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Counterfeit drugs in Nigeria: A threat to public health

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The production of counterfeit drugs is a broad and under reported problem particularly affecting poorer countries. It is an important cause of unnecessary mortality and morbidity, and loss of public confidence in medicines and health structures. Empirical observations show that there may be more counterfeit than genuine drugs in circulation. This article discusses the prevalence of counterfeit drugs in Nigeria. It highlights factors contributing to the preponderance of counterfeit pharmaceuticals and discusses strategies that may influence policy to combat the menace of counterfeit drugs. Major factors contributing to the prevalence of counterfeit drugs in Nigeria include ineffective enforcement of existing laws, non- professionals in drug business, loose control systems, high cost of genuine drugs, greed, ignorance, corruption, illegal drug importation, chaotic drug distribution network, demand exceeding supply amongst many others. Counterfeit drugs pose great threats to the attainment of the millennium development goals 4, 5 and 6 which hopes for a reduction in infant mortality, improved maternal health and combating human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), malaria and other diseases. Due to the complexity of the counterfeit drug problem, no single technique can eliminate the public health threat posed by counterfeit pharmaceuticals. A multi-disciplinary and cross-functional approach will help combat the prevalence of counterfeit drugs in Nigeria.

Key words: Counterfeit drugs, public health, Nigeria.

INTRODUCTION

The deleterious implications of counterfeit drugs is understood to be a central challenge to the integrity of public health systems around the globe, as well as a direct threat to individual health and welfare (Finlay, 2011). Until recently, the most infamous internationally recognised dealings in fake drugs was Grahams Greens fictional account of a British fake penicillin peddler who was eliminated in the sewers of post war Vienna in the Third Man (Greene, 1950). Unfortunately, hostile dealings are very much a contemporary reality (Newton et al., 2002). The prevalence of counterfeit drugs appear to be rising and has not been countered by close cooperation between pharmaceutical companies, government, and

international organisations concerned with trade, health, customs and excise, and counterfeiting. The issue of drug counterfeiting has been reported mostly in local newspapers (Kelesidis et al., 2007). There is little published medical research assessing their prevalence, public health impact, or probable countermeasures (Newton et al., 2002). Few studies have reported a high incidence on the availability of counterfeit drugs, however, majority of these reports do not contain quantitative data supporting these claims.

The World Health Organisation (WHO) defines counterfeit drugs as "drugs that have been deliberately or fraudulently mislabelled with respect to identity and/or source"

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(WHO, 2011). The products could include incorrect ingredients, may misstate the amount of the active ingredients, or are manufactured under circumstances that lack quality control. Counterfeit drugs in Nigeria include preparations without active ingredients, toxic preparations, expired drugs that are relabelled, drugs issued without complete manufacturing information and drugs that are unregistered with the National Agency for Food and Drug Administration and Control (NAFDAC). Current estimate suggests that 10% of prescription drugs sold worldwide are counterfeits, fake or contaminated, and in parts of Africa and Asia, the figures exceed 50% (Newton et al., 2001; Cockburn, 2002).

Counterfeit pharmaceuticals remain one of the world's fastest growing industries. Recent trends suggest an increase in counterfeit drug sale to over $70 billion in 2010, an increase of over 90% from 2005. A report by Pfizer, a global pharmaceutical firm, on counterfeit drugs states that profits from counterfeiting today surpasses gains made from heroin and cocaine (PGS, 2007). While the issue of counterfeit drugs has long been treated as an illicit case of intellectual property infringement, the view has often masked what is in fact a public health crisis. In light of this, this article aims to discuss the prevalence of counterfeit drugs in Nigeria and highlights strategies which may influence policy to help eliminate the public health threat posed by counterfeit pharmaceuticals.

Scope of the problem

The counterfeiting of all manner of products is on the rise globally. In Nigeria today, there is counterfeiting of documents, currency, software and electronics, amongst many others. However, no other product has the capacity to harm, as much as kill its consumers, as do illicit pharmaceuticals. The era 1985 to 2000 heralded the regime of counterfeit drugs, unlicensed drug vendors, illegal pharmacy stores and hospitals (Erhun et al., 2001). The menace of counterfeit drugs became prevalent in the last two decades and the present situation is alarming in the West-African sub-region, including Nigeria. Empirical observations show that there may be more counterfeit than genuine drugs in circulation (Osibo, 1998). A worrisome aspect of the counterfeit drug hazard is that the effects of consuming such drugs go unnoticed, except in cases where it results in mass deaths. The effects of counterfeit drugs on patients are difficult to quantify and are mostly hidden in public health statistics. There are no reliable data on the mortality and morbidity resulting from the consumption of counterfeit drugs in Nigeria (Erhun et al., 2001). Most data on the epidemiology of counterfeit drugs are kept secret by the pharmaceutical industry and

by governmental agencies. The estimate of 192,000 patients killed by fake drugs in China in 2001 gives an indication of the magnitude of the problem (Cockburn et al., 2005).

