

The fight against fake drugs by NAFDAC in Nigeria

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44th International Course in Health Development (IChD)
September 24, 2007 – September 12, 2008

KIT (Royal Tropical Institute)
Development Policy & Practice/
Vrije Universiteit Amsterdam

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DEDICATION

*This piece of work is dedicated to my son **BRAVE**, for him to work hard in his lifetime and depend on **GOD** alone as his source and sustainer.*

ACKNOWLEDGMENT

I acknowledge the **ALPHA** and the **OMEGA**, the **GOD** who never starts a work he cannot finish, **JESUS** I depend completely on you.

My sincere appreciation goes to the Government of Netherlands for granting me the fellowship to participate in the 44th International Course in Health Development (ICHHD) 2007/2008.

Special thanks to the ICHHD course coordinators- Prisca Zwanikken, Yme van den Berg and Sanjoy Nayak in all their efforts in seeing to the success of the program. In addition, all the tutors of ICHHD. I will not fail to appreciate the course secretary, Rinia Sahebodin, with our large class; she was able to handle our problems individually.

My gratitude and appreciation also goes to my Thesis Adviser, who with his tight work schedule was able to read every bit of my work, this work would never have been completed without his wonderful input in re-sharpening my ideas. Thank you Sir.

I wish to specially thank our dear mummy, Prof. Dora. N. Akuyili, (Director General NAFDAC) she graciously approved my exit in order to do this course here in The Netherlands. I am strongly behind you in the fight against fake drugs in Nigeria.

I specially acknowledge the Special assistance to the Director General (NAFDAC) Mrs. E.U Awagu, who has been a great source of inspiration and encouragement to me.

To my darling sister Nkechi Chinelo Menkiti and her family in The Netherlands, words are not enough to express my appreciations to you, you are more than a sister to me, I see you as a mother and a good friend, you carried my problems and worries as if they were yours. May GOD bless you forever Amen.

Finally, to my loving husband Alex, thanks so much for all your supports and encouragements, One year away from you and our son Brave was like eternity to me, every passing day throughout the course my heart cried for your presence. I thank GOD for the wonderful gift of life given to us Dora Nneoma Chinelo Azorji.

ABBREVIATIONS

ABPI	: Association of the British Pharmaceutical Industry
ADDO	: Accreditation of Drug Dispensing Outlets
ASEAN	: Association of South-East Asian Nations
BMJ	: British Medical Journal
COPP	: Certificate of Pharmaceutical Product (COPP)
CSFDA	: Chinese State Food and Drug Administration
DRA	: Drug Regulatory Agency
DCA	: Drug Control Authority (Malaysia)
EAASM	: European Alliance for Access to Safe Medicines
EDM	: Essential Drug Monitor
EID	: Establishment Inspectorate Directorate
FRD	: Federal Research Division
GDP	: Good Distribution Practices
GFDB	: Ghana Food and Drug Board
GMC	: General Medical Council
GMP	: Good Manufacturing Practices
HAI	: Health Action International
IMPACT	: International Medicinal product Anti-counterfeiting Taskforce
IT	: Information Technology
MCA	: Medical Control Agency
MCC	: Medicines Control Council (South Africa)
MHRA	: Medicine and Healthcare products Regulatory Agency
NAFDAC	: National Agency for Food and Drug Administration and Control
NBA	: Nigerian Bar Association
NDHS	: Nigeria Demographic and Health Statistics
NDLEA	: Nigeria Drug Law Enforcement Agency
NHIS	: National Health Insurance Scheme
NNPC	: Nigeria National Petroleum Cooperation
NoMA	: Norwegian Medicines Agency
NPC	: National Pharmacovigilance Centre
OTC	: Over The Counter
PID	: Port Inspectorate Directorate
PMS	: Post marketing surveillance
POA	: Power of Attorney
PRS	: Planning Research and Statistics
PSN	: Pharmaceutical Society of Nigeria
QC	: Quality Control
RPSGB	: Royal Pharmaceutical Society of Great Britain
SAP	: Structural Adjustment Program
SON	: Standard Organization of Nigeria
TFDA	: Tanzanian Food and Drug Authority
UNESCAP	: Economic and Social Commission for Asia and the Pacific
UNODC (CP)	: United Nations Office for Drug Control and Crime Prevention
USFDA	: United States Food and Drug Agency

WHA : World Health Assembly
WHO : World Health Organization
WIPO : World Intellectual Property Organization

ABSTRACT

The problems of fake drug proliferation in Nigeria have affected the credibility of the Healthcare system and can exert very harmful effects on the consumer resulting to illness; disability and even death and anyone can be a victim. Some of the incidences have resulted in death even among children because most times the consumers do not know the quality of what they are buying or taking. This makes it imperative that there is need to intensify effort in fake drug eradication. National Agency for Food and Drug Administration and Control (NAFDAC) is the government agency in Nigeria that is fully empowered to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of drugs in order to ensure that safe and quality drugs are available to the public. As NAFDAC tasks herself dutifully in fighting fake drugs, more challenges comes up from unscrupulous drug dealer who sometimes have the backings of lawmakers and politicians making the stipulated drug laws and standard unattainable.

General objective: The objective of the thesis is to review the work done at my workplace (NAFDAC) in the efforts made in controlling the circulation of fake drug products.

Methods: I reviewed the work of NAFDAC to identify their strength and weaknesses in the fight against sale of fake drugs as well as the drug regulating authorities of some other countries to identify their areas of success. The major player in fake drug business and factors that influences fake drug proliferation was also identified

Study outcome/findings: The inability to close the unmonitored, unlicensed, unregulated chaotic open drug market that forms major drug distribution centre where many drug outlets patronize, has brought a wider spread of fake drugs without control. Government on the other hand, does not help the situation, as there is political setback in giving adequate penal sanctions to offender as stipulated in the drug laws. Some country's DRA under study monitors easily drug channels from licensed manufacturers down to the dispensary, and they license these channels before they can distribute drugs. Hence, they are able to know when fake drugs filters into the market. The reasons why people patronize drug outlets as their first line for treatment are that they are cheap, close proximity, no consultation fees, flexible payment method, perception of confidentiality; they feel that the quality of care and attention received are adequate, high stock out rate at the health facilities. Hence, closing such outlets, seizing, destroying and penalizing the violators, as often done by NAFDAC though good, but it might not give a lasting solution to fake drug proliferation, as availability, accessibility and affordability is low, consumers will always demand for such services.

Conclusion: NAFDAC has not been able to achieve good success in the fight of fake drug in Nigeria even with their intense efforts to do so. Some of the reasons are lack of adequate and continuous support of the government. Inadequate support from some stakeholders that are expected to join team with NAFDAC in the fight such as the customs, police and the judiciary.

Recommendations: The government should have a clear, firm and equitable legislation that addresses all important issues with appropriate sanctions for drug violators, provide financial support to the DRA especially in areas of staffing, GMP inspection, quality control laboratories

and enforcement, should stand its ground in defense of situation concerning public health. In addition, give full support when legislated sanctions are given to drug offenders. Support NAFDAC in closing the chaotic drug market by implementing the stipulated drug laws that drugs should not be sold at open market unless they are licensed to do so by the drug regulating authority.

NAFDAC with the help of the government should adapt the strategy used in Tanzania and Ghana where the government started a program for accreditation of drug dispensing outlet (ADDO). Through this initiative, unlicensed drug vendors are licensed, regulated and trained to understand basic pharmacy ethics in order for them to provide better services to consumers that patronizes them.

Recommendations for further research:

- How to provide good quality, affordable medicines in government clinics and hospitals.
- Action research on the strategies of licensing, training and regulating illegal drug vendors in Nigeria, as done in Ghana and Tanzania.

INTRODUCTION

GENERAL INTRODUCTION

Drug Faking is a global public health problem, because the effects can be felt from both the country of manufacture to the recipient countries. Hence, national measures for combating of fake drugs in country might be insufficient because of the advanced sophistications of those who manufactures and sells them (bates, 2008).

Nigeria is not an exception in the problems of fake drugs till date. Some people still prefer to self medicate when they are ill, and often time the drugs are bought from unlicensed drug vendors, whose drug quality is not sure. Through the past two decades in Nigeria, the problem of fake drugs has been a very big issue. In addition, fake drugs proved a major factor in contributing to high death rates. Over 150 children died in 1989 as a result of a formulation error in a drug. Such problems led to the establishment of NAFDAC, which would help create a fake-drug-free environment (NAFDAC consumer safety, 2003). The intent was to ensure effective registration of good quality drugs that are inexpensive in Nigeria. Since the inception of the new NAFDAC in April 2001, Professor Dora Akunyili the Director General has worked hard in combating the problems of sale of fake drugs, but yet the existence of such still continues and this makes me to wonder why. My questions are, ‘why does Nigeria still have in existence open drug markets? Why do Nigerians in Drug Business breach the stipulated drug laws and still get away with it and continue with their business, committing mass murder and smiling to their banks? How long do we fight the battle of fake drug even with the threats on our lives who want to preserve the health of the Nation?

The consistent raids by my organization on fake drug dealers who contravene the applicable laws and regulations, have helped in clamping down on the illegal drug traders But when things seems as if its getting better, these illegal drug sellers begin to emerge from their hideouts. I continue to wonder, why? Could it be that the Agency is not doing enough to stop the evil activities, or could the problem be from the drug sellers themselves. The tragic irony is that the problems of fake drug have refused to go away from the shores of Nigeria.

My thesis is by no means going to provide a solution to the drug problems in Nigeria. However, it prepares me on the challenges to be faced at home in finding the next alternative solution to the problem, and insight to my colleagues in combating the menace of fake drugs sold in the streets and open markets resulting in adverse effects to the consuming public. My work is therefore to review the program at my workplace and the way forward for a lasting solution.

CHAPTER 1.

1.1 BACKGROUND INFORMATION ON NIGERIA

This chapter provides information on Nigeria demographic, economy, and health profile. The aim of this chapter is to elicit the situational analysis of the country.

Background

The influence and control by British Empire over what would become Nigeria grew through the 19th century. In addition, 1 October 1960, Nigeria gained their independence. In 1999, a new constitution was adopted, after nearly 16 years of military rule that resulted to a peaceful transition to civilian government. The government continues to face the daunting task of reforming a petroleum-based economy, whose revenues have been mismanaged. In addition, ethnic and religious tensions is a long-standing experience in Nigeria, although both the 2003 and 2007 presidential elections were marred by significant irregularities and violence, Nigeria is currently experiencing its longest period of civilian rule since independence. The general elections of April 2007 marked the first civilian-to-civilian transfer of power in the country's history. (FRD, 2006)

Demography

Nigeria is the most populous country in the African continent and has a population of over 135million people with birth rate of 40.2 births/1,000 population in 2006. The population growth rate is 2.3%. Life expectancy at birth is 47 years. It is made up of 36 states and 1 territory, with more than 250 ethnic groups, the most populous and politically influential are the Hausa & Fulani 29%, Yoruba 21%, Igbo (Ibo) 18%, Ijaw 10%, Kanuri 4%, Ibibio 3.5%. Tiv 2.5%. The religions: are Muslim 50%, Christian 40%, indigenous beliefs 10%. The literacy level in the population among male is 75.7% and female is 60.6 % (NBS, 2005). The death rate is 16.6% death(s)/1,000 populations (HAI Africa, 2008).

Economy

Nigeria possesses a wealth of natural resources including oil and gas deposits, long hobbled by political instability, corruption, inadequate infrastructure, and poor macroeconomic management. It is undertaking some reforms under a new reform-minded administration. Although the country is primarily agrarian, the economy is now over- dependent on the capital-intensive oil sector because of failure of former military rulers to diversify the economy; the oil sector provides 20% of GDP, 95% of foreign exchange earnings, and about 80% of budgetary revenues. The largely subsistence agricultural sector has failed to keep up with rapid population growth - once a large net exporter of food, now must import food (FRD, 2006). The National poverty rate is estimated at 34.1% and 70.2% live on less than one dollar a day. The level of poverty affects everything from social cohesion and security to health (FRD, 2006).

Health

Nigeria runs a decentralized system with three levels of government. The federal that handles university teaching hospitals, the state handles general hospitals and local governments are mostly dispensaries. All three levels of government are responsible for provision of health care services. Although the country has tremendous potentials for growth and development, the health system still lacks basic amenities due to problems of inadequate funding, lack of political commitment and poor implementation plans. The total expenditure on health as percentage of GDP is 4.6%, and from government expenditure, it is about 1.5% (FRD, 2006). The Nigerian health system has been under reorganization. It promoted community-based methods of increasing accessibility of drugs and health care services to the population partly by implementing user fees. The idea was to increase access through community-based healthcare reform, but it was not working (Uzochukwu et al, 2002). The introduction of the National Health Insurance Scheme (NHIS) became a major concern to government due to the suffering from medical negligence of Nigerians especially the

poor who cannot afford basic health need. The majority of people still pay out of pocket for their medicine purchase as the NHIS is still in its pilot stage (Iyioha, 2007). Major illnesses are childhood diseases, malaria and HIV/AIDS with infant mortality estimated as 100 per 1,000 live births (NDHS, 2003)

TABLE 1: KEY HEALTH INDICATORS OF NIGERIA

UNDER-FIVE MORTALITY RATE	PER 1000 LIVE BIRTHS (2006)	191
INFANT MORTALITY RATE	PER 1000 LIVE BIRTHS (2006)	99
CONFIRMED CASES OF POLIOMYELITIS (2007)	-	278
DEATH CAUSED BY DIARRHEA IN CHILDREN<5	%	15.7
DEATH CAUSED BY MEASLES IN CHILDREN<5	%	6.3
DEATH CAUSED BY MALARIA IN CHILDREN<5	%	24.1
DEATH CAUSED BY PNEUMONIA IN CHILDREN<5	%	20.1
NEONATAL DEATH	%	26.1
DEATH CAUSED BY HIV/AIDS IN CHILDREN<5	%	5.0
HIV PREVALENCE AMONG >15 YEARS OLDS	PER 100 000 POPULATION	3547
MATERNAL MORTALITY RATIO	PER 100 000 LIVE BIRTHS	1100
MALARIA MORTALITY RATE	PER 100 000	209
TUBERCULOSIS PREVALENCE	PER 100 000 POPULATION	615
ACCESS TO IMPROVED DRINKING WATER	%	47
ACCESS TO IMPROVED SANITATION	%	30

Source: World Health Statistics, 2008

Definition of terms:***NAFDAC: National Agency for Food and Drug Administration and Control.***

It is a Nigerian government agency responsible for regulating and controlling the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, chemicals and prepackaged water. Its creation was inspired by a 1988 World Health Assembly resolution requesting countries' help in combating the global health threat posed by counterfeit pharmaceuticals, and amidst growing concerns about the growing problem of fake and poorly regulated drugs in Nigeria. (Nigeria First 2003)

In December 1992, NAFDAC's first governing council was formed. In January 1993, supporting legislation was approved as legislative Decree No. 15 of 1993, and January 1, 1994 NAFDAC was officially established, as a “parastatal of the Federal Ministry of Health”. NAFDAC replaced an earlier Federal Ministry of Health body, the Directorate of Food and Drug Administration and Control, which had been deemed ineffective, largely due to a lack of laws concerning fake drugs and political issues. (NAFDAC 2005)

Fake/counterfeit drug:

World Health Organization defines a “counterfeit” as “A medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.” (WHO, 2006).

There is no universal definition of fake drug as every country has there own meaning. In this thesis the definition of fake drug as defined by the Nigerian Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) will be used which 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. (WHO, 2008)

CHAPTER 2. PROBLEM STATEMENT, PRELIMINARY LITERATURE REVIEW, OBJECTIVE OF THESIS AND METHODOLOGY

This chapter gives an insight of the problems of fake drugs globally and in Nigeria as well as the preliminary Literature Review. The rationale of the study is discussed by following the stated objectives of the thesis, methodology and problem analysis diagram. It brings the reasons and importance of the study into focus.

