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Fake Drugs

Paul A. Adekunte[1], Matthew N. O. Sadiku[2], Janet O. Sadiku[3]

[1]International Institute of Professional Security, Lagos, Nigeria
[2]Roy G. Perry College of Engineering, Prairie View A&M University, Prairie View, TX, USA
[3]Juliana King University, Houston, TX, USA

ABSTRACT

Fake drugs, more precisely described by the World Health Organization (WHO) as falsified medical products, or substandard medicines, are medicines deliberately produced or presented in a way that misrepresents their identity, composition, or source – which are produced with criminal intent. The more broader problem also includes substandard medicines, which are authorized products that fail to meet established quality specifications. Fake drugs pose as a serious public-health, economic, regulatory, and security problem. They can result in treatment failure, poisoning, disability, death, antimicrobial resistance, financial losses, and reduced confidence in healthcare systems. Reports by WHO state that more than one in ten medicines in low- and middle-income countries are estimated to be substandard or falsified, although the exact prevalence varies substantially by country, product, and study methodology. However, fake drugs should not automatically be equated with every poor-quality medicine. The paper looks at the pros and cons of fake drugs and the plausible solutions to solving the challenges it poses to humanity.

KEYWORDS: *Fake drugs/counterfeit drugs/falsified drugs, expired drugs, NAFDAC, public health, drug resistance, Nigeria, false packaging, mislabeling.*

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INTRODUCTION

The availability of safe, effective, and quality medicines is fundamental to public health and national development. Basically, medicines are used to cure diseases, prevent infections, and to prolong life when they are genuine and properly used [1]. Contrariwise, the global proliferation of fake drugs has tended to undermine these benefits and posed as one of the most serious threats to health systems worldwide [2]. Fake drugs, which are also referred to as counterfeit, falsified, or substandard medicines, are known as pharmaceutical products that are deliberately mislabeled with respect to identity, composition, or source, or that fail to meet quality standards, for example, tablet labeled as amoxicillin containing chalk or no active ingredient [1, 3], as shown in Figures 1 and 2. Such drugs may not contain active pharmaceutical ingredient, have incorrect ingredient, an insufficient quantity of active ingredient, or harmful contaminants [4]. There are also instances where expired drugs are relabeled and reintroduced into the market [5]. Globally, the WHO has estimated that 1 in 10 medical products circulating in low- and middle-income countries is substandard or falsified, with Africa and Asia bearing the highest burden [1]. Expired drugs are genuine drugs that have passed their shell-life/expiry date set by the manufacturer. They are real at production but have degraded chemically, e.g., real paracetamol kept 5 years past expiry that has reduced potency and toxic breakdown products [3]. The most commonly falsified medicines are antimalarials, antibiotics, antihypertensives, antidiabetics, and vaccines [6]. These are with severe consequences of treatment failure, prolonged illness, development of antimicrobial resistance, organ toxicity, and death. It is estimated that falsified antimalarials alone cause over 500,000 deaths annually in sub-Saharan Africa [1].

In Nigeria, the problem of fake drugs assumed alarming proportions in the 1980s and 1990s due to weak regulation, porous borders, and structural adjustment policies (Structural Adjustment Programme - SAP) that encouraged unregulated

importation [4]. By 2001, studies indicated that about 40% of drugs in circulation were fakes [4]. This was what led to several tragedies, such as the 1990 paracetamol poisoning that killed over 100 children and the 2008-2009 contaminated teething syrup that killed 84 children in Lagos [1, 4]. For this reason, and in response, the Federal Government under the leadership of Professor Dora Akunyili (2001-2008) strengthened NAFDAC, leading to a reduction in prevalence to about 13-15% [4], as shown in Figure 3.

Regardless of these gains, the problems of fake drugs persisted due to poverty, high demand for cheap medicines, corruption in the supply chain, inadequate penalties, and the rise of unregulated online pharmacies [6, 7]. The Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act of 1988 provides for stiff penalties, including life imprisonment, yet enforcement remains challenging [8]

HISTORY

The history of fake drugs is as old as the history of medicine itself, but became a global public health crisis with the expansion of pharmaceutical manufacturing and international trade [1].

