

Fake Drugs: Incidences and Effects on the Nation's Health

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Abstract:

Drugs are remedies to life or to living a fulfilled life, particularly in today's world which has not only been filled with pollutants but with poisonous substances introduced into the earth by either natural alterations or by man through processes of civilization and industrialization. Drugs cure ailments and restore life in parts and even in whole when rightly used by man. Man relies on it because of the depreciating nature of the environment that calls for curative and protective measures. A drug is considered fake when its expiry date is overdue, or when it has contents different or slightly different from the inscription on the package. Bodies responsible for the regulation and checks of drugs are majorly responsible for national health. Fake drug consumption can cause depreciating and worsening state of health as well as death. To effectively combat the menace, stringent drug policies and regulations have to be implemented, and support given to the regulating bodies.

Keywords: Fake Drugs, NAFDAC, National Health.

Introduction

Drugs are substances or even medicines that change the functionality of living things when introduced into them. Man needs food for healthy growth and sustenance of life. On the other hand, diseases and ailments make the body to function inappropriately; that is when the need for drugs comes in, for the recuperation of the dysfunction in body systems. According to report on World Health Organization website, counterfeit medicine otherwise known as fake drugs are deliberately and fraudulently mislabeled with respect to identity or source. Also, branded and generic products can be counterfeited as they may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging (www.who.int/en/). Fake drugs include drugs that have less or no required and expected contents as well as drugs that have expired.

Some drugs lose their potency, shorten lives shelves and even become more toxic when transferred from the temperate regions to the tropical regions with unfavorable environmental temperature (Bamitale, 2013). Fake drugs include products without active ingredients (32.1%); products with incorrect quantities of active ingredients (20.2%); products with wrong ingredients (21.4%); products with correct quantities of active ingredients but with fake packaging (15.6%); copies of an original product (1%); and products with high levels of impurities and contaminants (8.5%) (WHO, 2013).

A fake drug in the Nigerian Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Decree as stated by WHO (2013) is defined as: "

- i. Any drug product which is not what it purports to be; or
- ii. 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
- iii. Any drug or drug product whose container is so made, formed or filled as to be misleading; or
- iv. 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
- v. 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."

National Agency for Food and Drug Administration Control (NAFDAC) is a body set up by the Federal Government of Nigeria for the regulation and control of manufactured, imported, exported, distributed, advertisement, sale and use of food, drugs, cosmetics, chemicals, medical devices and packaged water. According to Akunyili (2004), NAFDAC plays the following roles

- Safeguards the public through eradication of fake drugs and substandard regulated products from the society.

- Regulates and controls the importation, exportation, manufacture, advertisement, distribution, sale and use of regulated products.
- Conducts appropriate tests and ensures compliance with standard specifications.
- Undertakes appropriate investigation of the production premises and raw materials of regulated products.
- Compiles standard specifications, regulations, and guidelines for the production, importation, exportation, sale and distribution of regulated products.
- Controls the exportation and issue quality certification of regulated products intended for export.
- Establishes and maintains relevant laboratories for the performance of its functions.
- Ensures that the use of narcotic drugs and psychotropic substances are limited to medical and scientific use only.
- Undertakes the registration of food, drugs, medical devices, bottled water and chemicals.
- Undertakes inspection of imported regulated products.
- Pronounces on the quality and safety of regulated products after appropriate analysis.

According to Akunyili (2004), NAFDAC's identification of fake or counterfeit drugs include:

1. Drugs with no active ingredient(s) e.g. having only lactose or even chalk in capsules and tablets, e.g., olive oil in Supradyn capsules.
2. Drugs with active ingredient(s) different from what is stated on the packages, e.g., Paracetamol tablets packaged and labeled as Fansidar (Sulphadoxine+Pyrimethamine).
3. Clones of fast moving drugs – these are drugs with the same quantity of active ingredients as the genuine original brand.
4. Drugs without full name and address of the manufacturer.
5. Herbal Preparations that are toxic, harmful, ineffective or mixed with orthodox medicine.
6. Expired drugs without expiry date, or expired and re-labeled with the intention of extending their shelf-life.
7. Drugs not certified and registered by NAFDAC.

