



Factors Associated with Drug Counterfeit in Nigeria: A Twelve Year Review

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Authors' contributions

This work was carried out in collaboration between all authors. Author CFU did most of the literature searches and re-arranged the manuscript to improve its quality. Author MNA designed the study and wrote the first draft of the manuscript. Author ACOO was the first supervisor for the paper. Author OFE was the second supervisor for the paper. Author AUU read through the manuscript and made some corrections. Author SOI was involved in rearranging the references. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/BJMMR/2016/21342

Editor(s):

(1) Jingli Xu, College of Pharmacy, University of New Mexico, USA.

Reviewers:

(1) Paola Zucchi, Universidade Federal de São Paulo, Brazil.

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(3) Marcelino José Jorge, National Institute of Infectious Diseases, Brazil.

Complete Peer review History: <http://sciencedomain.org/review-history/12135>

Review Article

Received 13th August 2015
Accepted 9th October 2015
Published 7th November 2015

ABSTRACT

Background: Drug counterfeiting poses a great danger to every society. The actual prevalence of counterfeit drugs is difficult to ascertain presently but just like other crimes, drug counterfeiting is an underground business that often comes to light mostly when death occurs. About 10% of drugs circulating worldwide are fake drugs with enormous associated health risk. Preventing the problem is a primary duty of every responsible nation in order to save lives.

Objective: This paper aims at studying the factors associated with drug counterfeiting, its consequences and possible solutions.

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Methods: This article reviews relevant literatures published from 2004 to 2015 from medical journals, health survey reports, books, Google search and health-related websites such as World Health Organization.

Results: Several researchers have identified corruption and conflict of interest, poor health seeking behavior of Nigerians, high prices of locally manufactured drugs due to high taxes and tariffs, inadequate legislation, unordered drug distribution system, inadequate cooperation from government agencies and discriminatory regulation by exporting countries as the major factors associated with drug counterfeiting in Nigeria.

Conclusion/ Recommendations: Drug counterfeiting is one of the greatest atrocities of our time and it affects both developing and developed countries. There is an urgent need for the government as well as professional bodies to ensure massive public enlightenment and the effective enforcement of the existing drug laws in Nigeria.

Keywords: Counterfeit drugs; laws; Nigeria.

1. INTRODUCTION

Perhaps of all crimes, none is as potentially dangerous as drug counterfeiting. It is a deliberate act with full intention to deceive. According to World Health Organization (WHO), a counterfeit medicine or pharmaceutical product is one which is produced and sold with the intent to deceptively represent its origin, authenticity or effectiveness [1]. Counterfeit can apply to both branded and generic products [1,2]. Counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients [1,2,3]. It can also include expired drugs with altered expiration dates [2]. These kinds of counterfeits have the tendency to harm and in some cases, even lead to death for those unfortunate enough to consume them [2]. As the world's population keeps increasing, more people are suffering from ailments and therefore require drugs. Counterfeiters are well aware of this and take advantage of the situation to push out fake drugs- an avenue that produces quick money. All counterfeit drugs are 100% illegal, whether they are harmless or not. No product is spared by the counterfeiters, if it can be replicated to make profit.

The circulation of substandard medicines in the developing world is a serious clinical and public health concern [1]. According to recent estimate by the WHO, about 10% of drugs circulating worldwide and 25% in less developed countries are fake [4,5]. Africa and some parts of Asia are the most affected regions followed by Latin America. In Nigeria, the problem of fake drugs has significantly improved from 41% in 2002 through 16.7% in 2006 to 10% in 2011 [4,5]. Generally, all counterfeit drugs are substandard

but a substandard drug may not be considered as counterfeit if there is no intent to deceive [6].

