

Counterfeit and fake medicines and their threat to delivery of quality health care to our society: a way forward

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Abstract

Background: Counterfeit and fake drugs serve as a mean of generating illegal money to the culprits at the expense of the patient, health care providers and the entire healthcare system. The lucrative nature of this dirty business poses danger of the malicious so-called drugs being in the circulation, which consequently hamper the delivery of quality health care services to the populace. However, governments at various levels should not accede to the menace of counterfeit drugs by putting many strategies in place in order to subdue their hazardous impact on the community. This article aimed to review the prevalence of counterfeit and fake medicines in Nigeria, as well as various methods employed by the perpetrators in counterfeiting and faking medicines. It also highlights strategies to be adapted by the relevant government agencies in order to bring the peril to its minimum bearable level.

Methodology: An intensive study of the literatures and oral interviews on counterfeit and fake medicines in Nigeria was done. This was achieved through accessing public libraries and data from the internet. Additionally, reports from Zamfara State task force on counterfeit and unwholesome products was studied and reflected in this article.

Results: The threats depicted by continuing existence of counterfeit and fake medicines are real. The consequence include: Morbidity and mortality as a result of treatment failure, decreases confidence on healthcare providers, among other shortcomings. Nonetheless, the task forces counter faking efforts brought down the circulation of counterfeit and fake medicines to a lower level in recent time, although more could be done in order to curtail the menace.

Conclusion: Although governments are making a lot of efforts to limit the spread of counterfeit and fake medicines in the country, the change of tactics by the perpetrators among other factors, make the efforts insufficient for curtailing the menace, hence more need to be done.

Keywords: Counterfeit and fake drugs, Quality healthcare delivery, Healthcare system, Nigeria

Introduction

There are so many counterfeit/fake products amply available in the Nigerian markets.

Fake drugs, fake cosmetics, fake canned food, fake electrical appliances, fake spare parts, fake designer shoes, fake garment e.t.c., almost everything you can think of is

being faked. However, with the drugs included in the fake product list, the impact can be so horrifying because it is a matter of life and death (Chukwuanukwu 2015). Up to now the countries has not yet reach consensus on the single definition of counterfeit drug. However, the most widely accepted definition which is the working definition developed by the WHO, defined counterfeit drug or fake drug as drug made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or right, with view to deceive or defraud, and then marketing the copied or forged drug as the original. In reality, however, counterfeit drug is defined differently in different countries (WHO 2015).

The definition of Counterfeit drug as defined by the Nigerian Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) degree is:

- Any drug product which is purported to be; or
- Any drug or drug product which is so colored, coated, powdered or polished that the damage is concealed or which is made to appear to be better or of greater therapeutic value than it really is,

which is not labeled in the prescribed manner or which label or container or anything accompanying the drug bears any statement, design, or device which makes a false claim for the drug or which is false or misleading; or

- Any drug or drug product whose container is so made, formed or filled as to be misleading; or
- Any drug product whose label does not bear adequate directions for use and such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of use; or
- Any drug product which is not registered by the Agency in accordance with the provisions of the Food, Drugs and Related Products (Registration, etc) Decree 1993, as amended (Chinwendu 2008; Beregha 2014).

The prevalence of counterfeit drugs seems to be increasing especially in third world countries. Lack of or inadequate cooperation

among relevant stakeholders like pharmaceutical companies, government, and international organisations concerned with trade, health, customs, and counterfeiting has been one of the reason for the rise. The drug counterfeiting menace was mostly reported in local newspapers. There are little published research investigations which assess public health impact, prevalence, or possible countermeasures (Akinyandenu, 2013). The World Health Organization (WHO) estimated global sales of counterfeit medications at 32 billion USD, which is almost 10% of all medicines sold worldwide. In less developing countries, the percentage in circulation is much higher and could be more than 33%.

The risks for those involved in the dirty business in terms of either legal or financial penalties are minimal. Huge profits can be made through the trafficking of pirate products, regardless of the damage and destruction to human life. Moving freely among today's virtually anonymous distribution channels, the traffickers reap the benefits of seemingly endless price-driven consumer demand (Akunyili 2006; Akunyili, 2007).

What encompasses counterfeits drugs?