Scarcity of drugs and high prices of drugs (Chika, Bello, Jimoh & Umar, 2011.), weak drug legislation and regulations (WHO, 2013) are among the major reasons why people counterfeit drugs. Fake drugs are most prevalent in poor countries and form a third of medicines sold in some parts of Africa (Taylor, 2008) Capitalists take advantage of their poor or medium socioeconomic status and low or medium literacy level. Fake drugs are also found among drug addicts, in retail in Commercial buses, in chemists, as contraband goods, in borders of the country smuggled in by sellers and in some pharmacies.

Among the mostly faked drugs in Africa include antibiotics (Newton, Green, Fernandez, Day & White, 2006) as a result of its wide reliance in the area to treat infections, anti-malarial drugs (Atmnkeng, DeCock & Plaizer-Vercammen, 2007) as a result of increasing incidence of malaria due to mosquito bites and antiretroviral drugs (Ahmad, 2004) .

Incidences of Fake Drugs

The actual prevalence of counterfeit drugs is difficult to ascertain partly due to failure of the majority of member nations in the World Health Organization to report instances of drug counterfeiting occurring in their countries (Newton, McGready, Fernandez, Green & Sunjio, 2006). Less than 30% of drugs consumed in Nigeria are manufactured in the country while about 70% of the drugs consumed in Nigeria are imported from developed countries (Okoli, 2000).

Developing countries suffer greatly from fake drugs with reported incidence of about 60% between 1999 and 2000. Fake drugs thrive mostly in African and South Asian countries as they are either under-developed or developing, and rely on aids and as such are lured to receive any form of help from developing nations who capitalize on the situation to send in fake drugs. 25% of total medicine supplies in less developed countries according to WHO estimates constitute fake drugs (International Policy Network, IPN, 2009). Most of such drug is the antimalarial medication (Nordqvist, 2012) as about half of it imported to Nigeria in 2011 were fake (Bad Medicine, 2012).

Fake drugs especially counterfeit products have thrived in Nigeria of late (Erhun, Babalola, Erhun, 2001). In 2004, it was reported that approximately 48% of goods and drugs imported were either substandard or counterfeit while in 2007 an estimate of 70% fake or adulterated drugs was in circulation in Nigeria (WHO, 2006). Onitsha market is the biggest market in Nigeria that markets both material goods and drugs. Dora Akunyili reported in New Age Newspaper that about 30% of the drugs sold in Onitsha market were fake (Adeyemi, 2006). Drug markets in Araria and Aba had over 75% of fake drugs in 2002 (Ogbeide & Ogunnaike, 2013) and 90% of fake drugs were sold in Sabongeri market in Kano in 2004 (Ukwuoma, 2007).

The table below shows the mortality rate caused by consumption of fake drugs.

