple integration of a target resonance in relation to the spiked internal reference standard.<sup>[42]</sup> Compared to MS, NMR does not require the purchase of expensive authentic reference standards.<sup>[43]</sup> In counterfeited and adulterated dietary supplements, NMR presents a powerful technique for the analysis of different dosage forms.<sup>[41]</sup> <sup>1</sup>H NMR spectra are acquired fully automatically with specialized software. Such acquisition does not need more than 20 min per analysis comparable to an HPLC run.<sup>[44]</sup>

### 6.2. Mass spectroscopy (MS)

MS is a sensitive and robust detection method. The discovery of electrospray ionization (ESI) and matrix-assisted laser desorption/ionization (MALDI) MS have facilitated the characterization of polar biomolecules. Direct analysis in real time (DART) and desorption electrospray ionization (DESI) are employed in many fields such as mapping of analytes separated by thin-layer chromatography and the screening of illicit drugs.<sup>[45,46]</sup> DART and DESI represent screening tools of counterfeit drugs, and show potential in the fields of drug quality control, and to extend more for large-scale analyses such as metabolomics and proteomics especially when coupled to multivariate data analyses.<sup>[42,47]</sup>

### 6.3. Near-infrared spectroscopy (NIR)

NIR is a fast and non-destructive method and hence attractive for drugs analysis. Nevertheless, it is not always substance-specific and lacks exact structural determination tools needed as in the case of counterfeited drugs detection. Applications of NIR in the pharmaceutical industry include proof of identity of pharmaceutical raw materials and final products,<sup>[48]</sup> determination of active ingredients levels<sup>[49]</sup> and detection of counterfeit in drugs, e.g. Combiron (ferrous sulfate), Aldomet (methyldopa), Floxacin (norfloxacin) and

Tylenol (acetaminophen).<sup>[50]</sup> More recently, NIR is aided by chemometric tools for classification of unknown drugs. Aside from NIR application for the qualitative and quantitative analysis of drugs, it offers minimal sample preparation while providing information on moisture content, residual solvents, active constituents levels that can all over aid in the identification of counterfeited drugs.<sup>[51]</sup> In one study, NIR revealed that counterfeit drugs may contain active ingredients at right levels, albeit the excipients may not match the product composition stated on the product label.<sup>[52]</sup>

In a related development, fourier transform-NIR imaging system was capable of identifying counterfeit drugs based on variations in ingredients distribution within the product. The dispersal of caffeine was found homogeneous in genuine drug product but localized in the counterfeit one, revealing for several industrial procedure.<sup>[53]</sup>

### 6.4. Raman spectroscopy

Raman spectroscopy is a scattering method, in which the sample under investigation is illuminated with a high-powered diode laser beam, which delivers intensity required to obtain spectra as only ca.  $10^{-6}$  of the light intensity applied produces inelastic scattering. Raman spectroscopy is non-destructive, specific, requires no sample preparation, and has been increasingly employed for the screening of drug formulations quality through packaging.<sup>[54-56]</sup> Furthermore, Raman spectra provide information onto the low-wave number region, which is pivotal for the identification of inorganic compounds used as excipients in tablets. Evolving technologies such as spatially offset Raman spectroscopy permits for bulk and deep subsurface examination of coated tablets and capsules.<sup>[57]</sup> Raman spectroscopy was used to discriminate among ecstasy (3,4-methylenedioxyethylamphetamine) and other ecstasy equivalents.<sup>[52]</sup> Derived spectra were used to distinguish between geometrical isomers such as the amphetamine derivatives 3,4-methylenedioxyethylamphetamine and N-methyl-1-(3,4-methylenedioxyphenyl)-2-butamine, and further among different polymorphic/hydrated forms of the same drug.

NIR and Raman spectroscopy with multivariate data analyses were applied to differentiate authentic from counterfeited Lipitor® tablets.<sup>[58]</sup> An additional advantage of a Raman microscope is its high spatial resolution, which helps to derive spectra at various positions on a tablet cross section under investigation.