All kinds of medicines are being counterfeited. They can apply to both branded and generic products, ranging from medicines for the treatment of life threatening conditions such antihypertensive, anticancer agents, antidiabetics, antiretroviral drugs e.t.c. to inexpensive generic versions of painkillers (Buowari 2012).

Counterfeit drugs in Nigeria include:

Preparations without active ingredients; Toxic preparations; Expired drugs that are relabeled; Drugs issued without complete manufacturing information and Drugs that are unregistered with the National Agency for Food and Drug Administration and Control (NAFDAC) (Akinyandenu 2013).

Others are, drugs with active ingredients different from what is stated on the package; With correct ingredients; With wrong ingredients; With insufficient active ingredients and with fake packaging (WHO 2006).

Factors facilitating the preponderance of counterfeit drugs in Nigeria

Amongst other factors, these include: The ineffective enforcement of existing laws, Non-professionals in drug business, Loose control systems, Ineffective cooperation

among different stakeholders, High cost of genuine drugs, Greed, Ignorance, Corruption, Illegal drug importation, Chaotic drug distribution network and Demand exceeding supply (Erhun et al. 2001; Chinwendu 2008).

Consequences of drug counterfeiting

The business of counterfeit drugs is a lucrative crime that is increasing annually worldwide (Buowari 2012). The result of fake drug proliferation has led to:

Loss of confidence in health systems and health workers

The adverse events occurs as a result of the use of counterfeit drugs by the patients leads to loss of confidence in the healthcare providers and denied the confidence of the public on the nation's health system and drug control agencies. This has lead to the increased burden for health workers and other relevant drugs control and enforcement agencies like drugs regulatory authorities, customs officials and police officers. Additionally, the reputation of the original product is damaged and the pharmaceutical companies which invest huge resources in the developing innovative products suffer economically (Buowari 2012 and Akinyandenu 2013).

Endangering drug resistance and loss of medicine efficacy

Counterfeited antibiotics with low doses of active ingredients are potentially more dangerous than that containing no active ingredient at all in terms of the negative effect of drug resistance that may affect the entire community. Antibiotic resistance caused by drug counterfeiting might have contributed significantly to the inability to eradicate or control important infections such as malaria and tuberculosis in developing countries. Resistance connected with counterfeiting of some antimalarial drugs and antiretroviral drugs is reported by some researchers (Newton et al., 2003; Newton et al., 2006, Meremikwu et al. 2007; Chika et al. 2011).

Treatment failures

Treatment failure may occur as a result using counterfeit drugs that may contain incorrect ingredients or wrong ingredients or insufficient active ingredients or no even active ingredients at all. The problem of fake and counterfeit drugs is very important in medicine because of the associated health risks. Therapeutic failure may lead to loss of confidence by the patients to the entire healthcare setting. The situation is so bad that even when patients are treated with

genuine drugs especially antibiotics or antimalarial they no longer respond due to resistance induced previously by taking counterfeit and fake drugs. The worse part of it is the cause of mortality as a result of the drug failure. There are reported cases of deaths associated with the use of counterfeited drugs. In 1995, over 2,500 people died as result of unknowingly administrating counterfeited meningococcal-vaccines to the populace during meningitis epidemic in Niger republic (Attaran et al. 2011; Chika et al. 2011; Akinyandenu 2013).

Organ dysfunction or 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.

Adverse effects from incorrect active ingredients and 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 immune compromised. The use of fake and counterfeit drugs in these patients would be catastrophic and absolutely clinically disastrous and mortality rates will be increased.

Economic loss

There is significant economic loss as a result of drug counterfeiting which seem to be rising. The menace of counterfeited drugs is causing a heavy price to a lot of pharmaceutical firms which lose large amounts of money because their products being counterfeited and made available to the market at significantly reduce prices. Unfortunately, this unfair competition has lead to image tarnishing of some companies and even collapse of some of them (Akunyili 2005; Beregha 2014).

Drug counterfeiting denies the Nigerian people the right to safe, effective and quality medicines.

The era 1985 to 2000 heralded the regime of faking and quackery, counterfeit drugs, quack doctors, illegal chemist shops and hospitals, unlicensed drug vendors (Erhun et al. 2001). In 1990, 109 Nigerian children

died after being administered fake paracetamol (Aluko 1994).