2.1 PROBLEM STATEMENT

Fake drugs are a global public health problem causing death, disability and injury. These products often contain insufficient quantities of active ingredients or with the addition of toxic substances or even without any active ingredient. With these, a consumer does not receive the complete treatment benefits and will either not recover from or will have a delayed recovery. This causes morbidity, mortality and a significant burden on the economy. (WHO 2006).

In most African countries, fake drugs can come into both the legal, regulated chain and the illegal chain made of corner kiosks and informal drug sellers as sources of medicines. Though the sources are easily accessible, customers often receive inappropriate medicines of poor quality that can be fake mostly from illegal chain because it is unregulated. The sale of drugs by unqualified peddlers is a common trend in the developing world. These drug sellers often are the first point of contact for health care by consumers who patronizes them for reasons such as convenience, dependability of supply, and affordable price. The reason being that most times consumers do not find medicines in government clinics and the licensed pharmacies are often far and expensive. The consumers inability to judge the quality of medicines they take becomes a big public health problem as such drugs can be ineffective and harmful (BMJ 2005). Fake drugs have a capacity to deceive, particularly if they are copied to make it look like the original product so that purchasers are unlikely to be suspicious. Moreover, the process by which patients get their drugs is different from that for other consumer goods: doctors or health workers prescribe them. Even when patients choose their own drugs they may lack the specialized knowledge to detect whether the product they are buying is of good quality let alone be able to detect whether the product is Faked or not. (WHO 2007).

The problems of Fake drugs have embarrassed our 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 the death of many Nigerians. The situation became so bad that even when patients were treated with genuine drugs, there is no response due to resistance caused by previous intake of fake drugs. (Akunyili, 2005)

The problem of laxity of ineffective judicial system and widespread corruption are major reasons why it is easy to produce and sell fake drugs. It enables fake drug producers to sell their products cheaply to chemists who in turn sell to the consumers. The ultimate loser are the consumers and the doctors who are treating, as patients would not get relieved or cured and the doctor's reputation would be damaged as a result, giving bad image to the health system (Dhikav, 2003). Access to essential medicines by the population irrespective of their income status is very important for healthcare delivery services to succeed. Prices people pay for medicines are very high, making access to medicine very difficult (Lambo 2006). The chaotic drug distribution network and many unauthorized outlets, helps in fake drug circulation. There is poor

accountability to the disposal of medicine, which complicates the work of drug regulatory agency NAFDAC. (WHO 2006).

The high incidence of fake drugs in Nigeria is a fallout from the haphazard ways import license on drugs were issued to anyone by then politicians and military leaders in the 80's, disregarding the eventual public health implications of their actions. Some of the beneficiaries of the import license found out that a lot of money could be made from the drug business, and suddenly became emergency drug importers. With the booming market and competition, some of them looked at the option of importing fake products in order to have an edge over their competitors. In Nigeria today, it is common knowledge that drugs are treated as general merchandise, which can be obtained easily from open markets, moving vehicles, faceless medicine stores, ferries, and even in the provision stores. This is because the drug distribution business has been left in the hands of non-professionals who just want to make profit at the expense of the consuming public. Poor people are faced with a confusing myriad of health providers and drug sellers (NAFDAC consumer safety bulletin 2006)

NAFDAC, recently in 2007 seized 82 truck loads of fake, banned and expired drugs and closed five fake drug warehouses at the well known Onitsha drug market which according to a World Health Organization survey, It has a 30% fake drug prevalence as against 10% in other parts of the country (Nigerian Tribune, 2007).

Through the past two decades in Nigeria, the problem of fake drugs has been a very big issue. In addition, fake drugs proved a major factor in contributing to high death rates. The problem of fake drugs was so severe that neighboring countries such as Ghana and Sierra Leone officially banned the sale of drugs made in Nigeria. The issue of fake drugs did not just stop there, but it went to the extent that drugs were hawked even in commercial buses. All these problems affected Nigeria as a whole. On the one hand, but with the inception of the "new NAFDAC" in April 2001, some achievements were reached causing a reduction to the problems. (NAFDAC consumer bulletin, 2003)

According to World Health Organization, (2007) the prevalence of fake medicines is higher in countries with weak regulations, enforcement, and scarcity of supply of basic medicines, unregulated markets and unaffordable prices. Because of these, the quality, safety and efficacy of drug products especially in developing countries cannot be guaranteed. Drug fakers and their allies aggressively seek to avoid detection and they often disguise their activities. The production of fake drugs need not occur in large infrastructures or facilities but in ordinary households, small cottage industries or in backyards. The high demand for medicines and low cost of production prompts counterfeiters to continue because adequate drug deterrent legislation is lacking. The high cost of medicines gives way to consumers especially the poor to seek medicines outside the normal supply system. Poverty and poor drug distribution network are major factors that create a market for fake drug circulation. According to the Director General of NAFDAC, the weakest point in drug regulation is probably in the area of implementation and enforcement. The harsh socio-political interplays of the country over thirty years also caused some constraints and contributed to the weakening of drug regulation in Nigeria, this leads to faking and dumping of drug products through chaotic drug distribution channels. (NAFDAC consumer bulletin 2003)

2.2 PRELIMINARY LITERATURE REVIEW

In most developing countries, “**prevalence**” of 10-25% of the medicines may be counterfeit and can affect both developed and developing countries especially in countries that have weak regulation and enforcement in drug manufacture, importation, distribution supply and chain (WHO, 1999). According to an estimate by US based centre for medicines, one in 10 medicines sold worldwide is fake, and the sale of fake medicines will globally reach US\$ 75 billion by 2010 (WHO, 2006).

There are different **methods** of drug faking such as, tampering with original packages of large pack sized drugs, label swapping of two products manufactured by the same company, making the appearance of a counterfeit product look like original, labeling a low price drug products as the same with high price product label, passing off a company product for another product. (Erhun, 2001). Most drugs are identical to the real ones in terms of packaging, labels and even appearance because they are faked not by amateurs in drug business, but scientists and knowledgeable individuals whose aim is profit oriented (Lerer 2006).

In Burma, the **effects** of cheap drugs that are imitated causes more harm than good to the consumers and the ultimate price after consumption are more costly. With widespread poverty, the price of medicines should be a major concern because many people will go for the cheaper alternative unaware that the contents will do little or nothing to aid the illness (Seng 2006). In India, sale of fake drugs ranges from qualified pharmacists to shopkeepers and mobile salespersons with no formal training in drug business; this is similar in most developing countries. The consumer’s lack of knowledge on drug quality makes them vulnerable to the business interest of drug sellers (Nordberg, 2004)

The Nigerian supply of meningitis vaccines to Niger in 1995 during an epidemic also resulted in about 2500 death after vaccination. China, Nigeria and the former soviet republics are singled out regularly as center of drug counterfeit production (Health system trust 2008). The number of deaths and degree of deformity caused by fake drugs in Nigeria cannot be estimated or quantified, these blames comes to the government and NAFDAC in their poor ability to combat the problems that fake drugs brings to its population (Nigerian Tribune, 2007).

Variety of **factors** that encourage fake drug proliferation are: lack of political will and commitment, lack of appropriate drug legislation, absence of or weak regulation, weak enforcement and penal sanctions, corruption and conflict of interest, demand exceeding supply, high price of medicine, inefficient cooperation between stakeholders, lack of regulation by exporting countries (WHO, 2008). The limitations in scientific knowledge among drug sellers and low awareness of consumers, helps the continued existence of low quality drugs. (Skhahang, 2004).

Efforts is made by world Health Organization in collaboration with other international agencies in support of countries regulating agencies in fighting fake drugs, thus, less than 20% of WHO member state mostly from industrialized world have well developed drug regulation system (Ratanawijitrasin, 2002).

WHO also made guidelines for drug regulating authorities on what countries can do for effective regulation and enforcement. It state that DRA should be competent, independent with strong political backing, they must have a clear mission with sufficient legal power, appropriate organizational structure and facilities, adequate number of qualified staff that are motivated and experienced, adequate financial support and supportive tools such as standards, procedures and guidelines (WHO, 2008). At the other hand the government should be firm to ensure that the legislation are clearly spelled out, implemented, equitable for appropriate sanctions for any

violator, They should also give priority to any decision and policies concerning public health (WHO, 2008).

In February 2006, WHO created the first global partnership known as the International Medicinal Products Anti-counterfeiting Taskforce (IMPACT). This is to create awareness and action in the fight against fake drugs. IMPACT focuses on key areas such as (a) creating stronger legislation that will help empower those who deal with counterfeits and counterfeiters in the course of their work. (b) Regulatory implementation approach to ensure that standards for quality, safety and efficacy are implemented and distribution chains effectively controlled. (c) IMPACT will also help countries in monitoring borders through co-ordination of action between customs, police and the judiciary by working with the World Customs Agency, INTERPOL, and informal networks of enforcement officers. In addition, improving International collaboration especially to the developing world in order to identify the actual source of fake medicines plaguing their markets. IMPACT will also create International information networks to strengthen and monitor good trafficking, issue alerts from country to country (WHO, 2006)

In developed country like Australia, co-regulation of drugs is used which involves government representatives, pharmaceutical industries, health professional and consumers. These stakeholders, work together against fake drugs. It also operates a complaint and appeal system. This country ensures that adequate structures are put in place to create enabling environment in their drug agencies as well as adequate capacities on human resources to carry the workload (Ratanawijitrasin, 2002).

2.3 OBJECTIVE OF THESIS

OVERALL OBJECTIVE

The objective of the thesis is to review the work done at my workplace (NAFDAC) in the efforts made in controlling the circulation of fake drug products mostly sold at open markets, streets, buses etc and to find out what gaps the Agency need to meet. In addition, make recommendations on the way forward.

SPECIFIC OBJECTIVE

- To identify the players in the fake drug business
- To identify the factors contributing to the sale of fake drugs and the reasons for consumers patronage.
- To assess and analyze the work of the drug regulating agency in putting the problem of illegal traders to a stop
- To assess and analyze the work of the drug regulating agency in fighting fake drugs within the legal drug supply system in Nigeria
- To identify the strength and weaknesses of NAFDAC as the drug regulating agency in Nigeria
- To formulate appropriate recommendations for a way forward.

2.4 METHODOLOGY

The methodology is mainly descriptive and analytical with the use of secondary data collected from NAFDAC. An analysis of the problem influencing fake drug proliferation is represented in figure 1.

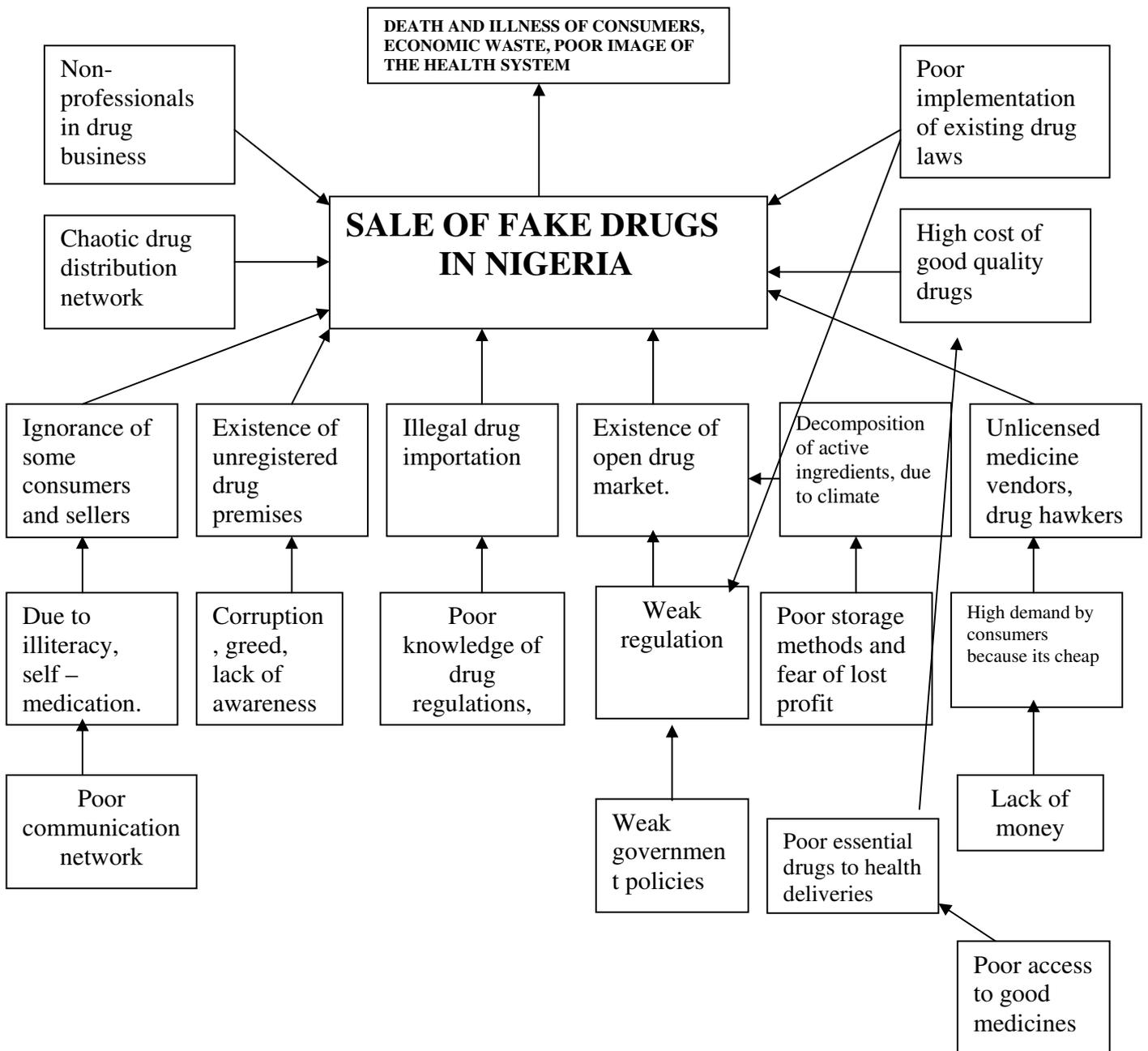
Use of KIT library and internet are useful search engine for most information used in writing this thesis as well as documented information from NAFDAC. The search engines consulted were mainly Google, PUBMED, and Science Direct.

Keywords are counterfeit medicines fake drugs, Drug sellers, NAFDAC, essential drugs, Nigeria, consumer safety, WHO strategies, drug policies, monitoring, campaigns, drug manufacturers, importers, pharmacists, drug inspectors, health system, enforcement, drug laws, registration processes, interventions, drug regulating agencies.

Personal working experience with the agency, the things experienced during raids carried out on fake drug sellers in open markets, shops, during surveillance activities etc. The problems and lapses during such raids is an insight to me on the way forward in the problem of fake drugs in Nigeria.

The thesis will be shared with (NAFDAC) a major player in the fight against fake drug in Nigeria, The Pharmaceutical Society of Nigeria (PSN), the Federal government and all stakeholders in the fight of fake drugs. The major limitation to the thesis is the period given to complete the work, together with the tight academic work. Distance from The Netherlands and home country also limited me from collecting more information as needed.

FIGURE 1. PROBLEM ANALYSIS DIAGRAM OF THE FACTORS INFLUENCING SALE OF FAKE DRUGS



CHAPTER 3. DOMAIN OF DRUG CONTROL AND THE INFLUENCING FACTORS

This chapter discusses the major players in fake drug business such as the drug manufacturer, drug importers, wholesalers and retailers, drug professionals, informal drug sellers, the consumers, as well as the drug enforcement unit. It gives an insight on the role played by each player. In addition, the factors influencing fake drug production, sale and demand are also identified.