### 6.5. Tensiography

It is a more modern system in which a pendant drop is illuminated from within by an optic fibre generator and receiver. The technology permits fingerprint patterns, which rely on surface tension, refractive index and colour. Through

fingerprinting each product, this technology can distinguish one drug supplier from another and further within batches from the same supplier. Such a technique was applied for the identification of counterfeit in penicillin.<sup>[59]</sup>

### 6.6. Batch-injection analysis (BIA)

BIA with an electrochemical detector is favoured as a movable analysis system. Such an experimental setup is simple and includes the introduction of minute amounts into the electrochemical cell. Following assembly of the BIA setup, several analyses are made possible (typically more than 200 injections). Portable electroanalytical devices have gained considerable interest recently aiming for biological and medical point-of-care analysis, which has the potential to be applied for the detection of counterfeited drugs in non-expert labs.<sup>[60]</sup>

### 6.7. Electric voltage microtomography system

It is used to differentiate between counterfeited and genuine medicines using image analysis. The image can be acquired by a thermal image camera or a conventional one. A series of 2D sections provided by a computed microtomography provides an image of the internal microstructure of the tablet in micron or submicron resolution using X-ray radiation. Image analysis involves three groups of quantitative parameters of tablet components distribution within each tablet to detect the weakness of the counterfeited drug.<sup>[61]</sup>

## 7. PORTABLE DEVICES FOR DETECTION OF DRUG COUNTERFEITING

With an increasing interest in developing on-site detection, simple methods for screening counterfeit drugs, portable paper and spectrometer devices have been developed. An inexpensive test paper based card was used for the rapid on-site screening of counterfeited drugs containing ampicillin, amoxicillin, rifampicin, isoniazid, ethambutol, and pyrazinamide. The paper devices contain several lanes separable by hydrophobic barriers, with dissimilar reagents placed inside each lane.<sup>[62]</sup> Paper analytical devices are developed for the rapid onsite testing of  $\beta$ -lactam antibiotics and anti-tuberculosis drugs, and for the identification of low-quality chloroquine, doxycycline, quinine, sulfadoxine, pyrimethamine, and primaquine antimalarial drugs.<sup>[63]</sup> These tests are considered simple and cheap enough to be conducted in clinics, pharmacies, and ports of entry as a quick assessment method for counterfeit medications. A microfluidic paper-based analytical device has been applied to identify the active ingredient in forged antibiotics class, e.g.,  $\beta$ -lactams, via an enzyme competition-based assay. The assay employs nitrocefin, a chromogenic substrate, to compete with  $\beta$ -lactam antibiotics in a reaction with  $\beta$ -lactamase, in which a yellow colour designates legitimate drugs whereas red specifies falsified drugs.<sup>[64]</sup>

Portable spectroscopic techniques, such as NIR and Raman spectroscopy are also gaining attention as effective tools for rapid identification of counterfeit and substandard pharmaceuticals. Recent evaluations of low-cost, handheld devices have demonstrated their ability to accurately quantify APIs in simulated falsified antimalarial, antiretroviral, and anti-tuberculosis medications.<sup>[65]</sup> Portable NIR spectroscopy, combined with advanced data processing and management systems, provides a fast, non-destructive, and dependable method for on-site detection and quantification of counterfeit Viagra tablets.<sup>[66,67]</sup> The effective application of portable Raman spectroscopy in detecting falsified medicines and identifying quality variations within the same generic brand has been well documented.<sup>[68]</sup>

## 8. CONCLUSION

Health and socioeconomic risks from substandard and counterfeit medicines are mounting and far greater than there were previously thought. Data collection and research on counterfeit drugs should continue and recommendations from international and local regulatory and health bodies should be firmly implemented. Among policies that can be enforced are the adoption of technology to track and trace drug counterfeits, encouraging cooperation with foreign governments regarding counterfeiting drugs, selling drug supplies only to licensed manufacturers, developing better quality control measures by drug manufacturers to prevent drug shortages, and applying firmer penalties for individuals or firms convicted of counterfeit drugs. One important line of defines is to increase public awareness of the risks and hazards that might emerge due to the consumption of fake or counterfeit medicines especially from online sources. Finally, recent developments in analytical procedures and technologies offer health and pharmaceutical authorities with highly effective and low-cost authentication processes for identifying counterfeit drugs and securing the supply chain.

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