Table 1: Mortality Rate of Fake Drugs in Countries

S/No	Type of Drug	No of Persons Dead	Country	Year(source)
1.	Adulterated heparin	62	China	2008(Harris,2009)
2.	Poisoning from Diethylene glycol	Hundreds of Deaths	Haiti, Bangladesh, Nigeria, India and Argentina	(WHO, 1995)
3	Meningococcal-vacines(containing no active ingredients)	60,000 were inoculated with vaccines received as gifts 2,500 deaths	Niger	1995-1996 (Akunyili, 2004)
4	Adulterated Heparin	80	US	2008(Jack, 2012)
5	Anti-malarials(prepared with an older, less effective anti-malarial called sulphadoxine-pyrimethamine)	At least 30	Cambodia	1999(WHO,2006)
6	Paracetamol cough syrup (prepared with diethylene glycol, a toxic chemical used in antifreeze)	89 children	Haiti	1995 (WHO, 2006)
7	Paracetamol cough syrup (prepared with diethylene glycol, a toxic chemical used in antifreeze)	30	India	1998 (WHO, 2006)
8	Sulphanilamide elixir formulation error (ethylene glycol solvent was used instead of non-toxic propylene glycol solvent)	76patients mostly children	USA	1938 (Akunyili, 2004)
9	Poorly compound chlorine syrup (developing chlorine poisoning complications)	4 children	Enugu, Nigeria	1989 (Akunyili, 2004)
10.	Paracetamol syrup (produced with toxic toxic ethylene glycol solvent instead of propylene glycol)	109 children	Ibadan, Nigeria	1990 (Aluto, 1994)
11.	Adrenalin (Fake cardiac stimulant)	2 children	Enugu, Nigeria	Akunyili (2004)
12.	Formulation error in a drug	150 children	Nigeria	1989 (Ogbeide & Ogunnaike, 2013)
13.	Heparin(i.e. blood thinning injection)	149	USA	2007-2008 (Console, 2013)
14.	Fake Chloroquine phosphate injection	14 children	Nigeria	1947 (Aluko, 1991)
15.	Cough Syrup (contaminated with anti-freeze)	84 children	Nigeria	2008 (Harris, Stevens & Morris, 2009)
16.	Heparin	62 people	USA	2008 (Harris, Stevens & Morris, 2009)

Most of the incidences of fake drugs are under-reported or never reported especially in developing countries. Some people, because of lack of or limited awareness and enlightenment attribute deaths caused by fake drugs to demonic powers such as witches and wizards. For instance, Akunyili (2004) noted that some deaths in Nigeria due to cultural cleavages are attributed to wicked ones or enemies, thereby inhibiting the proper report of cases.

Causes of Incidences of Fake Drugs

According to WHO (2013), increased incidence of fake drugs are caused by lack of political will and commitment; lack of appropriate drug legislation; absence of weak drug regulation; weak enforcement and penal sanctions; corruption and conflict of interest; demand exceeding supply; high prices of medicines; inefficient cooperation between stakeholders; lack of regulation by exporting countries and within free trade zones; trade

through several intermediaries and the perceived lessened effect on public health. Some of the specific reasons responsible for the prevalence of fake drugs are:

High Price of Drugs: People especially in less developed and developing countries go for drugs they can afford within their income rate. For example they would prefer cheaper malaria drugs to expensive ones like Lonart. High prices imposed by governments discourage companies especially small scale entrepreneurs from registering (Harris, Stevens & Morris, 2009). These encourage the use of substandard materials for drug production as their quest for making fast money increases with the deployment of substandard materials and their knowledge of not being assessed by the necessary bodies.

Fast Money Making Venture: Most people go into the business because it is a quicker way to make money. It yields more profit than ordinary money making ventures. This is because everyone depends on one form of drug or the other when his system malfunctions or is diseased. It is a dubious business that yields interest more than some the businesses. According to a report by Dora Akunyili in the Nigerian Tribune, most criminals are drifting from robbery, cocaine and hard drugs pushing to faking of drugs (Akinmade, 2006). They are out to make money and are less concern about the health of consumers even if it would lead to death of consumers (Console, 2013). Manipulations also set in diverse ways as a way of escaping the price standards and making gains. According to Maya (2007), "The price of one drug molecule, e.g., paracetoamol, may be fixed, the pharmaceutical companies may decide to add another molecule like tizanide or aceclofenac in combination with paracetoamol and introduce it into the drug market as a new drug in bid to escape the price control.

Mild and Less Severe Punishment to Defaulters: Makers of fake drugs will continue their live-threatening activities since the punishment the laws have promulgated for them are not as expensive as the profits they stand to rake in before they are caught. With a fine of #50,000 or less than one or three months imprisonment, the peril will abound. Such punishments are not severe enough to stop any defaulter.