3.1 THE PLAYERS IN THE FAKE DRUG BUSINESS:

3.1.1 DRUG MANUFACTURERS

Drug manufacturing consists of foreign manufacturers that can produce drugs for export to another country or local manufacturer that manufactures and sells within the country of production. There are also generic and branded drug manufacturers, a generic drug is a drug manufactured by a company who is not the original innovator, it can have the same active ingredients as a trade marked brand name version and is mostly less expensive than the brand-name version. It has common name for its identity as opposed to a brand used by a particular company for marketing purposes (WHO, 2000). Another clarification of drug manufacturers is the licit or illicit manufacturers. An illicit drug manufacturer produces drugs that are prohibited, unauthorized and are not allowed by law to be manufactured or sold.

In Nigeria, not all fake drugs are foreign products. We also have some unscrupulous local manufacturers involved in fake drug production; they are very smart in fake drug production. For example if they want to fake chloroquine tablet, they ensure that it maintains its bitter taste but instead of 200mg normal composition, it will have like 41mg and the consumers will not know the difference. Several of these fake drugs have been detected in the NAFDAC laboratory (Raufu 2003). The production of fake drugs need not occur in large infrastructures or facilities but in ordinary households, small cottage industries or in backyards (Raufu 2003). It is not clear who the actual fake drug manufacturers are in Nigeria because their business is dubious, they are always hiding from detection. There are big drug manufacturing companies such as Swiss Pharma, Pfizer, Novartis etc whose drug products have been faked by unscrupulous people (Akunyili, 2005). (Please see Annex 3, for NAFDAC list of identified faked drugs)

Branding drug products is done by manufacturers to promote profits and loyalty. Though a global risk can exist where products are at risk of attacks from illegal drug traffickers and competitors that operates in shadow, in addition the more successful a brand is the more it stands the risk of brand piracy (NAFDAC Consumer bulletin, 2003).

3.1.2 DRUG IMPORTERS/WHOLESALEERS/RETAILERS

Around 70% of drug in Nigeria are imported and India is a major drug exporter to Nigeria. Some Nigerian drug importers connive with some Indian manufacturers to produce fake and substandard drugs at a cheaper rate with less active ingredients. These drugs are imported into Nigeria, sold to the wholesalers and retailers who may or may not know if the drug is faked or not. The wholesaler and retailers are not monitored to know how they distribute their products; they can sell to any one for profit. The idea is all to make double gain for what the real cost of the genuine drug is (Raufu 2003). The Indian government has repeatedly sent to NAFDAC a list of blacklisted Indian manufacturers and companies involved in fake drug production, which will

enable the Agency in the fight to eradicate such (Raufu 2003). NAFDAC on its own also banned 19 Indian and Chinese companies confirmed to be fake drug producers from exporting drugs to Nigeria because most of their products were tagged “for export only” example, there was a case of poorly packaged Paracetamol tablets in blisters labeled “Not for use in Southeast Asia”. Some fraudulent importers now bring the products at a cheaper rate for sale in the country. Hence, the Agency believes that any drug that is not sold in the country of manufacture, will not be allowed into Nigeria and is working to ensure that such is enforced (Akunyili, 2005).

In Uganda, only drugs on their essential drug list are considered for manufacturing, importation and distribution with some exception spelled out by law. Drug importation in Tunisia is a centralized system where government owned central pharmacy imports 60% of all drugs used in the country (Ratanawijitrasin, 2002).

3.1.3 DRUG PROFESSIONALS (THE PHARMACISTS)

The main professional organization of pharmacist in Nigeria is the Pharmaceutical society of Nigeria (PSN). The organization was established in 1927, with membership over 7000 pharmacists (Erhun, 2001). Its main functions are to determine the skill and knowledge that is required of anyone who seeks to be registered as a member of the pharmacy profession, preparation and review of the code of conduct, regulate and control the practice of the pharmacy profession. PSN also has a panel that investigates and disciplines erring pharmacists. According to the PSN president, the main sources of fake drugs in Nigeria are India, China, Pakistan, Egypt and Indonesia (Erhun, 2001). The influx of fake drugs is quite worrisome to the health experts. It is difficult to get reliable data on mortality or morbidity caused due to the consumption of fake drug in Nigeria. The effect from fake drug consumption usually goes unnoticed, except in cases where it results to mass death. These problems made the PSN as a body to pressure Nigerian government in taking definite step towards the control of fake drug. Hence, the promulgating of the counterfeit and fake drug decree No. 21 of 1988 that prohibits the sale and distribution of fake drugs in open markets and created penalties for anyone who breaches the law. (Raufu, 2002). In 1987, an increased number of fake drugs were noticed in some market places, even in some pharmacy outlets chemical test showed that it contains small amount of active ingredient, some pharmaceutical companies felt it was due to laxity of inspection that contributes to the successful faking. On 31 October 1987, the pharmaceutical society of Nigeria (PSN) discussed the implication of fake drug manufacturing, marketing as well as possible remedies; they identified some major drugs that are often faked, antibiotics, antifungal agents, antihypertensive, malaria medicines, bronchodilators and hormonal preparations. They related the problem of drug faking to exchange control situation that causes scarcity and high price for drugs and that government can help reduce the problems through provision of essential drugs at reasonable price to the people which will in turn make fake drugs low priced and less attractive. (Anonymous, 1989).

In United States of America, pharmacists are allowed to work with foreign governments, International regulatory bodies as well as law enforcement agencies, this collaboration enables them to detect and combat counterfeiting (Spies, 2003). In Cuba, almost all pharmaceuticals operations are owned and managed by their government who determines how drugs are regulated and the members of their drug professional groups can get involved in drug regulation by joining the advisory committee (Ratanawijitrasin, 2002).

3.1.4 INFORMAL DRUG SELLERS

Informal drug sellers are people that sell medicines in an unregulated manner without professional consultation and with limited knowledge on pharmacy. One of their aims in drug business is the profit they make even when they are aware of fake drug proliferation. They can store and handle drugs in inappropriate ways that can endanger the drug potency (Goodman, 2007).

Informal drug sellers can be found in shops, kiosks, open markets, general stores etc, and can operate as itinerant hawkers. Just like any other business, their existence is maintained in accordance to consumer demands for easy accessibility, convenience and affordable supplies. They can be very friendly, approachable and promising to their customers. Their attraction to those that patronizes them is that they have cheaper products when compared to the formal outlets and their products can be given on credit because they often time source their products from cheaper places. Most of these drug sellers are less knowledgeable about the doses of medicine appropriate for a particular illness; they can over prescribe or under prescribe because their major aim is more on profit making and meeting up with competition from other sellers (Goodman, 2007).

3.1.5 DRUG BUYERS (CONSUMERS)

Fake drug consumers/buyers are exposed to dangers from hazardous drugs because they are entrapped in the web of fake drugs without respite and any one can be a victim. Many drugs are offered for sale in Nigeria without expiration dates and can be bought and sold over the counter or by hawkers selling alongside newspaper vendors (Personal Observation). A man who is sick can walk to any drug store and come out with loads of drugs without prescriptions in some cases, smooth talking drug peddlers in public buses save such man the walk to chemists. Consumers on the other hand may not know the quality of products they are purchasing (Agege, 1988)

The reasons why consumers prefer to patronize such outlets include geographical accessibility, shorter waiting times, longer opening hours, greater confidentiality, more personable social interaction, ease of seeking advice, lower cost and flexible pricing policies and no separate fee charged for advice. However, one of the problems associated with self-medication with drugs from these sellers is that in most cases, neither the drug seller nor the consumer is aware of the correct dosage and duration of treatment (Okeke, 2006).

3.1.6 THE CONTROLLER (NAFDAC ENFORCEMENT)

The objective of any drug regulatory agency is the protection and promotion of public health. The enforcement directorate arm of NAFDAC established under the provisions of the counterfeit and fake drugs (miscellaneous provision) act is charged with the responsibility of enforcing the provisions of the counterfeit and fake drug decree, which includes:

- Conducting surveillance on companies and persons suspected to be violating NAFDAC regulations and carrying out investigations on such persons and companies.
- Paying unscheduled visits to all ports of entry and border posts and interrogation of suspects
- Sampling of NAFDAC regulated products to the laboratory and compilation of case files
- Raiding of drug hawkers and destruction of fake and spurious regulated products
- Coordination of activities of state task force.

The establishment of the task force in Nigeria was seen as a welcomed development for the fight against fake drugs. (See detailed activities and strategies of NAFDAC below).

3.2 FACTORS INFLUENCING FAKE DRUG PRODUCTION, SALE AND DEMAND:

The influencing factors to be discussed are: non-professionals in drug business, chaotic drug distribution network, poor implementation of existing drug laws, ignorance, inefficient cooperation between stakeholders, illegal drug importation, corruption and greed, high cost of good quality drugs and demand exceeding supply.

A research carried out on PSN organization by on the reasons adduced for availability of fake drugs in Nigeria, The following results were given:

TABLE 2: REASONS ADDUCED FOR AVAILABILITY OF FAKE DRUGS IN NIGERIA

REASONS	# OF RESPONDENTS (=7)
Inadequate laws and Poor enforcement of the existing laws	7
Ignorance	7
Non health professionals in Drug business	6
Inadequate laws	6
High cost of good drugs	5
Corruption	4
Greed	3
Loose control systems	2

Source: Erhun, 2001

There are also other additional factors outside the above-identified ones from Erhun such as chaotic drug distribution network, inefficient cooperation between stakeholders and demand exceeding supply

1. *Non-professionals in drug business:*

A study carried out by Erhun 2001, showed 6 out of 7 respondents who believed that the presence of non-professionals in drug business is a major contributing factor to the availability of fake drugs in Nigeria. Under the Nigeria drug law, pharmacists have the authority to manufacture, sell, distribute, import, export, dispense and compound drugs. Community or retail pharmacists can acquire premises for sale and drug dispensing such premises are usually registered.

However, we also have the non- pharmacists such as the licensed medicine vendors that are holders of “patent and proprietary medicine vendors right” which is granted to them by government, they are non-professionals who might be less capable of identifying genuine from fake drugs. The minimum academic requirement for them to obtain a license is the first school-leaving certificate (Erhun, 2001).

These vendors are only allowed to sell over the counter (OTC) drugs but rather they sell different categories of drugs both prescription and over the counter drugs as long as they will make profit from it, such drugs can include antibiotics, narcotics, toxoids and antihypertensive for profit purposes with no adequate monitoring systems in place to check them (Erhun, 2001). Sometimes, they are seen prescribing drugs to their customers or even treating them and giving injections (personal observation).

These vendors are supposed to be monitored by the state ministry of health (MOH) pharmacy division. However, they are not monitored adequately because the officials can be corrupt and overlook many issues or may be incapable of the work (Okeke, 2006).

2. Chaotic drug distribution network:

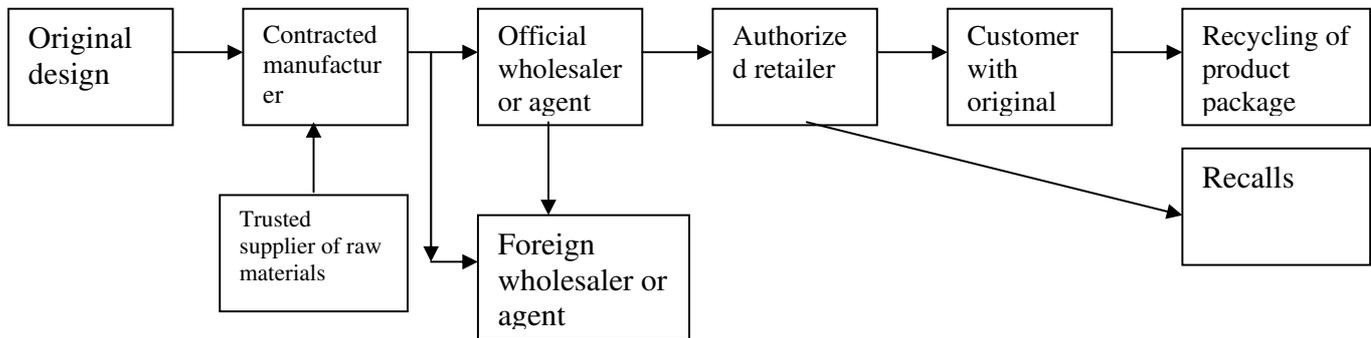
Drug distribution network in Nigeria consists of chaotic open markets that acts as major source for purchase to medicine stores, pharmacy outlets, private and public hospitals, wholesalers/retailers and pharmaceutical manufacturers, the result of these chaotic drug distribution makes drug monitoring very difficult. In addition, gives room to drug hawking in buses, kiosks, motor parks by illiterate vendors whose aim is profit oriented. The medicines are often time left under the sun in such conditions that could facilitate the deterioration of the active ingredients (Erhun, 2001). Medicines are sold just like any other commodity of trade. Poor drug regulation which has eaten deep into the system over the year, helped in the evolvement of drug markets which are not registered premises and is well established all over the country. Most of the drug wholesalers and importers supply drugs to these open drug markets because they make more profit from there. Drug sellers, health professionals have easy access to patronize the drug markets; it also gives services to the street drug hawkers and commercial drug sellers in buses (Akunyili, 2004). Efforts from NAFDAC, such as various raids and seizures of fakes to close the existing chaotic drug market and create an orderly Drug Distribution System suffered a set back due to its unacceptability from some pharmacists and politicians that are key stakeholders in drug matters who benefits from such open markets supports the existence (Akunyili, 2004).

In the United States of America, the drug distribution channel involves registered drug facilities that are monitored by the United States Food and Drug Agency (USFDA) as manufacturers; from there the drugs are shipped to their official pharmaceutical wholesalers and to the pharmacies for upward dispensing to individual patients (Spies, 2003).

According to Brains (2004), drug distribution chain consists of different actors in legitimate supply chain and the illegitimate supply chain. The legitimate supply chain consists of originality of products from the designers down to consumers; it is regulated and monitored at all levels. The original designers of the brand contracts to manufacturer who produces with the aid of the trusted suppliers. The products are then bought by wholesalers for distribution, from there the authorized retailers buys and dispenses to the consumers. Moreover, in case the product did not match expected specifications; the process of recall takes place.

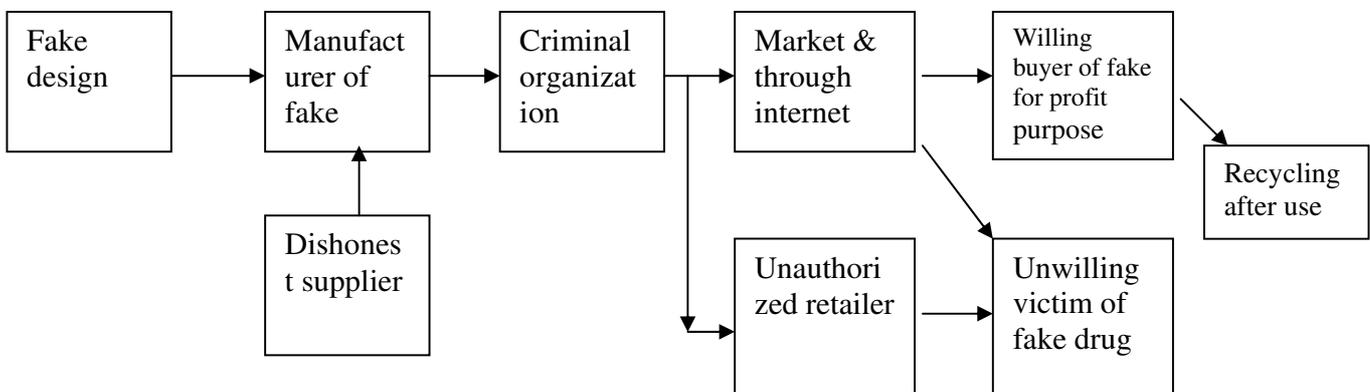
In Nigeria, the problem with the legitimate supply chain, where good manufacturers have there products registered with good intentions is in the area of monitoring each chain network to ensure that fakers don't come in between the line to supply or sell their products portraying it as original product. Drug registration licensing in NAFDAC stops with the manufacturers, who/how, the products are distributed and sold to the wholesalers, retailers etc is supposed to be checked as stipulated in the drug laws, but such functions are not carried out, maybe due to lack of finances and workforce (personal view).