Fake antimalarial medication has been threatening efforts to control malaria in Nigeria. In 2011, 64% of Nigeria's imported antimalarial drugs were fake. Nigeria is Africa's largest drugs market, and over 70% of its drugs are imported from India and China, which are considered to be the "biggest source of fakes" (Wikipedia 2015).

Way forward

In the last 20 years, Nigeria struggled to reduce the production and trafficking of counterfeit medicines in the country but lack adequate infrastructure and political will to properly enforce legislation and standards thus limiting the success (Garuba et al. 2009). The high trends of mortalities and morbidities prompted the public and the Pharmaceutical Society of Nigeria (PSN) to pressure the government to take decisive steps towards controlling the prevalence of counterfeit and substandard drugs in Nigeria. The government responded by establishing NAFDAC in 1993, and subsequently, promulgated the counterfeit and fake drug decree No. 21 in 1998. Consequently, from 2002 to 2006 about 16% decrease in drug failure rates was achieved and the circulation of counterfeit

drugs was reported to have been declined by over 80% to what it was in 2001 (Akinyandenu, 2013). In 2010, NAFDAC has also launched Mobile Authentication Service (MAS) using short SMS in order to authenticate the drugs (Roger and Aparna 2011; Martins Ifijeh 2015). Additionally, NAFDAC has also adapted and deployed handheld spectrometers (Truscan) which allows the inspection and authentication of products at the point of importations and sales.

Other cutting edge devices introduced by NAFDAC are Black eye, Radio Frequency Identification Devices (RFID) and Minilabs. All these are of cutting-edge technologies which the agency has embraced and used in the fight against counterfeited and substandard drugs and products in the country. The portable devices are used to scan a drug product and then give out detail information of the product content. By virtue of that the drug product with incorrect ingredient, wrong ingredient, insufficient ingredient, substandard ingredient or without any ingredient can be detected swiftly (Martins Ifijeh 2015).

Another important short term strategy for fighting counterfeit drugs is that, pharmaceutical companies focus more on

developing better technologies for protecting the identity of their genuine products. They develop complex labels and holograms which are difficult for counterfeiters to imitate (Akinyandenu 2013). Stiffer penalties would help sharpen the attitudes of fake drug dealers. The present director general of NAFDAC, Dr Paul Orhi has advocated for the passage of a new bill, which seeks life jail term and confiscation of assets upon conviction and compensation of victims, where fake drug is found to be the proximate cause of injury.

Health care professionals are in a good position to assist the government in fighting the problem of counterfeit drugs. Health professionals may have a high index of suspicion on the possibility of counterfeit drugs in cases of treatment failures or unusual side effects. They can educate themselves and patients on ways of identifying fake drugs using visual security tools which may include the size and shape of tablets, the quality of the print and the examination of holograms. Cases of suspected drug counterfeiting should be reported to the appropriate authority.

Shutting down these fake drug markets, producers, traffickers, and illicit tradesmen must be a top public health priority (Chika et

al 2011; Akinyandenu 2013). In recent time, Zamfara state task force on counterfeit and unwholesome products has embarked on routine inspections on drugs outlets in the state, and that has lead to the closure of many drugs outlets and confiscation of the illicit drugs found, worth of millions of naira (ZM HSMB 2015). Such moves should be supported and encourage by the state government in order to help win the war.

Conclusion

Counterfeit medicines pose a serious threat to public health and have taken a silent devastating toll on humanity due to the lack of reporting in some critically affected areas. The main victims of counterfeit drugs are poor and uneducated people who buy counterfeits because they are cheaper than the original products. The Nigerian governments are making some efforts to limit the spread of these unwelcome medicines in the country, by adapting cutting-edge technologies which are used in the fight against counterfeited and substandard drugs and products in the country. However, the efforts are insufficient to curb the serious threat posed by counterfeiting. The government needs to take more action in order to curtail the drugs counterfeiting menace, and some of the

immediate actions should include: Discouraging importation by increasing tax for imported drug products, since the government can easily regulate the locally manufacture products than the ones made overseas; Review of laws regulating manufacture, sale and distribution of drugs; Adapting law for stiffer penalties for drug counterfeiters to match the magnitude of their crime; Regular strict monitoring and supervision of premises involved in importation, manufacture and sale of drugs; Shut down all chaotic drugs supply chains; Giving incentives to those who provide information that leads to the conviction of the counterfeiters.