According to WHO, Nigerian health officials estimated that 70% of drugs in circulation in the country are either fake or adulterated [2,7]. The Ebonyi State Task Force on Counterfeit and Fake Drugs reported that approximately 48% of goods and drugs imported into the country were substandard or counterfeit [7]. In 2003, the WHO cited estimates that the annual earnings of counterfeit drugs were over 32 million U.S dollars. In 2009, Nigeria seized a large consignment of fake anti-malaria drugs with the label of 'made in India' but found out that the medicines were in fact produced in China and was imported into African countries. The authorities have maintained the incident is not isolated, indicating it was just a tip of the iceberg. According to a report released by the Organization for Economic Co-operation and Development (OECD), 75% of fake drugs supplied world over have some origin in India, followed by 7% from Egypt and 6% from China. In the case of India, while it is against the law to sell fake drugs for domestic use, there is no prohibition on the export of counterfeit drugs [8]. The menace of counterfeit and substandard drugs is no doubt one that has been on the front burner of national discourse as far as the safety of the health of Nigerians is concerned. This paper reviews the consequences of drug counterfeiting, the factors associated with it and possible solutions.

2. IMPLICATIONS OF COUNTERFEIT DRUGS

The problem of fake drugs is very important in medicine because of the associated health risks. Obviously, counterfeit drugs have adverse health, economic and social implications.

- Its negative impact on the society is more than that of either narcotic agents or the combined effects of malaria, HIV/AIDS and armed robbery [5,9,10].
- Fake drugs have led to therapeutic failures, antibiotic resistance, toxic effects and even deaths [9,10]. The whole essence of manufacturing pharmaceutical products is to ensure the well-being of the human body or to provide cure for diseases without endangering any organ, tissue or system of the patient. The reverse becomes the case where the product is counterfeit or substandard because the drug will complicate the patient's health situation.
- Fake drugs has embarrassed our healthcare providers and eroded the confidence of the public in our healthcare delivery system. The situation became so bad that even when patients were treated with genuine antibiotics, they no longer respond due to resistance induced by previous intake of fake antibiotics [9]. Fake drugs are now making their way from the black market directly to pharmacies where legitimate drugs are being sold and even communities also pay as these fake drugs result in increased demand for health care and more invasive interventions to treat illness that could be treated early on with medications [11].
- Drug counterfeiting has led to enormous economic loss and appears to be increasing annually. According to the WHO, about 32 billion US dollars were lost to drug counterfeiting business in 2004. This increased to 40 billion US dollars in 2006 and is projected to reach 75 billion US dollars in 2010. Many pharmaceutical companies are deprived of their rightful profits due to the unjust competition from this brutal crime and have even resulted in the collapse of some of the companies.¹⁰ For instance many multinational companies divested and left Nigeria out of frustration. E.g. Boehringer, ICI, Sandoz, Merck, Boots etc [5,9].
- The image of the country is at stake as the country becomes rated as one of the countries with the highest incidence of fake/ counterfeit drugs [12]. During an epidemic of meningitis involving 41,000 cases in Niger in 1995, the country was promised a donation of 88,000 vaccine doses from Nigeria, with Pasteur Mérieux and SmithKline Beecham as

manufacturers. In fact the vaccines were found to have been replaced on the way with spurious copies containing no active ingredient but with labeling meticulously copied from the original [12]. About 2, 500 people died in the country following the administration of the counterfeited vaccines to some 60, 000 people [10,13].

3. REPORTED CASES

There are reported cases of effects of counterfeit and substandard drugs in Nigeria. These are as follows:

- In 1989, poorly compounded chloroquine syrup killed several children in University of Nigeria Teaching Hospital (UNTH), Enugu in the early 80s of which there is no statistics, partly because many of the deaths were not even reported [9,14].
- In 1990, the "Paracetamol syrup disaster" occurred when 109 children died in Ibadan and Jos, after taking paracetamol syrup produced with the toxic ethylene glycol solvent instead of propylene glycol [9,14,15].
- In 2002, 3 patients reacted adversely to infusions manufactured by a Nigerian company. Some of the adverse reactions exhibited by the patients were severe rigor, vomiting, sweating, restlessness, seizure, impaired level of consciousness. The reactions stopped immediately after the administration of the infusions were discontinued. Investigations by the National Agency for Food and Drug Administration and Control (NAFDAC) on the offensive infusions collected from the hospital revealed that three (3) batches were heavily contaminated [9,14].
- In 2003, fake cardiac stimulant (Adrenalin) contributed to the death of three children during open- heart surgery at UNTH, Enugu. Further investigations by NAFDAC revealed that even the muscle relaxant used was substandard and the infusion was not sterile [5,9,14,16].
- In 2004, three Nigerian hospitals reported cases of adverse reactions from use of contaminated infusions produced by four Nigerian companies. After sampling infusions and water for injection from all over the country, results confirmed that some batches of infusion produced by the indicated companies were heavily contaminated with microorganisms [9,13,14,16].