1. The Pre-colonial and early period (Before 1900)

The adulteration of herbal remedies was very common in the ancient times. Sellers diluted or substituted medicinal herbs for profit [2]. With the development of modern pharmaceuticals in 19th century Europe, counterfeiting began to take organized form as patent medicines were widely imitated [3].

2. Early 20th century (1900-1960)

Increase in falsification was caused by the mass production of drugs such as aspirin and penicillin. In the United States, the 1938 Food, Drug, and Cosmetic Act enacted after the sulfanilamide tragedy of 1937, where diethylene glycol-contaminated elixir killed over 100 people [3]. This led to the first major regulatory response to fake drugs globally.

3. Post-independence Nigeria (1960-1980)

After Nigeria's independence in 1960, drugs were mainly imported from the UK and were of good quality under strict colonial pharmacy laws [4]. The Pharmacy Act of 1964 regulated practice was weak. Local manufacturing was minimal, and while the dependence on imports created opportunities for adulteration [9].

4. Rise of fake drugs in Nigeria (1980-2000)

The 1980s Structural Adjustment Programme (SAP) led to deregulation of import licenses. Unscrupulous importers flooded the market with cheap, unregistered drugs from Asia [4].

- 1990: Over 100 children died in Ibadan and Jos after taking paracetamol syrup adulterated with diethylene glycol [1].
- 1993: The Federal government established NAFDAC by Decree No. 15 to control fake drugs [4, 10].
- By 2001, WHO/NAFDAC studies showed 40% of drugs in Nigeria were fakes [4].

5. War against fake drugs (2001-2010)

Appointment of Prof. Dora Akunyili as NAFDAC Director-General in 2001 marked a turning point [4]. During this period was the:

- Destruction of fake drugs worth billions of naira.
- Closure of open drug markets in Onitsha, Kano.
- Introduction of NAFDAC registration numbers.
- Prevalence was seen to drop from 49% to 16.7% by 2006 and to ~15% by 2010 [1, 4].
- 2008-2009: "My Pikin" teething syrup contaminated with diethylene glycol killed 84 children in Lagos, leading to prosecution [4], as shown in Figures 4, 5 and 6.

6. Modern era (2010-Present)

The introduction of **Mobile Authentication Service (MAS)** in 2010: Consumers verify drugs via SMS scratch codes [4].

- 2015: WHO launched Global Surveillance and Monitoring System (GSMS) for substandard/falsified products [1].
- Rise of **online pharmacies** and COVID-19 vaccines falsification [2, 5], as shown in Figure 7.
- NAFDAC under Prof. Mojisola Adeyeye intensified use of Truscan devices and international collaboration with WHO and INTERPOL [4].
- Current prevalence in Nigeria estimated at 13-15%, which is still above WHO acceptable limit of <5% [1].

7. 2015-Date

In 2013, and which became fully operational in 2015, the WHO established the Global Surveillance and Monitoring System (GSMS) for Substandard and Falsified (SF) Medical Products in order to address the growing global threat [1, 11, 12].

WORLD HEALTH ORGANIZATION DEFINITIONS

- **Falsified**: Deliberately misrepresent identity, composition or source
- **Substandard**: These are authorized products that fail quality standards due to poor manufacturing
- **Unregistered:** Not evaluated/approved by regulatory authority [1, 4].

Types of fake drugs:

1. No active ingredient: e.g., chalk as paracetamol
2. Wrong active ingredient: e.g., wrong antibiotic
3. Insufficient active ingredient: Under-dosed antimalarials
4. Contaminated drugs: Contain toxic substances like diethylene glycol
5. Expired drugs relabeled: Change of expiry date
6. Herbal mixtures falsely claiming to cure HIV, diabetes [2, 3].

Prevalence:

- WHO estimates that 1 in 10 medicines in low- and middle-income countries are substandard or falsified [1].
- In Nigeria, NAFDAC estimates fake drugs constitute 13-15% of circulating drugs, down from 40% in 2001 due to enforcement [4].
- Most faked antimalarials, antibiotics, antihypertensives, erectile dysfunction drugs, and vaccines [2].

Causes: These are as a result of:

1. Weak regulation and porous borders
2. High demand and poverty: Cheap alternatives
3. Corruption in supply chain
4. Lack of public awareness
5. Online pharmacies selling unregulated drugs
6. Inadequate penalties for offenders [1, 7].