FIGURE 2: LEGITIMATE SUPPLY CHAIN



Source: Brain (2004)

FIGURE 3: ILLEGITIMATE SUPPLY CHAIN



Source: Brain (2004)

The illegal supply chain is made up of drug faker who can copy other products and present them as original. The product design is faked with the aid of fake manufacturer in criminal organization who distributes the drugs in the market and through internets. The products in getting to an unauthorized retailer who buys it for profit purposes even when he knows the source, dispenses the fake product to an unwilling victim of counterfeit.

3. Poor implementation of existing drug laws/inadequate legislation:

The weakest point in Nigeria’s drug regulation is probably in the area of implementation and enforcement. The harsh socio-political interplays of the country for over thirty years caused some constraint and contributed to the weakening of drug regulation that is still suffered presently. Weak regulation contributed to faking and dumping of fake products and the chaotic drug distribution network (NAFDAC, 2005).

Nigeria also has drug laws that have become overlapping and sometimes conflicting each other, these results to a legal framework that will fail to deter drug offenders or moves very slowly when allegation of wrongdoing is identified, making it difficult to try the offenders. Legislation and regulation forms the basis for drug regulation and where these two does not exist criminal activities associated with drug cannot be treated as a crime and drug counterfeiters will be encouraged to continue because there won’t be any fear of being apprehended. Penalties of drug

offences are not commensurate with the severity of the crime. Example, the maximum punishment for contravening the decree on fake drugs is less than N500, 000 (US \$ 3,600) or a prison sentence up to 5 years, with such fines, the offender pays easily and goes back to his drug business (NAFDAC, 2005). Stiffer penalties can help sharpen the attitudes of fake drug dealers (Ratanawijitrasin, 2002). Chinese government had put stiffer penalties in their drug laws for fake drug manufacturers and sellers, such as withdrawal of company's license, prohibition from drug production up to ten years. In addition death sentence as was the case of their former director general of their State Food and Drug Administration (SFDA) who took a bribe from a company and approved some fake drugs that killed some people (CSFDA, 2006)

4. Ignorance:

Ignorance as a factor contributing to availability of fake drugs can be due to the literacy level of population in Nigeria and it will be difficult for such people to distinguish between genuine drug products from fake and being that they want cheap and easy access to medicines, they patronize drug vendors. Others patronize because it is cheap and affordable for them and do not bother if it is genuine or not (Personal view).

5. Inefficient cooperation between stakeholders:

Lack of cooperation between the regulatory authorities, and other stakeholders such as the judiciary that oftentimes delays or averts judgments, police and customs services due to conflict of interest, bribery and corrupt practices makes the control of drug markets and enforcement of drug legislation very difficult. Such inefficiencies can create avenues for a drug faker to escape detention, arrest and penal sanctions and the problem still flourishing (NAFDAC Consumer safety bulletin, 2007). For example when NAFDAC inspectors were told to vacate from the ports of entry by the customs who feels that they were being prevented from making extra money for themselves. It is thus, difficult for NAFDAC to stand alone in the fight against fake drug proliferation

6. Illegal drug importation:

This is a major constraint at the ports. Some drug importers, in order to evade inspection and detection, can make false declarations about the nature/content of the products in their containers. They employ unimaginable concealment methods for their nefarious activities. In 2003, a large consignment of a controlled narcotic analgesic was concealed in T-shirts and imported from India via Lagos airport. In 2004, 32 containers of various pharmaceuticals were imported and manifested as motor vehicle spare parts. They were moved to various locations within the ports to avoid detection, NAFDAC inspectors have also found drugs concealed in the inner part of containers containing textiles, candles, shoes, etc. (Akunyili, 2004)

7. Corruption and greed:

Corruption and greed can be seen from the drug regulating authorities as well as the drug manufacturers/importers. Corruption and conflict of interests are the driving forces behind poor regulation, which, in turn encourages drug counterfeiting (WHO, 2007). The result is poor enforcement of law because the corrupt official has already collected huge sum from the drug counterfeiter, hence averting arrest and prosecution/conviction.

8. High cost of good quality drugs:

There are higher chances for fake drug proliferation when medicine prices are high; counterfeiters take the advantage to supply cheap fake drug products to consumers especially those who cannot afford the high priced good quality version in the legal sector. A survey conducted by World Health Organization (WHO) and Health Action International (HAI) in Nigeria 2004 to determine the prices people pay for their medicines showed a high rise in the prices for example people pay between 2 to 64 times international reference prices for medicines in various health facilities. In addition, that (90.2%) majority of Nigerians cannot afford good medicines as they live below income level of US\$ 2 a day (HAI-Africa, 2008). The baseline survey also showed a low availability of essential medicines in the health facilities, only 46% of key medicines were found in the health facilities. (HAI-Africa, 2008).

In Philippines, for example, there senate recently approved a bill called affordable medicines Act that will help lower the prices of drug so that it can be affordable and their domestic pharmaceutical companies to have a larger stake in their drug market. In addition, it will help reduce the incidence of imported fake drug into the country (Global insight, 2007)

9. Demand exceeding supply:

When the demand for a particular type of medicine exceeds the supply, criminal minded people tend to take advantage of that by producing and distributing fake as a substitute for the genuine type. Consumers in the other hand can purchase such product with hope that they are buying the genuine one, and most of the time these drugs are distributed through unauthorized channels (Erhun, 2001).

There is always demand for cheap drugs maybe due to easy access, it is more affordable or there is always stock out from the health facility. Hence, the illegal traders will want to quickly fill the gap of supply, and there are at all time market for them. Putting such illegal traders to jail or seizing/sealing their shops might not give a lasting solution to the problems.

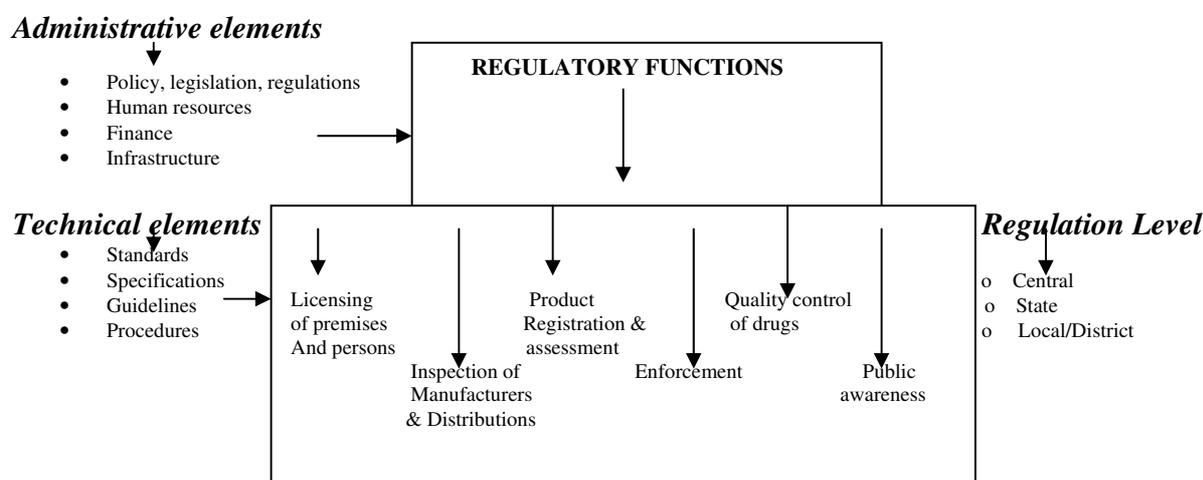
The Tanzanian Food and Drug Authority (TFDA) started the accreditation and certification of drug dispensing outlet (ADDO) by legalizing such illegal sector through the network program and allowing them sell only medicines listed in their essential drug list. Such way, the illegal drug dealers comes out from their hidings and TFDA now has easy assess to them in monitoring what they do (Ndomondo-Sigonda, 2003).

CHAPTER 4: DRUG REGULATING AGENCIES IN OTHER COUNTRIES IN THE FIGHT.

This chapter analysis the work of different country’s drug regulating agencies in the fight against fake drug. The countries were selected from different regions, Africa, Asia and Europe based on developed and developing countries. It will form the basis to compare with the work of NAFDAC in order to identify their weaknesses and ways of intervention. It can also shed new light on Nigeria drug situation by suggesting ways for improvement. The reasons are that drug problems can spill over from one country to another, drug policy of one country can affect another and the knowledge of what happened in one country can help another prepare for similar challenges in future.

The framework below reflects the functions in the regulation of medicines. The administrative elements carries out the regulatory functions which includes licensing of premises, persons and practice, inspection of manufacturers and distributors, product registration and assessment, enforcement, quality control of drugs and public awareness. Without adequate policy, human resources, finances and infrastructure, drug regulation will fail. The technical elements form the major requirements to be followed in order to maintain stipulate requirements. Every activity in the regulatory functions is expected to function in all level in a country.

FIGURE 4: STUDY FRAMEWORK SHOWING KEY COMPONENTS OF DRUG REGULATION FUNCTIONS



Source: Ratanawijitrasin (2002)

4.1 LICENSING OF PREMISES AND PERSONS

Before a license is granted either to persons or for the drug premises, the qualification of the person, adequacy of the premises as well as quality of available equipment and processes should be of utmost concern (Ratanawijitrasin, 2002).

The South African Medicine Control Council (MCC) is the drug regulating body charged with regulation and control of drugs in South Africa. The only people given license to manufacture,

import, distribute or dispense are drug practitioners (pharmacists) registered with their relevant Councils having registered premises. Medical practitioners and nurses are not allowed to dispense drugs unless they possess a dispensing license issued by MCC (MCC, 2000).

In the Netherlands, the general practitioners with license are allowed to open dispensaries. Malaysia allows their health assistants, nurses or pharmacy assistant to dispense drugs in such areas lacking pharmacists (Ratanawijitrasin, 2002).

The Medicine and Healthcare products Regulatory Agency (MHRA) of the United Kingdom gives license to pharmaceutical companies and any qualified wholesaler that gives satisfactory evidence that the drug they are manufacturing, distributing, supplying meets the stipulated safety and quality standards (MHRA, 2008)

TABLE 3: MULTI-COUNTRY LICENSING OF PREMISES AND PERSONS

Sources: NAFDAC, MCC, MEB, MHRA & Ratanawijitrasin, 2002

Licensing	Nigeria	South Africa	Uganda	Malaysia	United Kingdom	Netherlands
Manufacturing	Pharmacists by PSN	pharmacists	Pharmacists	Pharmacists	Qualified persons	Qualified persons
Importation	Should be under the care of a registered pharmacist	”	”	”	Pharmacists	Pharmacists
Wholesale distribution	”	”	”	”	”	”
Retail Pharmacy	”	Licensed premises Under the care of a registered pharmacist	Pharmacist (with annual renewal)	Pharmacists (but for drug items only)	”	Pharmacists
Hospital pharmacy	Pharmacist	”	”	”	”	Pharmacists
Other drug outlets	Varies from unlicensed premises to licensed vendor	Allowed in areas with inadequate pharmaceutical services but under supervision of a registered pharmacist	Varies	Varies		No available data

4.2 INSPECTION OF MANUFACTURERS AND DISTRIBUTIONS

Drug inspection is a very important tool for monitoring pharmaceutical operation to know if they follow the stipulated standard, this is done by inspectors' physical visits to drug facilities and by use of quality assurance laboratories. Well-qualified inspector with good knowledge of pharmacy adequately trained and having the necessary legal power should be used in order to avoid deception. (Ratanawijitrasin, 2002).

In South Africa, different provinces make their own inspection of drug distribution and purchasing arrangement which is they do to ensure safety and cost effectiveness. (MCC, 2000).

The U.K MHRA inspectorate group has the responsibility for drug inspection of manufacturers, which they assess with provision of their manufacturing authorization for compliance. They also have Good Distribution Practice (GDP) inspectors charged with assessment of the drug wholesalers. They make use of their large team of GMP and GDP inspector for monitoring both within and outstation (MHRA, 2008).

The work force in all country shows they employ professional, but the workers are over used in carrying out a lot assignments except in MHRA.

Malaysia drug distribution channel is inspected by there inspectorate sector of the state deputy director of health. In addition, all the countries have guidelines they follow for inspection as shown in table 5.

TABLE 4: MULTI-COUNTRY INSPECTION OF MANUFACTURERS AND DISTRIBUTION

Sources: NAFDAC, MCC, MEB, MHRA & Ratanawijitrasin, 2002

Inspection	Nigeria	South Africa	Uganda	Malaysia	United Kingdom	Netherlands
GMP and routine	Organized under NAFDAC	Organized under the drug agency	Organized under the drug agency	Organized under the drug agency	Under MHRA by their inspectorate group	Organized under the drug agency
Drug distribution channels	Difficult to inspect. Chaotic drug market	Provincial authorities	„	Inspectorate sector of the state deputy director of health	GDP inspectors	„
Human resources and workload	Qualified pharmacists, few staff & high workload (WL)	Professionals in drug High WL	Professional (pharmacist) Pharmacy assistants. High WL	Professional (pharmacist) High WL	Qualified & experienced professionals	Qualified & experienced professionals in drug High WL
WHO GMP guidelines	Adopted	Guideline of MCC & WHO	Adopted	Guideline of ASEAN	European union guideline	European union guideline

4.3 PRODUCT REGISTRATION AND ASSESSMENT

This is where marketing authorization/certificate and product licensing are issued to pharmaceuticals that meet minimum standards of efficacy, safety and quality. The effectiveness of registration process requires a good legal foundation, adequate and qualified staff, adequate resources, a data retrieval system and a system that is free from conflict of interest but with good accountability and transparency (Ratanawijitrasin, 2002).

The validity of certificates issued by all country under study is 5 year except Uganda that gives 1 year. The UK MHRA and MEB are the only countries that can make there own independent assessment on drug safety; others follow WHO guideline for registration and assessment. There is no available information about Uganda.

The countries under review also make use of external experts for registration assessment except NAFDAC.

TABLE 5: MULTI-COUNTRY PRODUCT REGISTRATION AND ASSESSMENT.

Sources: NAFDAC, MCC, MEB, MHRA & Ratanawijitrasin, 2002

Registration & Assessment	Nigeria	South Africa	Uganda	Malaysia	United Kingdom	Netherlands
Issuance of certificate & validity period	NAFDAC 5 years license validity for imported products. 2 years for local products	MCC License valid for 5 years	Drug committee . Valid license is 1 year	Drug Control Authority (DCA). Valid for 5 years	MHRA 5 years license	Medicine Evaluation Board (MEB). Validity of license is 5 years
SOP for staff	Complies with WHO standard	Available	No available data	Available	Available & Can make independent assessment on drug safety	Can make independent assessment on drug safety
Post-marketing checks	„	Adequate Complies with WHO standard	Available	„	„	„
Drug sell , supply & price	not under NAFDAC jurisdiction	Monitored by committee members from MOH	Monitored	Monitored	Monitored	Monitored
External expert support	None	Available Using reputable regulating bodies of other country	Available	Available	Available	Available

4.4 ENFORCEMENT

Enforcement in any drug regulating authority acts as the intelligence group that investigate cases, brings criminal prosecution, works with information provided by people and consumers, carry out raids and surveillance activities to places under suspicion of fake drug business.