- In the same year, 147 of the 149 brands of water for injection screened on routine sampling were found to be non-sterile [9,13,14,16].

4. PREDISPOSING FACTORS TO DRUG COUNTERFEITING

- **Corruption and conflict of interest:** Criminals have discovered that counterfeiting of drugs is financially lucrative and of relatively low risk, they now deriate from smuggling of narcotic and carrying of weapons to the counterfeiting of drugs [9,15,17,18].
- **Insecure and unfriendly environment:** Insecure and unfriendly environment hamper the effort of regulatory authorities. The threat to the security of lives of staff and properties continues to pose great challenges to food and drug regulation in Nigeria [9,15,17].
- **Poor health seeking behavior:** It is noted that the health seeking behavior of an average Nigerian is poor. Downs observed that self-medication is usually the first step taken immediately the symptom of an illness is expressed or recognized. This attitude, to say the least, encourages counterfeiting [19].
- **Collection of high taxes and tariffs from pharmaceutical products:** This leads to increase in drug prices, decrease in incentives to adequate supply of drugs and consequent scarcity of the drugs that may be exploited by the counterfeiters [10,20,21].
- **Demand exceeding supply:** When the demand for a particular type of medicine exceeds the supply, criminal minded people tend to take advantage of this by producing and distributing fake drugs as a substitute for the genuine drugs. Consumers on the other hand can purchase these products with the hope that they are buying the genuine drugs, and most of the time these drugs are distributed through unauthorized channels. There is always demand for cheap drugs as they are easily accessible and more affordable [22].
- **Heightened global control of narcotics:** It has been observed that the high global surveillance on the smuggling of narcotics and associated penalties has diverted attention to the low risk, yet highly lucrative crime of counterfeiting of medicines [10].
- **Inappropriate / inadequate legislation:** Most people indulge in the production of counterfeit drugs because the penalty for manufacturing or distributing counterfeit drugs is very lenient. In Nigeria, such an offence attracts a punishment of 3 months to 5 year's imprisonment or a fine of N500, 000 or alternatively a fine ranging from 70 - 3600 US dollars [5,10,20,22].
- **Sophistication in clandestine drug manufacture:** Drug counterfeiters have taken advantage of the growing access and sophistication in printing technology and now manufacture fake drugs affixed with fake NAFDAC registration numbers [5,9,23]. Cloning of fast moving drugs is so perfect that even the brand owners find it difficult to differentiate between fake and original drugs [5,9].
- **Unordered drug distribution system:** In Nigeria, drug distribution is completely unordered with drugs sold like any other commodity of trade. As a result of the poor distributing system, the drug agencies especially NAFDAC have not been able to phase out completely the already existing counterfeit drugs in the market. Almost all drug manufacturers and importers supply to the same drug market where health professional and drug sellers buy their drugs as well as patent medicine sellers that sell on streets and in commercial buses [9,20]. In addition, it is a common scene to see petty traders who sell kola nuts, cigarettes, oranges, among other items, in market kiosks, motor parks, and road sides, hawking drugs that range from over the counter items to antibiotics (popularly called "capsules"). The medicines are usually left under the sun in such conditions that could facilitate the deterioration of the active ingredients [4].
- **False declaration by importers:** Some counterfeit drug importers make false declarations about the contents of their containers. They stack drugs in the inner parts of containers of other items like clothes, motor spare parts and household items. NAFDAC has made seizures of drugs concealed inside clothes, duvets and shoes [5, 9].
- **Inadequate cooperation from Governmental agencies:** The absence of teamwork among the various agencies in Nigeria (NAFDAC, Customs, NDLEA, NPA, Shipping lines etc) creates a fertile ground for counterfeiters to escape

detection, arrest and sanction. Some of the criminally minded importers take advantage of this lack of cooperation to spread their illegal business [9].

