

# Fake and Counterfeit Drug: A review

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## ABSTRACT

**Background:** *Drugs are used to cure or treat disease, relieve symptoms, ease pain, prevent disease or symptoms, eliminate or reduce symptoms and to slow the disease process. The problem of fake drugs is wide spread affecting both developing and developed nations, assumes added significance in view of rapid globalisation and is assuming a dangerous dimension in most countries.*

**Methodology:** *A review of literature on counterfeit drug and its impact was done. The articles were accessed from public libraries, as well as online through internet search engines and relevant information extracted.*

**Result:** *The burden of counterfeit is enormous and can result in treatment failure, end organs damage and toxicity, death, economic loss as well as loss of confidence in the health care system.*

**Conclusion:** *Trade in counterfeit drugs appears to be widespread, affect both developing and developed countries. The fight against counterfeit and fake drugs is multisectoral and requires a prolonged approach. It requires all stakeholders to contribute actively in order to achieve success.*

**Key words:** *Counterfeit, drugs, review*

## INTRODUCTION

Drugs are used to cure or treat disease, relieve symptoms, ease pain, prevent disease or symptoms, eliminate or reduce symptoms and to slow the disease process. Fake means something that is not genuine but is presented as or appears to be genuine to make or produce something and claim it is genuine when it is not. Shelf life is the time taken for the preparation to become unfit for use either through chemical degradation of the active ingredient or physical deterioration of the preparation during storage. It can also be defined as the period a drug or product will remain satisfactory when stored under expected or directed storage conditions ordered by the manufacturer. Shelf life or expiry date of a drug is usually a maximum of five years. Counterfeit is something made for a dishonest purpose; an act deliberately designed to deceive.

The World Health Organization defines counterfeit drugs as one which is deliberately and fraudulently mislabelled with respect to identify and/or source<sup>1</sup>. Counterfeiting of commercial products is an age old practice which flourishes in many countries and is motivated mainly by the huge profits to be made. Trade in counterfeit drugs appears to be widespread internationally, affecting both developed and developing countries. The spread of counterfeit drugs is generally more pronounced in those countries where the manufacture, importation, distribution, supply and sale of drugs are less regulated and enforcement may be weak. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging with the wrong ingredients, without active ingredients or with insufficient active ingredients<sup>2</sup>. Counterfeit medicinal drugs include those with less or none of the stated active ingredients with added sometimes hazardous, adulterated, substituted ingredients, completely misrepresented or sold with a false brand name otherwise legitimate drugs that have passed their date of expiry are sometimes remarked with false date low quality. A counterfeit medication or pharmaceutical product is produced or sold with the intent to deceptively represent its origin authenticity or effectiveness. A counterfeit drug may contain inappropriate quantities of active ingredients or none may be improperly processed within the body for example absorption by the body, or may contain ingredients that are not on the label. Several technologies may prove helpful in combating the counterfeit drug problem. Fake drugs otherwise called counterfeit drugs are unfit for usage and human consumption and therefore constitute hazard to good health. Drug counterfeiting is a growing danger and not only in developing countries where it can account for up to 40% of the market<sup>3</sup>. Some counterfeiting is difficult to detect, investigate, quantify or stop. The quantity of counterfeit medication is difficult to determine. Counterfeiting occurs throughout the world, although there are claims it is more common in some developing countries with weak regulatory or enforcement regimens. A counterfeit drug may look like the genuine version of medication.

The business of fake drugs is a lucrative crime that is increasing annually worldwide. The problem of fake drugs is wide spread affecting both developing and developed nations, assumes added significance in view of rapid globalization and is assuming a dangerous dimension in most countries. Counterfeiters employ all types of things including setting up of fake companies and procuring fake certificates and documents for exporting and importing pharmaceutical ingredients as well as machinery<sup>4</sup>. Counterfeit drugs are illegal and may be harmful to health.

Easy access to counterfeit drugs especially in the tropics in large open air markets alongside fruits and vegetables makes this a flourishing business<sup>5</sup>. Often, the patients here obtain medicines from untrained vendors without prescription, in inadequate courses and without information<sup>6</sup>. Counterfeiting is greatest in regions where regulatory and enforcement systems for medicines are weakest. All kinds of medicines have been counterfeited branded and generic, ranging from medicines for the treatment of life threatening conditions to inexpensive generic versions of painkillers.