Over the past two decades, Nigeria struggled to reduce the production and trafficking of counterfeit drugs without adequate infrastructure or political will to properly enforce legislation and standards (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 incisive steps towards controlling the prevalence of counterfeit and substandard drugs in Nigeria. The government responded by promulgating the counterfeit and fake drug (miscellaneous provisions) decree No. 21 of 1998 which prohibited the sale and distribution of counterfeit, adulterated, banned, and fake drugs or poisons in open markets and without a license of registration. Additionally, NAFDAC was established in 1993 to help create a fake drug free environment with the intent of ensuring effective registration of good quality drugs (NAFDAC Consumer Safety, 2003). However, in 2001, under the leadership of Dr. Dora Akunyili as the new director general of NAFDAC, the agency underwent intense restructuring and reforms with the aim of revitalizing NAFDAC's mandate to "safeguard the health of the nation". As a result, drug failure rates fell to roughly 16% in 2006 from 2002 and the circulation of counterfeit drugs was reported to have been reduced by over 80% to what it was in 2001 (NAFDAC News, 2006).

Prior to these reforms, the prevalence of counterfeit drugs had a prominent and destructive impact on those who used them unknowingly (Garuba et al., 2009). In 1947, fourteen children were reported dead after being administered chloroquine phosphate injections and in 1990, 109 children died after being administered fake paracetamol (Aluko, 1994). In 1995, the Nigerian supply of 88,000 Pasteur Merieux and SmithKline Beecham meningitis vaccines to Niger during an epidemic resulted in about 2,500 deaths after vaccination (Attaran et al., 2011). Despite NAFDAC's reported successes, counterfeit pharmaceuticals still remain prevalent. In 2004, three Nigerian hospitals reported cases of adverse reactions from the use of contaminated infusions produced by four Nigerian companies (Akunyili, 2005). It was established that the infusions were heavily contaminated with microorganisms and 147 of the 149 brands of screened water for injection were found to be unsterile. In November 2008, 34 Nigerian children, aged 4 months to 3 years died and more than 50 were hospitalised with severe kidney damage after taking the drug "My Pikin" ("my child" in local pidgin), a teething mixture containing paracetamol (Bonati, 2009). The outbreak was due to the

use of diethylene glycol (DEG) as a solvent for the paracetamol. DEG was present because of inadvertent or deliberate substitution of propylene glycol, a less toxic compound than DEG, widely used in the pharmaceutical industry.

METHODOLOGY

In getting materials for this paper, electronic databases were searched for articles published in English between 2005 and 2011. The electronic databases searched included Pubmed central, Cumulative index to nursing and allied health literature (CINAHL), Cochrane, Medline, Embase, Web of science and Google scholar. Keywords used were: counterfeit drugs, public health, Nigeria. Titles and abstracts were screened and full text papers were retrieved for studies considered relevant and for studies that contained insufficient information to allow judgment of relevance. The full text papers and papers considered relevant were assessed against the inclusion criteria. Seven papers from Medline, three papers from Pubmed, nine papers from Web of science and nine papers from Google scholar were finally selected in writing this paper. Evidence from the selected papers suggests that anti-infective agents, particularly antibiotics and anti-parasitic agents are the most counterfeited products in developing countries. However, there have been reports of fake antiretrovirals in sub-Saharan Africa (Ahmed, 2004). Drug counterfeiting is not just prevalent in developing countries; it is a global problem. There have been reports of drug counterfeiting even in the developed countries. Counterfeit anti-ulcer (ranitidine) and anti-impotence (tadanafil) drugs have been reported in the United Kingdom in 1994 and 2004, respectively (Gibson, 2004); sub-standard thyroxine has also been reported in the United States (Dong et al., 1997). Counterfeit anti-cancer and anti-allergic drugs are equally predominate in the Western world (Newton et al., 2006).

HEALTH AND ECONOMIC CONSEQUENCES OF DRUG COUNTERFEITING

The problem of counterfeit drugs have embarrassed the Nigerian healthcare providers and denied the confidence of the public on the nation's healthcare delivery system. The result of fake drug proliferation has led to treatment failures, organ dysfunction or damage, worsening of chronic disease conditions and death of many Nigerians. Even when patients are treated with genuine drugs, no response is seen due to resistance caused by previous intake of fake drugs (Akunyili, 2005). Counterfeit drugs pose great threats to the attainment of the millennium development goals 4, 5 and 6 which hopes for a reduction in infant mortality, improved maternal health and combating HIV/AIDS, malaria and other diseases (WHO, 2012). It denies the Nigerian people the right to safe, effective and quality medicines. Counterfeit drugs rob the country of valued man power resources and economic benefits. Laxity of ineffective judicial system and widespread corruption are reasons behind the easy

production and sale of fake drugs in Nigeria (Chiwendu, 2008). It enables counterfeit drug producers sell their products cheap to vendors who in turn sell to the consumers. The major factors facilitating the preponderance of fake drugs in Nigeria have been reported to include: the ineffective enforcement of existing laws, non-professionals in drug business, loose control systems, high cost of genuine drugs, greed, ignorance, corruption, illegal drug importation, chaotic drug distribution network, demand exceeding supply amongst many others (Chiwendu, 2008; Erhun et al., 2001).