- **Discriminatory regulation by exporting countries:** Discriminatory regulation and control of drugs meant for export as against those for internal use in many countries have compromised the quality of drugs moving in international commerce. This practice has resulted in drugs labelled "for export only", not being subjected to the same strict regulation as those for internal use in the country of manufacture. Poor regulation of exports from manufacturing countries exposes the countries with non-existent or weak regulation to dumping of fake drugs [9]. This factor is particularly important in countries like Nigeria where 60% of the drugs in the country are imported and the indigenous pharmaceutical companies can only cater for 40% of the demand of its teeming population [5,10].

5. POSSIBLE STRATEGIES TO CONTROL AND PREVENT DRUG COUNTERFEITING

The drug and health agencies have evolved some strategies to help eradicate fake drugs and other substandard regulated products and create a strong regulatory environment in order to safeguard public health. Some of these strategies include:

- **Staff re-orientation and motivation:** This measure was taken to reposition NAFDAC staff for better effectiveness. Retrenchment of corrupt, redundant and incorrigible staff, staff training and re-training, effective delegation of duties and staff empowerment, compensation for hard work and leadership by example were highly encouraged. Any form of laxity or corruption was severely sanctioned [5,9,13,24].
- **Restructuring NAFDAC and modernization of regulatory processes:** NAFDAC was restructured into eight functional directorates as against the previous six and ten new state offices were established and the existing twenty-seven were strengthened to cover the thirty-six states and Federal Capital Territory. Three special inspectorate offices were also established in the three towns with the

biggest drug markets, Onitsha, Aba and Kano. NAFDAC laboratories were continuously upgraded, new warehouses and land border offices were constructed at some of the ports, new Standard Operating Procedures (SOPs) and guidelines were developed and there was automation of all the regulatory processes [5,9,24]. In 2010, NAFDAC launched an SMS-based anti-counterfeiting platform using technology from SPOXIL. GlaxoSmithKline (GSK) also adopted that system in February 2011. In April 2011, CNN published a video highlighting SPOXIL's solution in the fight against counterfeit drugs in Nigeria [8,25-28].

- **Public enlightenment campaign:** Massive awareness was created through various media such as erection of bill boards, jingles, television programs, alert notices, etc. NAFDAC's website www.nafdacnigeria.org was hosted in mid-2001, and it is fully operational. Public awareness campaigns have also been organized in most Nigerian high schools by organizing annual competitions and prize giving ceremonies on their understanding of the ill effects of fake drugs on the society. NAFDAC consumer safety clubs has also been established in most Nigerian high schools. These campaigns are geared towards educating the public on the dangers of fake drugs and have yielded several tremendous results [9,13].
- **Stopping the importation of Counterfeit drugs to Nigeria at source:** In a bid to stop the importation of fake drugs from the countries of production to Nigeria, NAFDAC have put in place some administrative guidelines which include: a factory must be Good Manufacturing Practice (GMP) certified before it can export drugs to Nigeria. The agencies official must inspect factories anywhere in the world before they register or renew registration for their drugs, food and other regulated products. NAFDAC has appointed analysts in India, China and Egypt who re-certify any drug from these countries before importation into Nigeria.¹⁸ Also, it is mandatory that all Nigerian importers provide NAFDAC with a pre-shipment information before the arrival of their drugs [5,9,13]. Since February 2003, Nigerian banks assist in the war against fake drugs. They insist on NAFDAC clearance before processing financial

documents for drug importers. This agreement is now a government policy because of its adoption by Central Bank of Nigeria. It is therefore highly recommended that banks around the world adopt this strategy as it will go a long way to deter the activities of counterfeiters globally [5,9]. Finally, before an imported drug is registered in Nigeria, it is ensured that the drug is being used in the country of production by insisting on Certificate of Free Sale signed by a Minister of Trade or Industry in that country and authenticated by Nigerian embassy or any commonwealth mission in a country without a Nigerian embassy [5].