Implications to humans

The implications are:

A. Health implications

- Treatment failure: Malaria, pneumonia persist leading to death [1].
- Drug resistance: Under-dosed antibiotics/antimalarials cause antimicrobial resistance [6].
- Poisoning and organ damage: Toxic contaminants cause kidney/liver failure. In 2008-2009, contaminated teething syrup killed 84 children in Nigeria [1, 4].
- Death: Estimated 500,000 deaths yearly in sub-Saharan Africa from fake antimalarials alone [1].

Economic implications

- Loss of money on ineffective drugs
- Increased healthcare costs from prolonged illness
- Loss of confidence in the health system [1].
- **Social implications**
- Loss of trust in pharmacists, doctors, and NADDAC
- Increased patronage of traditional healers [13].

The situation in Nigeria

- Regulatory Agency: NAFDAC was established in 1993.
- Landmark Actions: Prof. Dora Akunyili's war against fake drugs (2001-2008) helped to reduce prevalence from 40% to 15% [4].
- Recent Seizures: NAFDAC destroyed fake drugs worth billions of naira in Lagos, Kano, Onitsha [4].
- Mobile Authentication Service (MAS): Scratch code to verify via SMS [4].

Worthy of note is the fact that in most developing countries such as Nigeria, unscrupulous sellers often relabeled expired drugs with new expiry dates to resell them. At this point, an expired drug becomes a fake drug because of deliberate falsification [1, 2, 4]. In other words, all fake drugs are illegal by intent, and while expired drugs become illegal when sold, and become fake when relabeled.

Solutions

1. **Strengthen NAFDAC:** Through more funding, establishing more laboratories, and employing capable/well trained staff [1].
2. **Strict punishment:** Offenders are to be sentenced to life imprisonment under Counterfeit and Fake Drugs Act [8].
3. **Public enlightenment:** The public/consumers are to verify drugs with MAS before use [4].
4. **Secure supply chain:** Track-and-trace technology should be deployed [3].
5. **International cooperation:** This would be in collaboration with the WHO, and Interpol against trafficking [5].
6. **Buy only from licensed pharmacies,** consumers are to check NAFDAC number, expiry date, and seal [1].

How to identify fake drugs

The public and consumers can identify fake drugs if there is:

- No NAFDAC registration number
- Poor printing, spelling errors on pack
- Unusual taste, color, or crumbling
- No patient leaflet
- Suspicious cheap price [1, 4, 14].

CONCLUSION

Fake drugs are not just merely an economic crime but a direct threat to human life and national development. Sustained success in combating fake drugs will require strengthening NAFDAC via adequate funding and laboratories, strict enforcement of the Counterfeit and Fake Drugs Act with life imprisonment for offenders, expansion of track-and-trace and MAS technology, regulation of online drug sakes, and continuous public enlightenment to

purchase only from licensed pharmacies, so that consumers understand the risks of purchasing medicines from unauthorized sources. Addressing fake drugs will require a multi-sectoral approach. Governments should strengthen regulatory institutions, improve border and market surveillance, prosecute manufacturers and distributors of falsified medicines, and promote secure pharmaceutical supply chains. More information about fake/expired drugs can be obtained in the books in [15-24] and the following related journals:

BMJ Open

Tropical Medical & International Health

Frontiers in Pharmacology

Social Science & Medicine

The Lancet Global Health

PLOS Medicine

Journal of Pharmaceutical and Biomedical Analysis

Journal of Pharmaceutical Sciences

Research in Social and Administrative Pharmacy

International Journal of Pharmacy Practice

Drug Safety

The Lancet Infectious Diseases

African Journal of Pharmacy and Pharmacology

American Journal of Tropical Medicine and Hygiene

British Journal of Clinical Pharmacology

Journal of Pharmaceutical Policy and Practice

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Figure 1. Counterfeit medication
Source:
https://en.wikipedia.org/wiki/Counterfeit_medication



Figure 2. The battle against counterfeit drugs



Figure 3. National Agency for Food and Drug Administration and Control
Source:
https://en.wikipedia.org/wiki/National_Agency_for_Food_and_Drug_Administration_and_Control



Figure 4. A $500M Cape Breton drug bust



Figure 5. Drug arrest in manly gun seized from beacon hill home



Figure 6. James Craig trial Colorado dentist poison protein shakes



Figure 7. Buy New Follihair Tablet Online.