Fake medicines pose a public health risk because their content can be dangerous or they can lack active ingredients. Their use can result in treatment failure and contribute to increased resistance example, in the case of anti-malarial that contains insufficient active ingredients or even death. Paying for medicines can consume a significant proportion of individual or family income. Some people seek medicines that are sold more cheaply. These are often available from non-regulated outlets, where the incidence of fake medicines is likely to be higher as is often the case in the rural areas of developing countries. Counterfeiting medicines can be very lucrative. Due to worsening economic conditions and poor enforcement of existing pharmaceutical and customs regulations, third world countries are faced with a growing threat from counterfeit and substandard medicines. With expansion of illicit markets in urban areas, the sale of medicines of uncertain quality and origin are increased. Most victims of illicit trade are among the world's poorest populations that cannot afford to buy quality drugs through private sector distribution channels<sup>7</sup>. The era 1985-2000 in Nigeria has heralded the regime of faking and quackery, counterfeit drugs, quack doctors, illegal chemist shops and hospitals<sup>8</sup>. The menace of the fake drugs became prevalent in the last decade and the present situation is alarming in the West African sub region, including Nigeria.

### THE BURDEN OF FAKE AND COUNTERFEIT DRUGS

Counterfeit medicines pose a serious threat to public health. Up to 15 % of all drugs sold worldwide are estimated to be fake<sup>9</sup>. Fake medicines are found everywhere in the world. They range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. The problem is however much more severe in the developing countries. The World Health

Organization estimates that about 25% of the medicines consumed in developing countries are believed to be counterfeit<sup>10</sup>. Fake antiretroviral drugs have been reported in Africa<sup>11</sup>. Counterfeit of antimalarial drugs are widespread in developing countries. Almost all kinds of drugs are being faked ranging from antibiotics, through anticancer agents. The type of counterfeit drugs most frequently found in poor countries with huge burden of infectious diseases is principally antibiotics.

The circulation of substandard medicines in the developing world is a serious clinical and public health concern. Problems include under or over concentration of ingredients, contamination, poor quality ingredients, poor stability and inadequate packaging. Empirical observations have shown that there may be more fake than genuine drugs in circulation<sup>1</sup>. Drugs which have been rejected by regulators or manufacturers may be sold in markets and are considered counterfeit<sup>13</sup>. The same holds true for drugs which have expired and have been relabelled with a fake later expiry date. Fake antibiotics with a low concentration of the active ingredients can cause damage by stimulating the development of drug resistance. According to the World Health Organization several factors encourage counterfeiters such as

- Ineffective registration of medicines
- A large private sector health sector that is insufficiently regulated or where regulations are weakly enforced
- Places where most medicines can be bought without a prescription
- Places where many people practice self-medication
- The shortage or erratic supply of medicine
- Ineffective cooperation among different stakeholders
- High levels of corruption
- A poor population with little knowledge about health issues

Counterfeit products may include:

1. Products with the correct ingredients or the wrong ingredients
2. Products with insufficient or no active ingredients
3. Products with fake packaging
4. Medicines with active ingredients different from what is stated on the package
5. Expired medicines relabelled with the purpose to extend the shelf-life
6. Products without the name and address of the manufacturer
7. Expired products
8. Drugs with no expiry date
9. Medicines which do not contain any of the specified active ingredients despite what is written on the label

10. Products which contain the correct strength of the specified active ingredient
11. Products which contain the different quantity of impurities

Medicines must be safe, effective and of acceptable quality and should be used rationally in order to produce the desired effects with good clinical and therapeutic outcomes. Part of the reason for the poor quality of drugs is due to decomposition of the active ingredient, because of high temperatures and humidity of storage, where the amount of active drug is well below stated amounts. Use of these preparations could lead to therapeutic failure. Fake and poor quality drugs are rife in developing countries and are costing lives. The illicit trade in counterfeit drugs remain a great threat to the lives of people.

All drugs should be labelled in a language that is easily understood. The label on each individual container should at least contain the pharmacological name, batch number, dosage form, strength, formulation, name of manufacturer, quantity in the container, storage conditions, route of administration and expiry date.

Drugs should be obtained from a reliable source and comply with quality standards in the country. The only way for one to regain one's health is to take medications as prescribed by the doctor. Counterfeit drug is a major challenge to quality health care with devastating health, socio-economic and image effects on the citizenry.