References

1. Akinyandenu O (2013). Counterfeit drugs in Nigeria: A threat to public health. *African journal of pharmacy and pharmacology* 7(36):2571-2576
2. Akunyili D (2006). Lesson from Nigeria: The fight against counterfeit drugs in Africa. *Diabetesvoice* 51(3):41-43
3. Akunyili DN (2005). Counterfeit and Substandard Drugs, Nigeria's Experience: Implications, Challenges, Actions and Recommendations. In Talk for NAFDAC at a Meeting for Key Interest Groups on Health organised by The World Bank.
4. Akunyili DN (2007). Counterfeiting medicines: A serious crime against humanity. Proceedings of the Director General of the National Agency for Food and Drug Administration and Control (NAFDAC), April 10, Nigeria to the European Parliament in Brussels. pp. 1-7
5. Aluko SO (1994). Death for Sale: A case study of drug poisoning and deaths in Nigeria. *Soc. Sci. Med.* 38(1):97.
6. Attaran A, Bate R, Kendall M (2011). Why and How to Make an International Crime of Medicine Counterfeiting, *J. Int.Crim. Justice.* 9:3-7.
7. Beregha P (2014). The menace of fake drugs. *The Lawyers Chronicle.* Available online at: <http://thelawyerschronicle.com/the-plague-of-fake-drugs/>
8. Buowari OY (2012). Fake and Counterfeit drugs: A review. *AFRIMEDIC Journal* 3(2) July-Dec., 2012
9. Chika A, Bello SO, Jimoh AO and Umar MT (2011). The Menace of Fake Drugs: Consequences, Causes and Possible Solutions. *Research Journal of Medical Sciences* 5(5):257-261
10. Chinwendu O (2008). The fight against fake drugs by NAFDAC in Nigeria. 44th International Course in Health Development (ICHHD), September 24, 2007-September 12, 2008 at KIT (Royal Tropical Institute) Development Policy & Practice, Vrije Universiteit Amsterdam.
11. Chukwuanukwu B (2015). The return of fake drugs. Available online at : <http://www.vanguardngr.com/2015/05/the-return-of-fake-drugs/>
12. Erhun WO, Babalola OO, Erhun MO (2001). Drug Regulation and Control in Nigeria: The Challenge of Counterfeit Drugs. *J. Health Popul. Dev. Ctries.* 4(2):24-34.
13. Garuba HA, Kohler JC, Anna M (2009). Transparency in Nigeria's public pharmaceutical sector: Perceptions from policy makers. *Glob. Health* 5:14.
14. Martins Ifijeh (2015). Drug Counterfeiting has reduced drastically, Says NAFDAC. *Thisday.* Available at <http://www.thisdaylive.com/articles/drug-counterfeiting-has-reduced-dramatically-says-nafdac/210485/> Accessed on 15/07/2015
15. Meremikwu MU, Okomo C, Nwachukwu A, Oyo-Ita and J Eke-Njoku (2007). Antimalarial drug prescribing practice in private and public health facilities in South-East Nigeria: A descriptive study. *Malaria J.*, 6: 55-55.
16. Newton PN, Dondorp A, Green M, Mayxay M and White NJ (2003). Counterfeit

- artesunate antimalarials in Southeast Asia. *Lancet*, 362: 169-169.
17. Newton PN, Green MD, Fernandez FM, Day NPJ and White NJ (2006). Counterfeit anti- infective drugs. *Lancet Infectious Dis.*, 6: 602-613.
 18. Roger B, Aparna M (2011). The Impact of Improved Detection Technology on Drug Quality: A Case Study of Lagos, Nigeria. Available online at: <http://www.aei.org/docLib/Nigeria-Working-Paper-v1.pdf>
 19. WHO (2015). General information on counterfeit medicines. Available online at : <http://www.who.int/medicines/services/counterfeit/overview/en/>
 20. Wikipedia, 2015. Counterfeit medications. Available at https://en.wikipedia.org/wiki/Counterfeit_medications. Accessed on 19/07/2015
 21. World Health Organization (2006). Combating counterfeiting drugs, A concept paper for effective international cooperation. Available online at <http://www.who.int/medicines/events/FINALBACKPAPER.pdf>
 22. Zamfara state Hospital Services Management Board (ZM HSMB) (2015). Oral interview with the Director Pharmaceutical Services.

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