Ignorance: Lack of or low awareness stemming from little or no formal education encourages fake drug producers. Few people rarely check the expiry dates of drugs especially when bought from chemist shops. Only few consumers would be knowledgeable about the authenticity of the drugs they consume. The elite also fall a prey to the consumption of fake drugs especially those who buy online. Over fifty percent of drugs sold online have been reported to be fake drugs (WHO, 2012).

International Aids: Agencies that donate drugs mostly donate nearly expired drugs or drugs due for expiration. These drugs though not expired when donated, would take a while before they get to the beneficiaries or the less privileged. In 2004, after the December Tsunami in a part of Indonesia, 15% of the donated drugs were expired or about to expire and cost an estimated 2.4 million dollars to destroy (Pharmaciens Sans Frontieres Comite International, 2005). According to a 10-year drug donation review by WHO, close to half of the donated drugs to countries were inappropriately donated, as 57% had improper labels and 40% had expiry dates less than one year (Sukkar, 2009).

Effects of Fake Drugs on the Nation's Health

Intake of fake drugs can have deteriorating effect on users. Akunyili (2004, 2005) stated that the effect on health is more than HIV/AIDS, malaria and armed robbery attack combined together, as it kills en mass. Damages caused by fake drugs also outweigh the social problem caused by hard drugs, cocaine heroine and others because they are only consumed by a selected few compared to the former which is consumed by all. According to a CNN article of July 2012, fake prescription drugs cause nearly 100,000 deaths yearly, worldwide (Mariton, 2013). Fake drugs account for 20percent of the one million deaths worldwide yearly as estimated by WHO (Marshall, 2009).

Distribution or sale or consumption of fake drugs affects the nation as a whole. In the presence of the situation, patients and consumers continuously consume the products unknowingly in the bid to get better. This leads to an unchanged and deteriorating state of their health. This situation might contribute to the decrease in life expectancy of Nigerians to approximately 47 years as reported by the National Bureau of Statistics (2005). According to WHO, fake medicines have contributed to not less than 200, 000 malaria deaths that could have been prevented annually, approximately 900,000 suffers of tuberculosis are jeopardized with fake drugs, as half of the population will die prior to ineffective treatment (Harris, Stevens & Morris, 2009). The associated health risks include antibiotic resistance, therapeutic failure, toxic effects, economic sabotage and deaths (Chika, Bello, Jimoh & Umar, 2011). Treatment failures, organ dysfunction or damage and deteriorating state of chronic disease

conditions, (Chinwendu, 2008), lack of efficacy, dangerous side effects and loss of faith in western medicines resulting to use of traditional medicines are among the effects posed by fake drugs (Pfizers Global Health, 2011).

The whole country losses from the deteriorating effect of fake drugs as rich patients travel out of the country for medical treatment. The resources spent on the course of the treatment would have added to the nation's economy. Private healthcare centers that have access to unadulterated drugs may be by direct importation raise their charges to commensurate with their services.

Spiritually, one may not necessarily see the spiritual effects but consequences abound for every negative action. Actions be it good or bad go unrewarded as generations yet unborn grow up to live and suffer the effects. Purposeful dealers of fake drugs are not exempted from this as they tend to suffer consequences of their acts on the run.

The Fight against Fake Drugs in the Nation

1. Law Enforcement and stringent Punishment to Defaulters

Fake drugs thrive in the absence of effective judiciary system (Chinwendu, 2008). "WHO calculates that only about 20% of its 193 member states have well developed medicine regulations. Of the remainder, about half implement medicine regulation at varying levels of development and operational capacity, while the remaining 30% either have no regulation in place or have a limited capacity. These increase the risk of promoting smuggling and illegal manufacture and distribution of medicines" (BMJ, 2012). Drug faking will continue to thrive in environment(s) with less or no laws and punishment to defaulters. Three months jail term in Nigeria for perpetrators encourages this menace.