The U.K MHRA enforcement and intelligent group responsible for enforcing drug law in England, Scotland and Wales does so with the use of adequately trained intelligence officers. These officers works in very close collaboration with UK police forces, customs, prescription pricing authority, association of port health officers, environmental health units, Royal Pharmaceutical Society of Great Britain, General Medical Council , USFDA, US Drug enforcement Agency, WHO Anti-counterfeiting Taskforce (IMPACT) and all forces and regulatory authorities throughout Europe. With these close collaboration information on fake drug proliferation are easily reported and investigated. The enforcement and intelligent group employs enough staff within London and outstation to ensure that all gaps are covered and for easy case report and management, they are divided into four organized groups. Intelligence group, Operations, Prosecutions and Business (MHRA, 2008). One major way in which MHRA has successfully reduced the fake drug proliferation in their market is by licensing all steps of

medicine distribution channel from manufacturing, distributing, drug storage through the supply chain down to dispensing (MHRA, 2008). Other strategies used in tackling fake drugs are adequate communication to the public and healthcare professionals by providing 24 hour anti-counterfeiting hotline and provision of counterfeit medicines guideline for both pharmacists and a separate one for the public, the guideline educates them on how to avoid and report fake drugs cases (MHRA, 2008). Uganda collaborates with their National police in carrying out task force activities (Ratanawijitrasin, 2002).

4.5 QUALITY CONTROL OF DRUGS

Before the issuance of marketing authorization/certificate, the drug products are first sent to the quality assurance laboratory for analysis in order to ensure the quality of drug products before they are sold in the market. In any drug-regulating agency, the importance and adequacy of the laboratory system, the equipments, materials, infrastructure, and work force should be a priority for the success of regulation. (Ratanawijitrasin, 2002). This is because if a suspected drug product is seized, the laboratory will be used to find out the quality of such product and the kind of sanction that will follow the violator.

The table below shows that laboratory infrastructures and equipments are in all countries with the exception of Nigeria and Uganda. In addition, NAFDAC contracts some of the products to other laboratory institutions for analysis because the laboratories are inadequate to carry the volume of samples received and inadequate workforce.

TABLE 6: MULTI COUNTRY QUALITY CONTROL OF DRUGS

Sources: NAFDAC, MCC, MEB, MHRA & Ratanawijitrasin, 2002

Quality control of drugs (QC)	Nigeria	South Africa	Uganda	Malaysia	United Kingdom	Netherlands
DRA's own QC laboratories	Available 4 in number serving the whole country	Available	Available	Available	Available	Outsource its sample for QC
Adequacy of the laboratory's infrastructure, equipment	Inadequate to carry effectively the volume of products received for analysis	Adequate	Inadequate to carry effectively the volume of products received for analysis	Adequate	Adequate	Adequate capacity
QC contracted to other institutions	Yes	No	No	No	No	Yes
Reference standard available	Available	Available	unavailable	Available	Available	Available
Work force	Inadequate	Adequate	Inadequate	Adequate	Adequate	Adequate

4.6 PUBLIC AWARENESS

Public enlightenment campaigns is an effective strategy used in raising consumer awareness and combating the faking of regulated products through prints and electronic media, jingles, alert notices, billboards, advertising in journals, publications and workshops and seminars with stakeholders etc. These activities are geared towards educating the public on the rights of consumers to make informed choice, it can empower the public to recognize and reject

counterfeit products through enhanced public awareness. Regulating of drug information helps prevent inaccurate and misleading information to the public and gives a clearer understanding to consumers and health providers.

In Malaysia, they have consumer organizations that keep check and make recommendation to the decisions of their drug-regulating agency, they also raise questions to any issues which consumers need clarifications (Ratanawijitrasin, 2002).

Good communication network to the public and healthcare professionals are made available by MHRA by providing 24-hour anti-counterfeiting hotline and provision of counterfeit medicines guideline for both pharmacists and a separate one for the public, the guideline educates them on how to avoid and report fake drugs cases (MHRA, 2008).

Drug information to the public is usually distributed through their DRA bulletins and gazettes as well as collaborating with stakeholders that will influence public awareness. All the countries also have legal provisions guiding them for public enlightenment.

TABLE 7: MULTI COUNTRY PUBLIC AWARENESS OF DRUGS

Sources: NAFDAC, MCC, MEB, MHRA & Ratanawijitrasin, 2002

Public awareness	Nigeria	South Africa	Uganda	Malaysia	United Kingdom	Netherlands
Legal provision	available	available	available	available	available	available
Advertises prescriptive drugs	No	Only in journals	No	Only in journals	Only in journals	Only in journals
Publishes in bulletins and gazettes	Yes	Yes	Yes	Yes	Yes	Yes
Collaborates with stakeholders	Yes	Yes	Yes	Yes	Yes	Yes

4.7 CONTROLLING FAKE DRUGS IN THE ILLEGAL MARKET (Some country's examples)

In Tanzania, the government started the accreditation and certification of drug dispensing outlet (ADDO) which is a public-private partnership, this is because they found out that it constitutes the largest network for drug sale and people will always patronize such drug outlet because most time the consumers feel they get better care, confidentiality, flexible payment without consultancy charges. Rather than closing such outlets, government started conducting appropriate training for them in order for them to understand the laws governing dispensing practices, conducting lessons in skill management, record keeping and pharmacy practice ethics. This they did with the objective of transforming such unregulated outlets into a regulated system that is monitored in order for them to provide professional services to the underserved and ignorant consumers. Incentives were also given to these small drug outlets to stimulate transformation and motivate shop owners and dispensers to come out for accreditation (Ndomondo-Sigonda, 2003). With the accreditation, only drugs that are approved and registered by Tanzanian pharmacy board is permitted for sale by ADDOs

In Ghana, their licensed chemical sellers are indispensable group for health care provision as many people depend on them as their first line for medicine demand and supply. Some of these sellers though licensed also present threats to public health by providing to consumers incorrect, expired and fake medicines. Their initiative of care shop franchising model was created by

Ghana Social Marketing Foundation (GSMF) to enable the training of the franchisees that signs agreement and renovates their stores according to the franchise guidelines. The idea is that such outlets where demands are high can be easily monitored in addition they will symbolize trust, better services and supply chain to those that patronizes them. The GSMF takes responsibility of medicine procurement, distribution, monitoring and evaluation of franchisee, building the loyalty and trust of these drug sellers (Segre, 2008).

CHAPTER 5: FIGHTING FAKE DRUGS IN NIGERIA (STUDY RESULTS/FINDINGS)

This chapter discusses and assesses the work of NAFDAC as the drug-regulating agency fighting fake drugs proliferation in Nigeria. It also identifies their interventions, strength and weaknesses in putting the problems of fake drug to a stop.

5.1 NAFDAC ACTIVITIES AND INTERVENTIONS IN CONTROL OF FAKE DRUGS WITHIN THE LEGAL MARKET:

The activities of the “new NAFDAC” that was incepted in April 2001 will be discussed to see how interventions are carried out in controlling fake drugs within the legal, regulated market in Nigeria as well as some achievements that brought reduction to the problems and the areas that still needs amendment. This will be compared with other countries drug regulating Agencies. NAFDAC offices are located in the six geopolitical zones and in the 36 states of Nigeria with the national headquarter located at Abuja federal capital territory.

5.1.1 INSPECTION PROCESSES AS A CHECK TO DRUG FAKING

NAFDAC Nigeria has two directorates involved in inspection activities. They are the ports Inspectorate directorate (PID) in charge of imported products and the Establishment Inspectorate Directorate (EID) charged with locally manufactured products.

The principle behind GMP inspection is that quality is built into the product and not just tested for in the finished product. It is also seen as a vital component for control of pharmaceuticals. Please see Annex 5 for the Standard Operating Procedures (SOP)

For **GMP and routine inspection**, NAFDAC adopts the WHO guidelines for inspection visits but does not carryout routine inspections abroad mostly due to financial constraints. Manufacturing companies abroad are inspected once during product registration. These could make manufacturers not to adhere completely to the specified standards. However, for local products, inspectors’ carryout unscheduled routine visits to factories. The Ghana Food and Drug Board now carries out constant routine inspection of both imported and local facilities for drug regulation, this will gives them a better contact and monitor of activities of drug manufacturers (Agyarko, 2006)

Drug distribution channels in Nigeria are difficult to inspect. This is because it is chaotic and unlicensed, owned by illiterate traders whose interests are profit oriented. Other countries under study have defined ways of inspection in drug distribution. South Africa uses their provincial authorities in every province while UK and Netherlands adopts Good Distribution Practice (GDP), where inspectors’ monitors’ drug distribution from manufacturer to the point of dispensing after it has been registered. The Ghana Food and Drug Board now carries out constant routine inspection of both imported and local facilities for drug regulation, this will gives them a better contact and monitor of activities of drug manufacturers (Agyarko, 2006)

The **staff strength** in NAFDAC is around 1500 covering the whole states in Nigeria (NAFDAC Consumer safety bulletin, 2007). A country of about 140 million people, this increases the work schedule of staff and can cause inefficiency due to fatigue.

Other Interventions for inspection by NAFDAC

- Mandatory provision of pre-shipment information provided by all importers before their drug products arrives at the port of entry of Nigeria.
- All Nigerian banks are working with information from NAFDAC to make drug importers to get the Agency's clearance first before financial documents are processed for them.
- Issuance of guidelines to airlines that might lift drugs for importers without proper authorization from the Agency.
- In addition, any importation of unregistered drug product attracts penalty fine and seizure until the product is registered.
- Carries out post marketing surveillance in accordance with WHO specifications..
- Procedures are set for mopping up fake drugs that are already in circulation.
- The local factories in Nigeria, besides being inspected at the time of product registration are also inspected once in three months without prior notice. This is done to ensure that they are consistent with current GMP and have not deviated from the conditions under which the product was registered.
- Factories with poor GMP, their products are not allowed into the country.
- Seizures of fake and expired drug products by PID and EID officers worth billions of naira, which are eventually destroyed.

Observations and analysis

- There is no organized routine inspection within the period of the five-year valid license. GMP inspection is done just without any follow up inspections. With this no one hears if the company is maintaining its GMP or not and if the drug batches produced are of good quality.
- If the factories of local drug manufacturers are inspected routinely to ensure that they are consistent with good GMP, NAFDAC should plan on how to apply same to imported products because that is the main source where the bulk of drug products comes into the country.
- The sample of imported drug products for registration are not being drawn by inspectors at the point of GMP inspection for onward submission for analysis in the laboratory rather the company's representative brings in the products for analysis. This might make the company to produce good drugs just to ensure they passed laboratory test then goes back to produce low quality products after they are issued registration license.
- The wholesaler and retailers are not monitored to know how they distribute their products; they can sell to any one for profit.

5.1.2 DRUG PRODUCT REGISTRATION AS A CHECK TO DRUG FAKING

The product registration process is the time when the mechanism that checks drug faking and adulteration are put in place, it is a valuable means used by government to control the ways products are manufactured and offered for sale in Nigeria to ensure safety and good quality of the products. Please see Annex 5 for the SOP.

To compare with other countries DRA in the study,

The **5 years valid license** is too long for a developing country where fake drug is a big problem; Uganda DRA gives only one-year license which will aid in closer monitoring of drug products.

Drug sale, supply and price, according to Nigerian drug law it is one of the activities of the Agency, but it is unmonitored by NAFDAC as they feel that it is not under their jurisdiction to regulate how products are sold as company has already paid high tariffs to obtain their license. Once a drug product is registered, sometimes one does not hear about what happening with the product until the company comes back for renewal. Other countries under study have a monitoring unit in place.

External expert's support for registration and assessment is unavailable. The support from foreign experts who can come and teach the staff new ideas are lacking,

Legislation is weak due to judicial and political influences. This affects the effectiveness of drug laws and issuances of sanctions to violators.

Interventions in NAFDAC drug product registration

- For drug product to be registered in NAFDAC, the drug factory must be WHO pre qualified or be GMP certified before the product can be exported to Nigeria.
- India is one of the major importers of drug products to Nigeria, NAFDAC appointed analysts in India that help in certification of any drug product before it leaves the shores of India to Nigeria.
- NAFDAC made the importers to insist to their manufacturers abroad that the product for importation have affixed NAFDAC registration number on the outer packaging of the product before bringing it to the shores of Nigeria. (NAFDAC, 2007)
- Compilation of all products Registered with the agency in the gazette and “NAFDAC green page” for the public to be aware of the registered products and what to buy.
- The fast registration process of two months maximum as directed by Director General NAFDAC helped the agency in solving the problems of delay and the companies getting their license on time. Under the “new NAFDAC”, three thousand six hundred and thirty (3,630) products were registered under one year as against five thousand, seven hundred and thirty five (5,735) products that were registered within seven year under the old “NAFDAC”.

Observations and analysis:

- Even though NAFDAC is established in all 36 states in Nigeria and in the Federal capital territory, Abuja. Product registration for local products is carried out in one central zone of Lagos. The process is that staff based in the states are expected to after inspection to draw samples from the company for upward sending for analysis and registration in Lagos. In addition, states that have one of the laboratories within their zones, analysis the products and sends the laboratory report to Lagos for registration process. The inefficiency of the process can creates gaps in adequate control of drugs products that are registered, thus, fake drugs can filter into the supposed legal market.
- Most of those local products for analysis in the process of bring it to Lagos are spoiled or damaged on the way, reducing the quality, because of the distance from one state to another
- In the process to meet up the two months period of registration as given by management, the quality control officers will now be in a hurry to analyze such product in the process the officer might be worn out with workload and might not give accurate results.
- In the process to avoid delay sometimes, imported products are registered before the GMP inspection is carried out, this gives poor image to the Agency rather importers

should be advised to start their registration processes on time so that we can avoid registering products whose GMP cannot be determined on time. A case that happened where after the product had been registered, the inspectors went to the country only to find out that the company is not in existence, hence documentations provided by importers are not enough proof that such company will be in existence.

5.1.3 ENFORCEMENT ACTIVITIES AS A CHECK TO DRUG FAKING

The creation of the enforcement directorate with the inception of the “new NAFDAC” has helped in catching up with drug fakers and increased the public confidence in the Agency. Two key factors that play crucial roles in the activities of enforcement are surveillance and promptness, the usefulness of these two key factors has given better interventions. Nevertheless, there are always conflicts of interest with some stakeholders and NAFDAC enforcement in Nigeria. The customs in the ports might want to collect bribe from drug dealers, the judiciary sometimes averts laws and penal sanctions to violators, as well as the police. This affects the enforcement activities in achieving proper results. The UK MHRA keeps close collaboration with important stakeholders whose influence can affect the detection, investigation and arrest of violators.

Interventions from NAFDAC enforcement

- With tip off from public, victims of fake drugs and through reports from health professionals, fake drug dealers can be traced and apprehended.
- Constant raiding on drug hawkers whereby the product are confiscated and destroyed, especially when they cannot provide proper invoice of purchase with location address that could aid the enforcement team to trace the drug fakers and distributors.
- Making all property owners aware of who rents their warehouse and uses it for storage of fake drugs, will be held responsible if tracing the fake drug dealers proves difficult. This has given prompt information to the enforcement concerning drug fakers.
- Plan to establish a model drug market in the six geo-political zones of the country under the control and management of pharmacists. The objective is to create a better drug distribution network that can easily be monitored.

These interventions by the enforcement officers gave some of the mentioned results below:

- Closure of some major open drug markets for a short period of 3-6 month at Ariaria drug market in Abia state in 2002 for 6 months, Kano drug market in 2004 for 3 months and more recently the Onitsha drug market in 2007 where the prevalence rate of fake drug stands at 30% as against 10% in other parts of the country according to a WHO survey.
- Seizure of around 82 truck loads of fake, banned and expired drugs at the Onitsha drug market of Anambra state, and discovery of five fake drug warehouses during the raid.
- Dismantling of some fake clinics inside Onitsha market where they carryout illegal abortions, gives treatment and injections to people with fake infusions.
- Confiscation and destruction of seven 20 feet containers worth =N=100 million from Onitsha market.