THE NIGERIAN PHARMACEUTICAL MARKET

There is a large market for drugs in Nigeria with over 130 existing pharmaceutical manufacturers (Erhun et al., 2001). Despite the enormous numbers of these pharmaceutical industries, only 60 are in active manufacturing. This is against the installed capacity of the industry to produce between 50 and 75% of the nation's drug needs. With the production capacity below 30%, much of the nation's drugs are imported (Okoli, 2000), with a bulk of the import coming from Asia. Drug counterfeiters see Nigeria as a good base for their criminal but lucrative trade. Bate and Boateng (2007) reports that India and China are the market leaders in pharmaceutical manufacturing and the biggest culprits of drug counterfeiting globally. Much of the global outsourcing is contracted to firms in Asia, both for manufacturing and increasingly, for services. A statistics by the European commission described India as the source of 75% of counterfeit drugs (Chika et al., 2011). It is therefore not surprising that most of the counterfeit drugs in Nigeria originate from India (Raufu, 2003). However, this is not to suggest that the problem is limited to Asia. In many cases, the goods are only misbranded in places far from the production site.

AVAILABILITY OF COUNTERFEIT DRUGS

The loose control system in the Nigerian economy has contributed to the circulation of fake and counterfeit drugs in the country. A major function of NAFDAC is the regulation and control of imported products. This is done by having inspectors at various airports and seaports. Registration of pharmaceuticals is a criterion that must be passed before any drug is released into the Nigerian market. A condition for registration is the analysis and testing of the drug to ensure quality and safety. Unfortunately, the forensic laboratory, which is the major public laboratory for the purpose of quality control analysis, is not adequately equipped to cope with the volume of requests, particularly for analysis of imported

drugs (Chiwendu, 2008). These loose control systems are exploited by counterfeiters to manufacture, import and distribute fake and adulterated products. There is therefore a need for government to provide funds for the agency to enable the purchase of equipment necessary for testing and analysis of all drugs, both imported and locally manufactured, in the bid to assure the quality and safety of drugs in the Nigerian market. This has however been put in motion with the deployment of the handheld spectrometers which allows the inspection and authentication of products at the point of sale (Roger and Aparna, 2011).

Various laws regulate and control the manufacture, sale and distribution of drugs in Nigeria. Sadly, empirical data shows that the situation is far from adequate (Erhun et al., 2001). The weakest point in Nigeria's drug regulation is in the area of implementation and enforcement. Some Nigerian drug laws conflict each other resulting in a legal framework that deter offenders, thus making it difficult to try offenders. This encourages drug counterfeiters to continue with their criminal acts. A review of the law is therefore essential to help ensure stability in the legislation and regulations guarding drug laws in Nigeria. An 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 (Chika et al., 2011). In 2006, the WHO launched the International Medical Products Anti-Counterfeiting Task Force (IMPACT) to assist countries strengthen their detection and enforcement systems and work with industries to develop secure measures as high-tech pharmaceutical packaging. Pharmaceutical companies should develop complex labels and holograms which are difficult for counterfeiters to imitate.

The penalties for drug offenders are not commensurate with the severity of the crime. Currently, the maximum punishment for contravening the decree on fake drugs in Nigeria is N500,000 (US $ 3,000) or 3 months to 5 years jail term upon conviction (Akunyili, 2007). Stiffer penalties would help sharpen the attitudes of fake drug dealers (Ratanawijitrasin and Wondemagegnehu, 2002). It would make the practice harder and less lucrative for drug counterfeiters. The present director general of NAFDAC, Dr Paul Orhi has advocated for the passage of a new bill, which he hopes will be made into law. The new law 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 (Odiegwu, 2011). Drug counterfeiting is a grievous crime comparable to murder, hence use of lenient punishment is inadequate. Harris et al. (2009) however argue that use of extremely harsh punishment such as life jail term may be associated with an increased risk of drug counterfeiting being hijacked by organised criminals.