2. NAFDAC Collaboration with other National Agencies

For a successful fight against fake drugs in the country, NAFDAC should partner with agencies like Standards Organization of Nigeria (SON), National Drug Law Enforcement Agency (NDLEA), Pharmacists Council of Nigeria (PCN), Nigeria Police Force (NPF), Nigeria Custom Service (NCS), Consumer Protection Council (CPC), Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN), Association of Food Beverages and Tobacco Employers (AFBTE), The National Institute for Pharmaceutical Research and Development (NIPRD), The Consumer Association of Nigeria, The Federal Environmental Protection Agency (FEPA), Institute of Public Analysts of Nigeria (IPAN), Pharmaceutical Society of Nigeria (PSN), National Association of Government Approved Freight Forwarders (NAGAFF), Association of Nigeria Custom Licensed Agents (ANCLA), Patent and Proprietary Medicine Dealers Association (PPMDA), National Union of Road Transport Workers (NURTW), and National Association of Road Transport Owners (NARTO).

3. Close Examination of Exported, Imported and Donated Drugs

All drugs imported into the country should meet the standard requirement before being allowed into the country. Drugs donated by any organization should be thoroughly scrutinized, as some agencies donate drugs that their expiration dates are almost due. Expiration date of donated drugs should not be less than two years. This is because it takes some time before the drugs get to beneficiaries. At times it takes more than twelve months because of the processes and stages it might have to go through before getting to the beneficiaries.

4. NAFDAC Collaboration with Technologically Developed Nations and International Agencies

Association with highly technologically developed nations (e.g., India, Peoples Republic of China, USA, Canada, Ghana, United Kingdom,) and International Organizations (e.g. UNICEF, World Health Organization, WHO, European Union, Centers for Disease Control and Prevention, CDC, International Atomic Energy Agency, IAEA, Department For International Development, DFID, Partnership For Transforming Health Systems, PATHS, Micronutrient Initiative, MI and the Global Alliance For Improved Nutrition, GAIN) will build and foster International Cooperation (NAFDAC, 2009).

5. Ban of Imported Drugs from Countries with Fake Drugs Incidences

Most recently, China has been noted to import fake drugs worth millions of naira mostly antibiotics, oral contraceptives even food products such as wine and cosmetics such as skin lightening creams into the country (Muanya, 2013). A formidable workforce can promote the safety of national health with the determination and preparedness of the key team leaders.

6. Partnership with Local Distributors

International Pharmaceutical Industry must continuously seek partnership with qualified local distributors and retailers (Pfizer Global Health Fellows, 2011). That is the only way to institute checks and balances in the grassroots.

7. Drug Destruction

The destruction of fake drugs when carried out in earnest reduces more and further incidences of it. Lack of appropriate facilities for destruction encourages re-use.

Conclusion/Recommendations

Fake drugs are drugs intentionally packaged with contents slightly or totally different from the purported drug. Consumption of these drugs leads to threatening health challenges that result in death. This situation affects the health of the nation and might reduce the life expectancy below 47, if urgent measures are not taken to avert the case. NAFDAC, in conjunction with both national and international bodies can help curb the increase, sell and consumption of fake drugs.

The following are recommended:

Truscan which is a hand held device that detects counterfeit medicines on the spot should be made accessible and available to all consumers. Government and non-governmental organizations should fund the purchase of this instrument to make it affordable or get to the reach of the rich and the poor who may not be able to afford it.

Public awareness, seminars and workshops should be organized for the awareness of perils of fake drugs. Dealers on fake drugs are indirectly sending people to their early graves and as well destroying lives. Their punishment should be commensurate with their activities. Life imprisonment or death should be the penalty of those found in such criminal acts.

Everyone should be involved in the war against fake drugs since it affects everyone, young and old. Government, private bodies, non-governmental organizations and individuals should all work towards combating fake drugs. Manufacturers of fake drugs should be exposed, and rewards given to reporters, and stringent measures taken to ensure that their identities are not divulged to prevent attack from defaulters.

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