- Barring of 31 companies in China, Pakistan and India from bringing in their products into the country because they were reports that they collaborates with some illegal drug dealer in Nigeria.
- Seizure of some controlled drugs such as pethidine, pentazocine, diazepam which are special drugs that are handled and documented carefully by pharmacists but were sold indiscriminately in Onitsha market. In addition, banned drugs such as analgin, phenylbutazone, stolen drugs of high dose vitamin A, and TB drugs, vaccines and other thermo-labile drugs like anti-rabies vaccines, tetanus-toxoid, polio vaccines that were left in open shelves in the market at temperature of over 40C.
- Destruction of fake drugs worth billions of naira from Onitsha drug market.
- Seizure of 12 trucks 20ft container of fake drug product at Abule Oshun, badagry expressway worth around =N=200,000,000 million naira
- Seizure and destruction of 10 lorry load 20ft container of fake drug products worth around 500 million naira at Ojo military cantonment.
- Over 100 destruction exercises from April 2001 to January 2006 of fake products
- Up to 45 convictions were secured in respect of counterfeit-drug related cases, and over 56 cases are still pending in court

Observations and analysis:

- There are always conflicts of interest with stakeholders and enforcement in Nigeria. The customs in the ports might want to collect bribe from drug dealers, the judiciary that averts laws and penal sanctions to violators, as well as the police. This affects the enforcement activities in achieving proper results.
- There is inadequate security at mini ports of entry creating avenues for drug fakers to bring in their products. This could be due to inadequacy of the workforce to cover every likely area of entry.
- The maximum punishment for dealing with fake drug is a fine of =N=500,000 thousand naira or five year prison sentence, which is not strong enough to deter drug peddlers because they make so much money in the expense of peoples live.
- There are no incentives in security, insurance for the enforcement officers that risks their lives fighting fake drug in the country as occasions have shown attacks of officer during or after raids.
- There are inadequate work forces to cover all mini unnoticed ports of entries where drug dealers can use as avenue to import fake products.
- Nigerians are not strict in implementation of the drug laws that is the reason why the market cannot be permanently closed because of powers capable of influencing the laws

The Chinese State Food and Drug Administration (SFDA) has put up plan that can help monitor medicines electronically through their labels. This requires drug manufacturers to affix their products with such labels for easy detection of products country of origin, manufacturer, type of product and the specification. Most especially, for easy detection of fake drugs (EAASM, 2008)

5.1.4 PUBLIC ENLIGHTENMENT PROGRAM AS A CHECK TO DRUG FAKING

NAFDAC is empowered under its enabling law section 14 to use the resources it has in publicizing and promoting its activities, this includes public enlightenment campaign which is an effective strategy that can be used in consumer awareness and combating faking of regulated

products. (NAFDAC consumer safety, 2007). The use of public enlightenment campaign as a strategy involves dialoguing, educating as well as persuasion through different means such as jingles on television, prints and electronic medias, alert notices for consumers, use of billboards, publications of the lists of all identified fake regulated products in the media, use of workshops, seminars and advocacy to stakeholders.

The U.K MHRA has 24 hour hotline communication from the public which NAFDAC does not have yet but consumer complaints are always welcomed.

The Ghana Food and Drug Board (GFDB) are recently introducing the use of mobile phone SMS text messages to authenticate the drug quality a consumer buys. This technology is called M pedigree that tends to track drugs electronically from the original producers to the pharmacy shops where drugs are dispensed. It enables the drug buyer to know the source of the product. This technology will be efficient since 90% of the population uses mobile phone (Amankwah, 2006)

Interventions of NAFDAC public enlightenment program

- Extension of enlightenment campaign on fake drug awareness to Nigerian high schools in order to catch up with younger generation, this is done through organized annual competitions to know what their understanding is on the ill effects caused by fake drug products in the society.
- Establishment of NAFDAC consumer clubs in high school, because youths are believed to pass information to their peers and others, to educate young ones on the dangers of fake drugs.
- Collaboration with other relevant stakeholders such as NDLEA, Nigerian Bar association (NBA), Standard Organization of Nigeria (SON), police, customs port authorities etc as contained in the enabling decree to liaise with relevant stakeholders both outside and within the country that can help in the goal of fighting fake drugs.
- Establishment of National Pharmacovigilance Centre (NPC) that is responsible for promoting rational and safe use of medicines.
- Regular publications of list of identified fake/substandard product in NAFDAC quarterly bulletin and in the newspapers for the public to know.
- Advocacy visits done by the Agency to International regulatory authorities in China and India to help in the issue concerning importation of fake drug products.
- Publication of a blue print that covers the year 2005-2010 as a guide for the campaign on fake drugs.
- Launching of the “NAFDAC green page” a directory of all registered products for the enlightenment of the public to be aware of the authenticity of the regulated products that are in circulation.
- Publishing alert notices of products in circulation that has problems for public awareness.
- Organized seminars and workshops for small, medium and high enterprises, to explain NAFDAC guidelines and what is expected from them.

Observations and analysis:

- NAFDAC program for public awareness is better than before because it has made a lot of the public aware of drug fakers and how to identify registered products.
- Public empowerment through enlightenment campaign by the Agency.

- There is no strategy formed to reach the still existing drug sellers in some rural places, forming a strategy to reach and reorganize their activities as done in Tanzania is important.
- Campaigns are often done in urban areas leaving out the rural dwellers that might have little or no access to information.
- NAFDAC works as stipulated in the enabling decree to collaborate with stakeholders. However, some of the stakeholders does not give full cooperation at the time of need.

5.2 NAFDAC ACTIVITIES AND INTERVENTIONS IN CONTROL OF FAKE DRUGS WITHIN THE ILLEGAL MARKET:

The illegal drug markets are made up of unlicensed, unregulated premises where drugs should not be manufactured sold or dispensed. According to Nigerian drug laws (Please see annex 4) it is an offence to sell drugs in open markets without proper permission from the authority in charge of drug regulations.

Drug market in Nigerian consists of unlicensed, unregulated and chaotic open markets situated at Onitsha, Aba and Kano. These markets sell all sorts of drugs both prescription and OTC. Traders themselves who are difficult to identify could manufacture some of the drugs and drug importers of registered and unregistered products supply some. They are also the source of drug purchase to most hospitals, kiosks that are not licensed, pharmacies etc. The essence is profit oriented. (Please see NAFDAC enforcement interventions above for activities to solve the problem)

5.3 SWOT ANALYSIS OF NAFDAC AS ORGANIZATION

The author from her personal observations as a staff of NAFDAC prepares this SWOT analysis.

TABLE 8: SWOT ANALYSIS OF NAFDAC AS ORGANIZATION

<p><i>strengths</i></p> <ul style="list-style-type: none"> • Registers quality and reliability products. • Reduced cases of fake drug dealers. • Better quality assurance for consumers. • Strong disciplinary action on staff. • Focused staff with experience. • Have product lists of all registered products in the “green book”. • High public enlightenment. • New idea innovations ongoing for future. • Management is committed and confident • International recognition. 	<p><i>weaknesses</i></p> <ul style="list-style-type: none"> • Failure to close all open drug markets. • Limited routine GMP abroad. • Insufficient workforce. • Limited budget. • Do not have a detailed plan yet for conducive office space especially in Lagos. • New staff needs immediate training. • Enforcement staff needs constant training. • Monotony of job, need rotation of officers • Poor salary scale
<p><i>opportunities</i></p> <ul style="list-style-type: none"> • Collaboration with relevant stakeholders. • Increased awareness of companies to register their products. • Profit margins is better due to higher tariff charged. • Consumers, companies and staff responds to new ideas. • Training and GMP inspections overseas. • New specialized computer system applications. • Youth involvement to help spread the message and keep pace with time • Good image created by present management. 	<p><i>threats</i></p> <ul style="list-style-type: none"> • Legislation could influence negatively by averting sanctions to violators • Environmental risks without compensation • Existing open drug distribution network. • Threats to officers by drug dealers • Key staff leaving. • Possible negative publicity. • Vulnerable to reactive attacks by drug companies, stakeholders and the legislative arm • Fear for the image and performance of future NAFDAC after the present management • Lack of prompt staff promotion

Discussion of SWOT analysis:

Strengths: The strength of the “new NAFDAC” under Prof. Dora Akunyili gave a better image to Nigeria as a whole in the national and international bodies because of her commitment and ideas for a better agency that can help in fake drug eradication, these was extended to every staff member. The work is handled with transparency to everyone and is open to receive complaints from the public. Strong disciplinary approach to any erring staff such as dismissal, demotion, warnings has reduced redundancy at work. In addition, products are registered by following WHO stipulated guidelines which has helped in better quality assurance and reduced drug faking.

Weaknesses: Inability of the agency to close the chaotic drug markets that stand as source for drug purchase and distribution has lowered their goal in creating a country free from fake drugs. Adequate materials and workforce needed in fighting fake drugs are lacking because of limited budget from government support, as NAFDAC alone will not be able to financially handle some necessities like increasing staff salaries and training, conducive office space, routine inspections abroad etc.

Opportunities: The increased tariff for NAFDAC services gave the opportunity for the agency to carry on as much as they can in areas that need attention since the support is low from government. Areas as some trainings, provision of computer system, enlightenment campaigns and collaboration. This has brought involvement from youth and awareness for the need of registration.

Threats: Without a full support from government, the work done by the agency will be for nothing. The negative influences that comes a times from lawmakers where sanctions for violators are averted, drug companies and people who might want to tarnish the image of the agency and some stakeholders threatens the hope of the agency to continue in the fight. Risks of attack to people’s lives especially from some drug dealers abound, and nothing is done by government to provide security and compensation. The lack of prompt staff promotion can easily make key officer to leave when a better opportunity comes there way.

CHAPTER 6. DISCUSSION OF STUDY RESULTS/FINDING

6.1 DISCUSSION OF LESSONS LEARNT

Players in fake drug business: The major players in fake drug business and their various roles were identified such as the drug manufacturers, importers, wholesalers and retailers, drug professionals, informal drug sellers, consumers and the enforcement.

Factors that contributes to fake drug proliferation and reasons for consumer's patronage: The problems of fake drug is global and it can affect public health by causing illness, death, disability as well as reduce the image of the health system. Different countries through their government and DRA are in the same fight. The strategies used by them in finding solution are a revelation for a way forward. Some of the identified factors that contribute to this fake drug proliferation in Nigeria are poor implementation of existing drug laws, inefficient cooperation between stakeholders, illegal drug importation, corruption and greed, high cost of good quality drugs and demands exceeding supply. In addition, some of the identified reasons why people patronize drug outlets as their first line for treatment are because the prices are often cheap, close proximity, no consultation fees, flexible payment method, perception of confidentiality, they feel that the quality of care and attention received are adequate, high stock out rate at the health facilities. Hence, closing such outlets, seizing, destroying and penalizing the violators, as often done by NAFDAC though good, but it might not give a lasting solution to fake drug proliferation. This is because with low accessibility, availability and affordability consumers will always demand for their services.

In Tanzania, the government started a program for accreditation of drug dispensing outlet (ADDO), through the initiative these vendors are trained to understand basic pharmacy ethics in order for them to provide better services to consumers that patronizes them.

Ghana also have similar program called care shop initiative, through their training to the vendors are also able to monitor the drugs supply chain.

Efforts of NAFDAC in controlling fake drug proliferation:

The present management of NAFDAC has worked hard to address the problems of fake drugs in circulation in Nigeria, by accessing every possible avenue in their capacity such as strategic public enlightenment even through dialogue and persuasion to eradicate fake drugs distribution, seizing and destruction of fake drugs etc. Distribution of fake pharmaceuticals in Nigeria evolved as part of a market system controlled by traders in open markets. While these traders are not trained in dispensing and storage of medicines, yet major pharmaceutical companies and fake drug traders rely on them as distribution channels because they are effective in fast distribution of any drug and because pharmaceutical companies are more concerned of their profits (Akunyili, 2007).

The idea of creating a good drug distribution network "model mart" for an ordered, conducive drug environment that can be monitored for sale and distribution of pharmaceutical products under the supervision of a pharmacist was proposed, but it has not worked because of political influences.

Government efforts for the protection of health of its citizens are important. It can ensure quality medicinal products are supplied through an established, licensed supply chain in care of the professionals in order to minimize fakes, better monitoring system and building confidence in consumers (Sagar et al, 2006). Monitoring drug distribution chain is important for fake drug detection. The UK MHRA, makes use of their Good Distribution Practice inspectors to monitor the chain and every level in the chain must be licensed from manufacturer, distributors,

wholesaler, retailers and dispensers. This helps them ensure that fake drugs do not filter into the chain. The South Africa MCC, allows only licensed pharmacists get involved in drug manufacture, importation, distribution and dispensing

Drug peddlers are encouraged to continue because the laws are not deterrent enough to curb them. The Nigerian judiciary does not help matters as cases are lingered in court for far too long. Justice is sometimes denied to the Agency even with adequate evidence and witnesses against drug dealers. How then can all interventions strategies work out effectively when the laws guiding them are neglected by the very hands that made them.

Chinese government introduced stiff penalties such as withdrawal of license and prohibition of drug production to any violator of drug law.

CHAPTER 7. CONCLUSION AND RECOMMENDATIONS

7.1 CONCLUSION

The review of fight against fake drug proliferation in Nigeria by NAFDAC has not been very successful because of the above-discussed problems, even with the good efforts made by the present management.

Without a full and continuous support of a National government, it will be a very difficult situation for any DRA to be successful in fully implementing its stipulated guidelines and laws. The government should have a clear, firm and equitable legislation that addresses all important issues with appropriate sanctions for drug violators, provide financial support to the DRA especially in areas of staffing, GMP inspection, quality control laboratories and enforcement, should stand its ground in defense of situation concerning public health. In addition, give full support when legislated sanctions are given to drug offenders (WHO, 1999).

Every one must play his/her role if the fight against fake drug in Nigeria is to be won. From the authorities in charge of drug control, the federal government, International committee, drug manufacturers and pharmacists, all sectors, the health system down to the consuming public irrespective of one's status should stand together. Report of issues or individuals with questionable character in drug business to the appropriate authorities. These will help in achievement of NAFDAC set objective in safeguarding the health of the nation.

7.2. RECOMMENDATIONS (THE WAY FORWARD)

According to World Health Organization (2007), the issue of corruption needs prevented coordinated applications of two basic strategies:

- “Discipline-based approach” (top-down): In this strategy the attempt to prevent corruption by policy makers and through stipulated legislations by giving adequate punitive measures for violator of drug laws, when the drug manufacturers and sellers understand the consequences of faking they will be afraid to face the punishment, hence corrupt practices are prevented.
- “Value-based approach” (bottom-up): This strategy promotes institutional integrity through the promotion of moral values and ethical practice, for example motivating ethical conduct of public servants.

This approach by WHO for combating corruption should be adapted by both NAFDAC and the legislative arm of government.

For NAFDAC

- Creating a good drug distribution chain that is licensed for easy monitoring. (From manufacturer to wholesaler to pharmacy to patients). This we can do with adequate government support and creating another unit called Good Distribution Practice (GDP) that monitors drug distribution as is done by UK MHRA.
- Training program especially to enforcement officers. This training can sort the help of NDLEA and military personnel's. WHO guidelines for combating fake drugs should be followed.
- The tariff placed for drug importation should be reviewed, because it creates high cost in the market as importers want to make back what they lost during registration, hence

poor people who cannot afford the genuine drug because of price goes for the cheap types that might be fake.