### CONSEQUENCES AND DANGERS OF COUNTERFEIT MEDINES

The medicine may not be effective because it does not contain enough or even any active ingredient. The medicine may be dangerous because it contains too much of an active ingredient or contains other unknown harmful ingredients.

The medicine may have been manufactured or stored in an uncontrolled environment that does not have the appropriate measures in place to ensure that medicines are safe and effective.

**1. Treatment failure:** Treatment failure and even death can result with the use of counterfeit drugs. Eliminating them is a considerable public health challenge. Defining the extent of counterfeiting is difficult for a number of reasons. Other associated health risks include antibiotic resistance. The problem of fake and counterfeit drugs is very important in medicine because of the associated health risks. Therapeutic failure may be associated with the use of fake drugs containing insufficient or

no active ingredient leading to loss of confidence by the patients. The situation is so bad that even when patients are treated with genuine antibiotics and antimalarial they no longer respond due to resistance induced previously by taking counterfeit and fake drugs.

- 2. End organ damage:** Ingestion of counterfeit drugs can result in damage to the liver, kidneys, heart and the central nervous system. The liver is responsible for breaking down drugs while the kidneys eliminate them from the body. When these poisons are taken into the body they can damage the vital organs.
- 3. Toxicity:** Another important challenge is the management of target or most vulnerable groups of patients with high risk of toxicity or adverse effects and therapeutic failures which can lead to fatalities. They are the neonates, geriatrics (old people), pregnant women and those with reduced kidney or liver functions as well as the immunocompromised. The use of fake and counterfeit drugs in these patients would be catastrophic and absolutely clinically disastrous and mortality rates will be increased.
- 4. False vital signs:** The use of fake and counterfeit drug can result in false values of vital signs.
- 5. Death:** Disease sufferers are made to bear far greater burden than they ordinarily should and sometimes innocent lives are lost due to the scourge of fake and unwholesome pharmaceutical products. Thousands of people die each year after taking drugs that contained useless and harmful ingredients. Ineffectiveness of the counterfeit products leads to steady progression of the disease which eventually results in death. Lifesaving drugs have also been detected to be counterfeited.
- 6. Loss of confidence:** Therapeutic or adverse events results in loss of confidence in the health system and the system of drug control and enforcement. The reputation of the original product is damaged and the pharmaceutical companies which invest huge resources in the developing innovative products suffer financially. Patients may lose confidence in the health care professionals.
- 7. Economic loss:** Economic loss as a result of drug counterfeiting is enormous. Many pharmaceutical companies lose large amounts of money because their products are being counterfeited and sold at cheaper rates. Drug therapy has financial

implications both on the individual and the national economy. When the wrong drug or counterfeit is used it is waste and when excess or under dose of the right drug is used, it is also wasteful. It affects the individual finances because there is an increased cost of therapy. Man hours are also lost to illnesses that would have resolved much earlier if the right drugs were taken.

## CONCLUSION

Trade in counterfeit drugs appears to be widespread internationally and affects both developing and developed countries<sup>1</sup>. The spread of counterfeit drugs is generally more pronounced in countries where the manufacture, importation, distribution, supply and sale of drugs are less regulated and enforcement may be weak. To achieve the goal of health for all, the menace of counterfeit drugs needs to be controlled. Counterfeit medicine poses a serious threat to public health and has taken a silent devastating toll on humanity due to the lack of reporting in some critically affected areas. In addition to past and present losses due to fake drugs, the future of global health is at risk. Disease causing agents can develop resistance to genuine drugs.

The media has a role to play as a watch dog not only for the counterfeiters but also for any laxity and corruption on the part of the regulatory authorities<sup>5</sup>. It is the duty of the dealers and consumers to remain within the proper supply chain and not to go astray looking for cheaper medicines. Clusters of treatment failure may be due to fake drugs and also needs to be reported<sup>13</sup>. The consequences of the use of counterfeit medicines vary from therapeutic failure to occurrence of serious adverse effects and even death. The main victims of counterfeit medicines are poor and uneducated people who buy counterfeits because they are cheaper than the original products. Many people are unaware of such health issues and the dangers of counterfeits. Counterfeiting is more frequent in countries where drug distribution is badly organised or regulated. The disturbing aspect of the counterfeit drug menace is that the effects of consuming such drugs go unnoticed most of the time except in such cases where mass death results. The fight against counterfeit and fake drugs is

multisectoral and requires a prolonged approach. It requires all stakeholders to contribute in order achieve success.

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