- **Beefing up of Surveillance at all ports of entry:** NAFDAC also stepped up surveillance at both land and sea borders, which led to the counterfeiters resorting to the use of airlines. As a result, NAFDAC can now ground any aircraft that carries drugs to Nigeria without proper authorization [5,9].
- **Mopping up fake drugs already in circulation:** To mop up fake drugs already in circulation, NAFDAC has the power to confiscate and destroy drugs if sellers fail to provide a proper invoice of purchase. NAFDAC also has the power to arrest the landlord of any premises where fake drugs are warehoused if nobody accepts ownership [5,9].
- **Decreasing tariffs and taxes imposed on genuine drugs:** This will also help in reducing the extent of the problem by decreasing the costs of the drugs to the final consumers [10].
- **Streamlining and strict enforcement of registration guidelines:** All drugs must comply with laboratory standards and inspection requirements before they are registered. NAFDAC registration number must be affixed on the label of all products to enable the public identify registered drugs. Drug registration renewal is done every five years except for herbal medicines which is done yearly. Drugs can be imported for 10 years, after which the importer must start local production [5,9].
- **Monitoring Good Manufacturing Practices (GMP) of Local Manufacturers:** NAFDAC monitors local manufacturers of drugs routinely [9,13]. Compliance directives are issued and enforced. Prosecution is carried out as a last resort when necessary [9].

- **Initiation of the West African Drug Regulatory Authorities Network (WADRAN):** NAFDAC has initiated and is currently heading this network which is a forum where heads of drug regulatory authorities in West Africa can share strategies and experiences and carry each other along in the fight against drug counterfeiters. This was necessitated by the fact that when drug counterfeiters were chased out of Nigeria, they relocated to other West African countries and became a problem for them. It therefore became necessary to work in concert in order to ensure that these criminals do not find a safe haven anywhere in the sub region [5,13,29,30] NAFDAC initiated WADRAN in 2008 and it is made up of 12 countries in West Africa [13].

6. CONCLUSION

Drug counterfeiting is one of the greatest atrocities of our time and it affects both developing and developed countries. The major factors associated with drug counterfeiting in Nigeria are corruption and conflict of interest, poor health seeking behavior of Nigerians, high prices of locally manufactured drugs due to high taxes and tariffs, inadequate legislation, unordered drug distribution system, inadequate cooperation from government agencies and discriminatory regulation by exporting countries. Preventing the problem of drug counterfeiting is a primary duty of every responsible nation. The government, drug manufacturing industries, health and drug agencies, health care providers and the general public are necessary partners in this regard.

7. RECOMMENDATIONS

- The government should ensure massive public enlightenment because it is a great way of educating the public on the effects of drug counterfeiting. Greater emphasis should be in the rural areas where control and monitoring of the sources of the drugs in circulation is difficult. People should be informed about newer strategies to identify fake drugs such as the use of SMS text message to check the authenticity of a particular pharmaceutical product.
- There should be effective enforcement of the existing drug laws in Nigeria. Also, tougher penalties should be given to drug counterfeiters. This will definitely serve as

a deterrent to drug counterfeiting in the country.

- Government should reduce high taxes and tariffs on local pharmaceutical products.
- Government in collaboration with NAFDAC, should stamp out corruption among the staff of law enforcement agents. These officials should be monitored regularly and corrupt officials should be identified and dismissed.
- Regular inspection of shops and markets where medicines are sold. This should be done by NAFDAC officials in collaboration with officials from the army and police in markets such as the open air drug market in Onitsha, Anambra State, Nigeria, where it is believed that the bulk of fake drugs distributed in Nigeria originate.
- Incentives should be given to individuals who provide useful information that leads to the conviction of drug counterfeiters. The Chinese government honors information with as much as 6, 000US dollars.
- Health care professionals (HCP) should be more involved in the fight against counterfeit drugs. This can be done by organization of periodic seminars, workshops and conferences. These HCP can educate themselves on how to identify fake drugs. Any confirmed case of drug counterfeiting must be reported to the appropriate authority. Most HCP are usually in a hurry and do not bring out time to report identified cases.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
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