- Public enlightenment strategy to reach petty drug sellers that enter moving transport buses, because they feel they can easily make quick sale without being detected by the authorities. This we can do by meeting with the transport unions and telling them that they too will be sanctioned if they allow such in their buses.
- In addition, regulating and licensing of such vendors in unregistered premises as is done in Ghana and Tanzania can make them come out from their hideouts, this will enable us to train them and monitor their drug supplies.
- Tight security at all ports of entries in Nigeria should be encouraged in order to curb the activities of illegal drug importers who will not want to go through the process of drug registration. Availability of trained officers and collaboration with other drug agencies can help.
- Every state in the country where NAFDAC is situated should have its mini laboratory for prompt analysis; this will reduce the stress of staff that has to travel very long distance with loads of product for registration.
- There is the need for NAFDAC to develop better strategies in promoting public awareness since the drug fakers have become very sophisticated in their activities making it more difficult to distinguish originals from fake.
- There should be a planned routine inspection visits for imported products. This is because five years is too long to believe that a company still keeps a good manufacturing practice as was seen during the first inspection before registration.
- Collaboration with other drug agencies and experts like the Nigerian Drug Law Enforcement Agency (NDLEA) when necessary to aid the Agency during raids and registration.
- Enough work forces to cover all mini unnoticed ports of entries where drug dealers can use as avenue to import fake products.
- To make incentive of staff commensurate to what obtains in other government Agencies involved with oil production; this will remove the eyes of officers from collecting bribes in order to solve some of their pressing needs that the salaries cannot afford.
- Creation of a good working environment for staff as this will increase effectiveness and productivity.
- Adequate incentives and welfare such as security, insurance for the enforcement officers that risks their lives fighting fake drug in the country as occasions have shown attacks of officer during or after raids.

For Government:

- There is need for the federal government to have a well defined drug laws that must be compulsorily implemented by every government administration that comes to power and by every arm of the legislation such as the judiciary that handle cases of violators, without fear or favor of anyone. Because it is discouraging that the Agency makes so much efforts to arrest offender, but the cases will be delayed or denied in the court of law.
- Drug offence should be taken more seriously because it involves human lives; any one that violates the drug law resulting to death of people should as well receive stiff penalty or life imprisonment as the maximum punishment.

- Punishment for drug laws should be made stiffer
- The government should empower NAFDAC by provision of adequate workforce, equipments and materials for enforcement activities as well as provide finance for building of quality assurance laboratories that is well equipped in every state of the country, as these will reduce the workload of staff and increase efficiency.
- Support NAFDAC in there new strategy of building a model mart for a coordinated and well monitored drug distribution. NAFDAC alone will not be able to wipe out the existing open markets where fake drugs flourishes. Adequate government support is needed to implement what is stipulated in the drug law that medicines should not be sold at open markets.
- In order to enhance affordability of medicines, it is recommended that the country adapt a pricing policy that aims to reduce the high price and disparities between prices reduce the heavy tariff placed on pharmaceutical industries which adversely affects the cost of manufactured drugs
- Provision of good quality, affordable medicines in government clinics and hospitals (this is recommended for further research)
- Increase salary incentive of staff to limit the temptation of collecting bribes from fake drug dealers.
- There is need for the Nigerian law to be strict in implementation, the judiciary should stop the delay in prosecution of offenders and adjournment of cases that requires immediate action.
- The use of patents and proprietary medicine vendors that are non-professional in drug business should be reviewed. Since consumers will always patronize them, government should buy the idea of training them on basic pharmacy ethics and making their illegal business legal through regulation and licensing. This will make drug distribution easier to monitor and consumers purchasing only from licensed outlets. This already works in Ghana and Tanzania.
- There should be an organized program under the care of PSN to improve the services of mini drug outlets and medicine vendor, by training them on basic pharmacy ethics. In addition, regulate their activities as is done in Tanzania ADDO program and in Ghana. (this is recommended for further research)

For Manufacturers and Drug dealers

- Should distribute their products only to licensed premises and people, as this will create a better drug distribution channels that can be monitored.
- Adhere to all stipulated regulations of WHO and Drug Regulatory Agencies of both the country of manufacture and export.
- Manufacturers should develop strategy to monitor tightly their products in the legal drug supply chain to ensure that their products are not faked
- It is important and necessary for genuine manufacturers to brand their products by imparting vital product information and designs on them for easy identification

For Pharmacists society of Nigeria (PSN)

- Should not allow any drug premises that is not registered and monitored by PSN to operate.

- Ensure that all drugs sold in any registered premises are registered by NAFDAC
- Collaborate with other countries pharmacy council to buy new ideas on fake drug detection

For Consumers/buyers

- To purchase drugs only from sources that are registered by PSN and only product registered by NAFDAC, these should be done through continues public awareness
- Be alert at all time in double checking what they buy, and being alert to detect differences in quality of packaging, label and ensure the drug has leaflets and NAFDAC registration number before consumption.
- Consumers should report immediately of any drug whose quality is in question or adverse reaction felt for any drug product.

GENERAL RECOMMENDATION:

GOOD GOVERNANCE

For the success of this fight, it is recommended that all stakeholders follow eight characteristics that form good governance as recommended by (UNESCAP, 2008) below. All stakeholders in drug business as well as the rules of law should participate, be consensus oriented, accountable, transparent and responsive at all levels, should be effective and efficient at all time, equitable and inclusive and follows the rule of law.

This will give us full assurance of minimized corruption, and people will be heard and justice taken for violation and responds constantly to present and future situations that can come up in our fight against sale of fake drugs in Nigeria. (UNESCAP, 2008)

FIGURE 5: GOOD GOVERNMENT DIAGRAM



Source: UNESCAP (2008)

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Annex

ANNEX 1: FUNCTIONS OF VARIOUS DIRECTORATES IN NAFDAC: (NAFDAC, 2005)

Several units make up NAFDAC:

- The Legal Unit is charged with offering legal advice on “law arising from Employee-Employer relationship and is the custodian of legal documents and all agreements relating to the Agency.”
- The Public Relations Unit is headed by the Director-General’s office. Its main function is to inform, sensitize, enlighten and create awareness concerning the role of the Agency. The agency is divided into eight directorates with the last two newly added.
- Internal Audit provides a means of measuring the effectiveness of the system of internal control and accounting, and carries out special investigations.

The agency is divided into eight directorates:

Registration and regulatory affairs, Establishment Inspectorate, port Inspectorate, Laboratory services, Narcotics and controlled Substances, Planning, Research and Statistics, Finance and administration and Enforcement. (NAFDAC 2005)

NAFDAC has various main functions. According to the requirements of its enabling decree, the Agency was authorized to:

- Regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of drugs, cosmetics, medical devices, bottled water and chemicals.
- Conduct appropriate test and ensure compliance with standard specifications designated and approved by the council for the effective control of quality of food, drugs, cosmetics, medical devices, bottled water and chemicals.
- Undertake appropriate investigation into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottle water and chemicals and establish relevant quality assurance system including certification of the production sites and of the regulated products.
- Undertake inspection of imported food, drugs, cosmetics, medical devices, bottled water and chemicals and establish relevant quality assurance system including certification of the production sites and of the regulated products.
- Compile standard specifications and regulation guidelines for the production, importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water and chemicals.
- Undertake the registration of food, drugs, medical devices, bottle water and chemicals.
- Control the exportation and issues quality certification of food, drugs, medical devices, bottled water and chemicals intended for export.
- Establish and maintain relevant laboratories or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions.

1. *Registration and Regulatory Affairs Directorate (R&R)*

- Registration of drugs, food, medical devices, cosmetics, chemicals, detergents, drinks, bottled and packaged water
- Formulation and periodic review of regulations to control products registration by the agency
- Process and manages all documentation relating to the clinical trials of novel drugs and new chemical entities
- Monitors clinical trial to ensure compliance with study protocols in order to safeguard the health and safety of the trial participants
- Ensures that only drugs of proven safety and efficacy are allowed to be manufactured, imported, sold or distributed in Nigeria.
- Review with the help of experts published reports on clinical trials
- Conducts scheduled and unscheduled visits to trial sites for the purpose of audit
- Development of modalities for certification of food items for export
- Control of advertisement of regulated products
- Investigation of consumer complaints and post registration surveillance activities to ensure that products still meets registration standards
- Processing applications for global listing of supermarkets/restaurants and fast food items
- Coordination of foreign GMP inspection
- Workshop organization, training and seminars for agency's staff and other relevant stakeholders

2. *Laboratory Services Directorate:*

- Analysis and pronouncement on quality and safe food, drugs, medical devices, cosmetics, chemicals, detergents, drinks, bottled and packaged water
- Quality control of Agro chemicals
- Post registration monitoring of regulated products
- Research method development
- Investigation on public complaint samples
- Serves as reference laboratory for other government Agencies

3. *Port Inspectorate Directorate(PID):*

- To regulate and control the importation of food, drug, medical devices, chemicals, cosmetics, detergents drinks and water
- Screening of import documents before the issuance of pre-release stamps
- Bonding of unregistered NAFDAC regulated products for mandatory registration and release
- To undertake the inspection of imported food, drugs, medical devices, cosmetics, chemicals, detergents, drinks, bottled and packaged water at the ports of entry before release

- To control the exportation and issue quality certification of food, drugs, medical devices, cosmetics, chemicals, detergents, drinks, bottled and packaged water intended for export as well as issuance of certificate of pharmaceuticals products (COPP)
- Compiles standard specifications and guidelines for the importation and exportation of medical devices, cosmetics, chemicals, detergents, drinks, bottled and packaged water

4. *Establishment Inspection Directorate (EID):*

- Current good GMP inspection of local establishments engaged in the manufacture, sale, storage, distribution and use of food, drug, medical devices, chemicals, cosmetics, detergents drinks and water
- Conduct inspection of overseas establishments intending to register and sell their products in Nigeria to ensure compliance with standard requirements
- Investigate consumer complaints/alert notices
- Draws samples of NAFDAC regulated products for purposes of laboratory analysis, exhibits for prosecution, and stability studies
- Carryout post marketing surveillance

5. *Enforcement Directorate*

- Conducting surveillance on companies and persons suspects to be violating NAFDAC;s regulation
- Carrying out investigations on such persons and companies as well as interrogation of suspects
- Sampling of NAFDAC regulated products to the laboratory and compilation of case files
- Raiding of drug hawkers
- Destruction of fake and spurious regulated products
- Co-ordination of activities of state task forces

6. *Narcotics and Controlled substances directorate:*

- Controls and documents the importation, distribution and use of Narcotics, psychotropic substances and chemicals
- Promotes activities geared towards reduction of demand for psychoactive drugs as well as rational use of drugs in general
- Ensures Nigeria's obligation under the international Drug Treaties with respect to licit transactions in Narcotic drugs and psychotropic substances are fulfilled
- Ensures that narcotic drugs and psychotropic substances are available only for medical and scientific purposes
- Carry out public enlightenment and education activities on drug abuse
- Maintains close collaboration with NDLEA and liaise with United Nations Office for Drug Control and Crime Prevention (UNODCCP)

7. Planning, Research and Statistics (PRS)

- Undertake and coordinate research programs on the storage, adulteration, distribution and rational use of food, drugs, medical devices, cosmetics, detergents, drinks and water
- Compile and publish relevant data resulting from performance of functions of the agency
- Sponsor such National and International Conferences as it may consider appropriate
- Liaise with relevant establishments within and outside Nigeria in pursuance of the functions of the agency
- Develop work plan for the agency
- Monitor and evaluate programs, projects and implementation of work plan
- Manpower training and development including workshops, conferences and seminars
- Providing secretariat for senior/top management meetings, evaluation and appraisal of documents, correspondence to maintain good image of the agency
- Keep records of approved development plans, projects of the agency and their execution time schedule where specified
- Preparation of annual budgets and rolling plans in collaboration with administration and finance directorate
- Attending trade fairs at National and International levels in liaison with the Public Relations Unit to project the image of the agency.
- Coordinate pharmacy Internship and Industrial Attachment Training
- Coordinates the Agency's overseas GMP inspection

8. Administration and Finance Directorate:

- Coordinates general day to day financial functions of the agency and necessary account books
- Disburse funds of the agency as approved by management
- Pay all staff salaries as at when due
- Pay all overhead costs promptly
- Collect and lodge all funds due to the agency
- Keep proper documentations relating to all funds collected
- Prepare budget estimate for the agency
- Prepares financial report and submit to parent and other necessary government bodies
- Handles staff recruitment/appointment, promotion, transfers and posting in the agency
- Deals with complaints of staff misdemeanors/misconduct and recommends proper disciplinary action to be taken by the agency
- Issuance of query to erring staff
- Documentation of new staff, prepares staff nominal roll and issues identity cards
- Keeps records of all the agency's rented and owned properties
- Handles staff medicals and insurance
- Computes gratuity, pension and death benefits for staff
- Handles the agency's security services

- Coordinates matters relating to NAFDAC council
- Liaising with the appropriate ministry in sourcing for and collecting all establishment circulars relevant rules and regulations guiding the conduct of government business
- Receiving and dispatching the agency's mails
- Handling the agency's Sanitation and environment matters

NAFDAC envisions that by making these functions known, that its actions will be apparent “in all sectors that deal with food, cosmetics, medical devices, bottled water, and chemicals to the extent of instilling extra need for caution and compulsion to respect and obey existing regulations both for healthy, living and knowledge of certain sanctions or default”. Despite the establishment of NAFDAC, the concept of fake drugs did not still end. Dissatisfied with progress in combating fake drugs, former President Olusegun Obasanjo administration dissolved the management of NAFDAC in August 2000. In April 2001, a new management, with Dr. Dora Akunyili as Director-General, was inaugurated. The new management re-organized the agency, and has been successful in the recent past. (NAFDAC, 2005) For several years, Nigeria was drowned in an ocean of fake drugs. Then “Prof. Dora Akunyili approached her job with zeal, to help in ridding the Nigerian market of fake drugs. Although there is improvement in reduction of fake drug since her inception in 2001, problems of fake drugs still avails in Nigeria.

ANNEX 2: GLOBAL PERSPECTIVE ON FAKE DRUGS (Spies, 2003)

Counterfeiting is a global problem. Many goods moving through international commerce are counterfeited. Industry data shows that 5-7% of world trade, valued at about US\$280 billion is lost to counterfeiting. It is estimated that about US\$ 20 billion worth of products in the information technology (IT) sector move through unauthorized channels annually. The pharmaceutical industry are reported to move through various authorized and unauthorized channels. These channels make it possible for counterfeits, expired, repackaged and relabeled products to be shipped internationally.

Several criminal networks involved in drug faking and counterfeiting have evolved over the years. They include manufacturers, importers, distributors and retailers. Other collaborators are inspection agents, shipping and clearing agents and corrupt government officials of drug regulatory agencies, customs and police. Drug counterfeiting was highlighted at the World Health Organization's conference of experts on the rational use of drugs, held in Nairobi in 1985. At the World Health Assembly (WHA) in May 1988, a number of countries expressed concern over counterfeit drugs that were circulating in their markets. The Assembly adopted resolution WHA 41.16.12 which requested governments and pharmaceutical manufacturers to cooperate in the detection and prevention of the increasing incidence of the export or smuggling of falsely labeled, spurious, counterfeited or substandard pharmaceutical preparations.

The World Health Organisation (WHO), since 1984, has been collaborating and collating data related to counterfeit drugs. This has enabled the organization to develop a database on counterfeit drugs. WHO received 771 reports of counterfeit drugs from different countries between 1984 and 1999. 22% of these reports came from industrialized countries, while the rest came from developing countries. Forty six confidential reports of counterfeit drugs were received by WHO from 20 countries from January 1999 to October 2000. About 60% of these reports came from developing countries while the remaining 40% are from developed countries.

Counterfeit pharmaceutical products previously were thought to be a substantial and increasing problem of low-income countries, most of the time caused by weak administrative systems. At the global forum of pharmaceutical anti-counterfeiting held in Geneva, in September 2002, many participants brought to light the counterfeiting problems that existed in their various countries. There have been cases of court actions resulting from patients treated with fake drugs in United States; U.S has one of the most regulated and policed pharmaceutical markets. Counterfeit medicines has been detected through referrals from public and professional bodies, whistle blowers and covert test purchases, according to a report presented by the medical control agency (MCA) of the United Kingdom. It is noteworthy that the types of counterfeit pharmaceutical found in the UK are similar to those found in other countries, includes look-a-likes, identical copies, relabeled products, expired authentic and rejected authentic products that found their way back to the markets.