Health care professionals are in a good position to assist the government in fighting the problem of counterfeit drugs. This is most useful in countries that lack the resources needed to combat this crime. The presence of non-professionals in the pharmaceutical business is a contributing factor to the availability of counterfeit drugs in Nigeria. These non-professionals are less capable of identifying fake drugs and are more out to make profit than seek the general wellbeing of the community. Health professionals may have a high index of suspicion on the possibility of counterfeit drugs in cases of treatment failures or unusual side effects (Chika et al., 2011). 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. Sadly, a survey by Odili et al. (2006) of 69 pharmacists in Lagos, Nigeria revealed that of the 42 (61%) respondents who have come across at least an incidence involving fake drugs, only 13 (31%) bothered to report the case to the appropriate authority. This finding reveals the lack of interest of healthcare professionals on the problem. It is essential for health personnel to contribute to the fight against the menace of counterfeit drugs in Nigeria. Appropriate authorities should monitor non professionals such as patent medicine vendors in the pharmaceutical business to help eliminate the prevalence of counterfeit drugs in Nigeria.

The high cost of drugs allows for the proliferation of counterfeit drugs in Nigeria and poses a major challenge to public health. Most genuine drugs are expensive and counterfeiters take advantage to supply cheap fake drugs to consumers, especially those who cannot afford the high priced good quality version in the legal sector (Chiwendu, 2008). The high cost of drugs have made access to medicines very difficult (Lambo, 2006). Majority of Nigerians cannot afford good medicines. 70% of the Nigerian population live below the poverty line (Central Intelligence Agency (CIA), 2011). The low input in local manufacture of drugs has also contributed to the high cost of drugs. Most raw materials are imported and equally attract high tariffs. Devaluation of the Nigerian currency is equally a contributing factor. The high prices makes drug unaffordable. People opt for cheaper drugs which are counterfeits in many cases. Local manufacture of drugs should be encouraged and there should be a reduction in drug importation. Importation of counterfeits across national boundaries is part of this increasingly complex problem (Finlay, 2011). Heavy tax should be

placed on drug importation to discourage importers; however, Chike et al. (2009) suggest that decreasing taxes and tariffs placed on genuine drugs may help reduce the problem by decreasing the cost of the drug reaching the consumers.

The drug distribution network in Nigeria consist of chaotic open markets that act as major source of purchase to pharmacy stores, hospitals, wholesalers, retailers, medicine stores and pharmaceutical manufacturers. Most importers supply drugs to open drug markets because they make more profit from there. The lack of strict monitoring and regulatory mechanisms allows for easy access to legitimate channels of distribution, making counterfeiting an appealing source of illicit revenue (Finlay, 2011). There is poor accountability to the disposal of medicines which complicates the work of the drug regulatory agency, NAFDAC (WHO, 2005). Monitoring of the supply chain at every stage of distribution is essential to ensure continued supply of good quality drugs in the Nigerian drug market. This should be integrated into the duties and activities of NAFDAC. Inter-agency involvement from within government and enhanced cooperation between governments, as well as improved partnerships with legitimate private pharmaceutical and supply chain industry actors will be required to reduce the chaotic drug network in the country.

Greed, ignorance and corruption are other factors contributing to the prevalence of fake drugs in Nigeria. Corruption and greed is seen from the drug regulating authorities and the drug importers and manufacturers. The effectiveness of regulatory bodies is negatively affected by the high level of official manipulations and corruption in the Nigerian healthcare system. It is common knowledge that the law enforcement agency are paid off to look the other side while the business of fake drugs flourishes. Corruption and conflict of interest are the driving forces behind poor drug regulation, which directly encourages drug counterfeiting (WHO, 2007). Beyond the widening public health challenge posed by this growing and increasingly lucrative crime, evidence suggests that counterfeit and fake drugs are also providing material support to criminals and terrorist organizations working to undermine national security (Finlay, 2011). Shutting down these fake drug markets, producers, traffickers, and illicit tradesmen must be a top public health priority.

Conclusion

Due to the complexity of the drug production and distribution system, there is no single technique that can eliminate the public health threat posed by fake pharmaceuticals. As such, a layered strategy is fundamental, involving a wide array of inter-agency actors from within and outside the government; enhanced cooperation between international bodies and improved partnership with legitimate private supply chain to help reduce the prevalence of fake drugs in Nigeria. Immediate action would include: Increased awareness on the counterfeiting of drugs to the public; reduction in the importation of drugs and increased local production of drugs which would make drugs cheaper and readily available; increased tax for drug importers to discourage importation; legal gap analysis and review of laws regulating manufacture, sale and distribution of drugs; passing into law stiffer penalties for drug offenders consistent with the magnitude of crime; strict monitoring of premises involved in sale of drugs; monitoring of the supply chain at each stage of drug distribution; development of a transparent and verifiable chain of custody from point of production to point of sale; enhanced early authentication procedure in validation of manufacturing sites and formal registration/validation of all importers from a public health perspective; and enhanced enforcement to inhibit the growth of counterfeiters.

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