Report from Russia showed that 12% of drugs in circulation are counterfeit and that there is a growing problem of look-a-like drugs. This problem could be attributed to a lack of enforcement of prescriptions and qualified medical personnel to handle the health care environment. The distribution of drugs also poses a problem, there are about 40,000 small outlets and kiosks selling

drugs. New pharmacies on wheels have also joined in this business of distributing drugs and causing further chaos.

Interest in the problem of counterfeiting is relatively new for transitional economies, such as Ukraine. It is estimated that the amount of counterfeit drugs found in some countries of the former USSR is up to 30%. In Ukraine, this figure goes up to 40% and as high as 80% for certain pharmaceutical products. This is because there is no control of import and distribution of pharmaceutical products despite a national legislation for the control of the pharmaceutical market.

It is believed that in some extreme cases within Asia, companies may be producing legitimate goods at one end of the factory and counterfeits at the other. Another WHO report indicated that India is responsible for about 35% of the world's fake drugs, which is worth US\$ 200 million annually, representing 20% of the world's total drug market. Recognizing the dangerous trend in spurious drug trade, the Indian Government established the Mashelkar Committee which recommended stringent punitive system for spurious drug makers, including death penalty for those who cause "grievous body harm or loss of life. Offences related to spurious drugs would also be made cognizable and non-bailable.

Studies carried out on seven hundred samples by the pharmaceutical security institute in the Philippines showed that 7% of products marketed were definitely counterfeit. In Lebanon in 1982, factories around Beirut were reported to be faking about 57 Western drugs due to the civil war and Israeli invasion. These drugs were still killing people long after the guns had stopped.

It appears that drug piracy was officially allowed to thrive in countries, such as Lebanon and Thailand, since the governments failed to address the counterfeiting problem in their countries. Even in Britain, with its wealth of copyright and drug laws, this silence prevails. The official reason for the silence is that patients run greater risks if the fear of fakes put them off taking the real product. However, a spokesman for the Association of the British Pharmaceutical Industry (ABPI) was reported to have stated the real reason for the silence. "It is difficult to declare a problem without damaging legitimate business. In other words, they believed there was more money to be made by keeping silent"

In African countries, the incidence of fake and counterfeit drugs is difficult to estimate because of poor communication, the non-existence or ineffectiveness of drug regulatory authorities, poor drug procurement practices, low literacy levels, low awareness of the existence of fake and counterfeit drugs, political instability, and high level of smuggling of pharmaceutical product in the region.

The Essential Drug Monitor (EDM) report on transforming drug supply in Dar es Salam, Tanzania sums up the picture in most African countries. "There was chronic shortage of drugs at health facilities, supplies were erratic as was government funding, resulting in poor drug supply management and irrational use of drugs. Drug quality was questionable and pharmacy premises were often unsuitable, hot, humid, and cluttered with piles of drugs, some of which had expired. Pharmacists had low professional visibility. This mirrors clearly the situation in many African countries with the exception of a few countries such as South Africa, Nigeria, Ghana, Gambia and Egypt, which have some level of systematic drug regulation and drug distribution.

Within the West African sub-region, there are very high activities in inter-boundary trade on pharmaceuticals. Many West African countries, such as Togo, Benin, Chad, Niger, Ghana and Cameroon buy their drugs from Nigeria because Nigeria has the biggest drug market in the sub-region. In the Republic of Benin, for instance, this inter-boundary trade is known as the “parallel market”. An EDM report quotes the Benin National Office of Health Protection as estimating patronage of this parallel market to be around 85% of the population. These counterfeit drugs were generally reported to come from Gabon, Nigeria, and from Asia, Europe and North America. This market is often controlled by traveling sales persons who have no training and lack all necessary skills to dispense drugs. In view of this trade on pharmaceutical products between Nigeria and other neighboring countries, the situation in Nigeria naturally reflects that of the other countries in the sub-region. Even though the counterfeiting of pharmaceutical products is a global phenomenon, some countries including Nigeria, are more affected than others.

Fake drugs were first noticed in Nigeria in 1968, when the crown agents divested as the sole distributors of pharmaceuticals in Nigeria. The problem assumed greater proportions during the import license era of the early 1980 and worsened with the adverse economic effects of the structural adjustment program (SAP) introduced in mid 1980's. The situation got progressively worse with time until 2001 when NAFDAC started aggressive war against fake drugs.

A 1989 study conducted by Denham Pole in Nigeria indicated that 25% of samples studied were fake, 25% genuine and 50% inconclusive. A study conducted in Nigeria in 1990 by former Deputy Director General of WHO, Adeoye Lambo, for a pharmaceutical firm in Lagos showed that 54% of drugs in every major pharmacy shop were fake, a figure that had risen to about 80% in the subsequent years. In another study of 581 sample of 27 different drugs from 35 pharmacies in Lagos and Abuja (Nigeria), 279 (48%) of the samples did not comply with set pharmacopoeia limits and the proportion was uniform for the various types of drugs tested.

The first phase of the study in six major “drug markets” across the country by NAFDAC in 2002, to measure the level of compliance to drug registration revealed that 67.95% were unregistered by the Agency. A repeat of this study in 2003 revealed an 80% reduction. The second phase of the study to be conducted in collaboration with WHO and DFID includes laboratory testing and further investigations of the surveyed drug products will reveal the level of fake and substandard drugs in the country.

ANNEX 3: NAFDAC LIST OF SOME IDENTIFIED FAKED DRUGS
(NAFDAC Consumer bulletin, 2005)

S/N	<i>Identity of product being faked</i>	<i>Genuine</i>	<i>Faked type</i>
1	Fansidar Sulfadoxine+Pyrimethamine 500/25mg 3 tablets	Fansidar Sufadoxine + Pyrimethamine 500/25mg 3 tablets Made in Nigeria by: Swiss pharma Nigeria ltd, 5 Dopemu road Agege Lagos. Under license of F. hoffman, la Roche ltd Basel Switzerland. Store below 30oC stated as part of labeling instruction on the park. Swipha and Fansidar neatly embossed on the blister sachet. Product registered by NAFDAC with registration No.04-0154 printed on the pack.	Copied the name and address on the original product. Store in cool dry place stated as part of the labeling instruction on the pack. Fansidar and Swipha roughly embossed on the blister sachet Faked product of the genuine with copied NAFDAC Reg. No. of the original
2	Pfizer Norvasc 10mg AMLODIPINE BESYLATE 10 tablets	Produced by Heinrich Mark Nachf.Gmbh & Co. KG,ILLERTISSEN, GERMANY under authority of PFIZER INC: New York, USA. Date markings and batch # are embossed on the pack Sachet has Pfizer logo. Registered by NAFDAC #04 - 1386	Copied the name and the address on the original product. Date markings and batch # printed on the pack Sachet has no Pfizer logo Faked product with copied NAFDAC # not registered.
3	Ampiclox Capsules 500mg	Ampiclox Capsules 500mg Manufactured by Smith Kline Beecham Contains stated content of active ingredients. Registered by NAFDAC with Reg.# 04-0181	Ampiclox Caps By wings pharmaceuticals Pvt. Ltd. J-13, Uddyog Delhi- India With very low content of active ingredients
4	Chemiron capsules (X 120's)	Manufactured by Chemiron International LTD Plot 12, Block B, metal Box Road Ogba, Ikeja, Lagos. Packet has clearly defined picture quality. Shelf life listed as 3 years Date markings has bold print of months in letter (abbreviated) Capsules have brilliant red color. Registered by NAFDAC with Reg.# 04-0944	Packet has a blurred poor picture quality. Shelf life listed as 2 years Date markings has smaller prints of months in figures Capsules are dark red in color. Counterfeit product not registered by NAFDAC.

ANNEX 4: NIGERIAN MEDICINE LAWS

Nigeria has different laws that are stipulated for drug regulation, control, manufacture, sale and distribution, such as:

Poisons and Pharmacy Act, Cap 366 of 1990.

This Act regulates the compounding, sale, distribution, supply and dispensing of drugs and provides different levels of control for different categories of drugs and poisons.

Food and Drugs Act Cap 150 of 1990.

This Act prohibits the sale of some foods, drugs, cosmetics and medical devices as the treatment for diseases. It also prohibits the importation, exportation, distribution and sale of specified drugs, prohibits practices that tend to mislead packaging, labeling, and advertising, as well as food and drug manufacturing in dirty/unsanitary conditions. It gives the power to appoint inspecting officers as well as food and drug analysts.

Counterfeit and Fake Drugs (miscellaneous provisions) Act, Cap 73 of 1990.

This Act prohibits the production, importation, manufacture, sale and distribution of any counterfeit, adulterated banned or fake drugs. In addition, prohibits people from selling any drug in an open market without proper permission from the authority in charge of drug regulation.

Pharmacists Council of Nigeria, Decree 91 of 1992.

It repealed the Pharmacists Act of 1964. This decree established the Pharmacists Council of Nigeria which is charged with the following responsibilities: (a) Determine the standard of knowledge and skill required of persons seeking to become registered members of the pharmacy profession, (b) Establish and maintain a register of persons qualified to practice as members of the Pharmacy profession, (c) Prepare and review the code of conduct, and (d) Regulate and control the practice of the Pharmacy profession. The Council has an investigating panel and disciplinary committee to discipline erring pharmacists as appropriate.

National Agency for Food and Drug administration and control Decree No. 15 of 1993.

This is the decree establishing the National Agency for Food and Drug Administration and control (NAFDAC). The Agency performs the following functions: (a) Regulate and control the importation, exportation, manufacture, advertisement, distribution, sale, and use of food, drugs, cosmetics, medical devices, bottled water and chemicals, (b) Conduct appropriate tests and ensure compliance with standard specifications designated and approved by the council for the effective control of the quality of food, drugs, etc., as well as their raw materials and production, including processes in factories and other establishments. (c) Undertake appropriate investigations into the production premises and raw materials for food, drugs, etc. and establish relevant quality assurance systems, including certification of the production sites and regulated products. (d) Undertake inspection of food, drugs etc. (e) Compile standard specifications and regulations and guidelines for the production, importation, exportation, sale and distribution of food, drugs, etc. (f) Undertake registration of food and drugs, etc. (g) Establish and maintain relevant laboratory or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions. The Federal task force on counterfeit and fake drugs established under the provisions of the counterfeit and fake drugs (miscellaneous provisions) Act also operates as a directorate within NAFDAC.

Drugs and related products (registration) Decree No. 19 of 1993.

This decree makes provisions for the prohibition of the manufacture, importation, exportation, advertisement, sale or distribution of drugs, drug products, cosmetics or medical devices unless it

has been registered in accordance with the provisions of the decree. It also stipulates the procedure for applying for registration of a drug product, conditions under which information supplied by an applicant is disclosed, and provisions for the suspension or cancellation of certificates of registration and clinical trials. Penalties for contravention of provisions of this decree are also stipulated within.

These above-mentioned laws show that the government has positively responded by installing adequate legislation to forestall a chaotic drug distribution situation in Nigeria and reduce the incidence of fake drug manufacturing and sale. However, the problem is in strict adherence and implementation of the laws, which should be taken seriously by both government and all Nigerians so that the problems of fake drugs will be a history in the future. (Erhun, 2001)

ANNEX 5: NAFDAC STANDARD OPERATING PROCEDURES (SOP)

SOP for drug Inspection:

The importation of fake drug products into the country gave the need to conduct audit in the facilities both abroad and locally. For inspection abroad, only manufacturers with current WHO GMP certificate are eligible for inspection and registration as exporters of drugs to Nigeria. The local representative for the imported product are given some time to notify the manufacturers abroad before the inspectors embarks for the journey. Two or three trained inspectors are usually sent for GMP audits abroad or locally using a uniform detailed checklist. The inspectors' audit covers all aspects of manufacturing process, which includes: Environmental hygiene/sanitation, equipment, standard operating procedures (SOP), labeling and labeling materials, packaging and packaging materials, quality control laboratory, effluent management, local regulatory control permit, storage of finished products, raw materials, recall procedures, staff welfare, safety devices, WHO GMP certification or certification by regulatory authorities of other countries

SOP for drug registration:

The mode of drug product application for imported product for all intending importer must submit to NAFDAC the following documents:

- **Power of Attorney (POA)** that is notarized by notary in the country of manufacture, issued by the manufacturer of the product, signed chairman or president of the company stating the name of the product to be registered. This (POA) must also give the authority for the product to be registered with NAFDAC.
- **Certificate of Manufacture and free sale** which shall be authenticated by the Nigerian Embassy in the country of origin of the product, issued by a relevant health/regulatory body and it must indicate the name of the manufacturer and products to be registered.
- **Certificate of Pharmaceutical products (COPP)** which must be issued by the relevant health/regulatory body in the country of manufacture and authenticated by the Nigerian Embassy in the country of origin.
- **Certificate of Incorporation** of the importing company with the corporate Affairs Commission in Nigeria.
- **Certificate of Registration of Brand name** with the trademark registry in the Ministry of Commission in Nigeria.
- **Superintendent Pharmacists License to practice** issued by the pharmacists council of Nigeria.
- **Pharmaceutical premises license** issued also by the pharmacist council of Nigeria
- **Application letter for import permit** submitted by the company's local representative
- **Letter of invitation for factory inspection abroad** submitted by the company's representative stating the full location address of the manufacturer.

After the submission of all satisfactory required documents, an import permit is issued with a payment of =N=10,000 naira to allow importer bring in only the sample that will be required for analysis in the laboratory this will be accompanied with 5 copies of dossiers for laboratory evaluation and vetting. The product must conform to labeling requirements by carrying the following information: (1) Full name of the Manufacturer, (2) Full location address of the manufacturer (3) Product name (brand and generic name where applicable), (4) batch number, (5) direction for storage and use. Any drug product that bears a sound-alike name of an already

registered product or has close resemblance will not be considered for registration. In addition, all labeling must be in English and must be exact with the ones sold at the country of manufacture. Any failure in compliance may result in disqualification and delay in registration process. The costs for registration is process is =N=890,000. Product that complied with all requirements and passed the laboratory analysis will be considered for registration after which a license certificate of registration is issued with a payment if =N= 100,000. This certificate has a validity of five years in which the product can be imported and sold in the market, each registered product has a given NAFDAC number that belongs to that product alone, it differentiates a registered product from the non-registered ones, the product will be due for renewal after the expiry of five years. NAFDAC still reserve the right to revoke or withdraw any registration status within the validity period if any form of falsification is found (NAFDAC, 2007). If there is any suspicion in the documents submitted for registration, investigation and verification is carried out with the aid of Nigerian embassy located at the country of manufacture.

The mode of drug product application for local manufacturer intending to register and sell their products must submit to NAFDAC the following documents:

- **A Copy of the current annual license to practice** that is issued by pharmaceutical council of Nigeria (PCN).
- **Copy of current premises retention certificate** issued by PCN.
- Evidence that a **satisfactory inspection** of the dosage form line has been carried out by NAFDAC. This is important because it helps to ensure that the manufacturing premises are complying with GMP guidelines, it will also help in elimination of any confusion, mix ups, contaminants that may arise during the process.
- **Certificate of Analysis** carried out in other laboratory before submission to NAFDAC
- **Certificate of trade mark registration**
- **Two copies of dossier** on the product for registration

If the documentations are found satisfactory, the company will be required to organize pre-registration inspection where the inspectors reviews formulation of the drug products and further assessment of GMP to ensure consistency and compliance. The total tariff for registration of locally manufactured products is =N=70,000. This will be due for renewal in two years with 50% of total cost as the tariff charged (NAFDAC, 2007)