ASSESSMENT OF THE ACTIVITIES OF NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC) IN THE CONTROL OF FAKE DRUGS IN KADUNA STATE

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ZARIA, NIGERIA

DECEMBER, 2019

DECLARATION

I declare that the work in this dissertation entitled "Assessment of the activities of NAFDAC in the Control of Fake Drugs in Kaduna State" has been carried out by me in the Department of Public Administration. The information derived from the literature has been duly acknowledged in the text and a list of references provided. No part of this dissertation was previously presented for another degree or diploma at this or any other institution.

Kenneth Zheihnom KURASON _____ _____

Name of Student **Signature** **Date**

CERTIFICATION

This dissertation entitled ASSESSMENT OF THE ACTIVITIES OF NAFDAC IN THE CONTROL OF FAKE DRUGS IN KADUNA STATE by Kenneth Zheihnom KURASON meets the regulations governing the award of the degree of Master of Science in Public Administration of the Ahmadu Bello University, and is approved for its contribution to knowledge and literary presentation.

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DEDICATION

This dissertation is dedicated to God Almighty and to my Late Sister in the person of Bridget T. Kurason.

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ABSTRACT

The proliferation of drugs as a global cancer, has eaten deep into the healthof the general public. It is the greatest evil of our time and the highest weapon of terrorism against public health, as well as an act of economic sabotagethat has led to organ dysfunction, disabilities, worsening of disease condition, loss of public confidence in public health and led to the death of many in the globe and Nigeria is not an exception.Most of these drugs are brought into the state and not necessarily produced within Kaduna State threatening the health of the people in the state. It is for this reason that the Federal Government of Nigeria established NAFDACwith the goal of eliminating counterfeit pharmaceuticals, foods and beverages products ensuring that available medications are safe and effective. This necessitated the need to assess the activities of NAFDAC in the control of fake drugs in Kaduna State.The specific objectives of the study are to determine the effect of the contribution of inspection of imported regulated products by NAFDAC on the control of fake drugs in Kaduna State; to examine the contribution of registration of drugs by NAFDAC on the control of fake drugs in Kaduna Stateamongst others. The study adopted "Fishbein Model and Social Control Theory by Travis Hirschi'' as theoretical framework to underpin the study. The study adopted a survey design where data collected from structured questionnaires and interview were analyzed using both descriptive and inferential statistics. The total population of the study is 1, 664 with 313 as sample size. The study adopted purposive and simple stratified sampling technique for the study. The chi-square cross-tabulation test was used in testing hypotheses of the study using SSPS version 20.However, relevant documents that contain secondary data for the study are the NAFDAC's Act, NAFDAC's Score Cards, and NAFDAC's Campaigns, amongst others. The findings of the study shows that some of the factors affecting the

inspection of drugs in Kaduna State ranges from shortage of personnel or inspectors to monitor drug activities in Kaduna State due to large coverage size, shortage of scan machines to enable personnel detect fake drugs easily to even chaotic drug market in the state. Hence, the study recommends that the government should be willing to recruit new hands who are specialist in their various fields of endeavor having the technical-know-how to help NAFDAC in the execution of her activities and to ensure adequate coverage of the state in other to carry out routine checks, etc. Furthermore, the government should continue to empower NAFDAC to strengthen her efforts in the control of fake drugs in the state by acquiring modern machines to upgrade the central laboratory and promote manpower training and development. These, will go a long way to discouraging counterfeiters or fakers of drugs and reducing the quantum of existing fake drugs in the state.

CHAPTER ONE:

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ABBREVIATIONS

ADR -Adverse Drug Reaction

AFBTE -Association of Food, Beverages and Tobacco Employers

AFFCON -Association of Fast Foods and Confectionaries Operators of Nigeria

AIDS -Acquired Immune Deficiency Syndrome

DFID -Department for International Development

FDA -Food and Drug Administration

GDP -Good Distribution Practice

GMP -Good Manufacturing Practice

GSMF -Ghana Social Marketing Foundation

HIV -Human Immunodeficiency Virus

IMPACT -International Medical Products Anti-Counterfeiting Taskforce

INTERPOL- International Police

LGA -Local Government Area

MCC -Medicines Control Councils

NASSI -National Association of Small Scale Industrialists

NIPRD -National Institute for Pharmaceutical Research and Development

NMRA -National Medicines Regulatory Authority

OTC -Allowed to Sell Over the Counter

PCN -Pharmaceutical Council of Nigeria

PSI -Pharmaceutical Security Institute

PSN -Pharmaceutical Society of Nigeria

SOP -Standard Operating Procedure

TPB -Theory of Planned Behaviour

TRA -Theory of Reasoned Action

WHO -World Health Organization

CHAPTER ONE:

INTRODUCTION

1.1 Background to the Study

One of the greatest global threat is faking or counterfeiting of drugs as deliberately and fraudulently produced or mislabeled with respect to its identity or source. This has been a cancer, which has eaten deep into the marrows of societies affecting the state of health of people. The World Health Organization reported that nearly one-third of identified counterfeit drugs contain no active ingredients, while more than 20 percent either have incorrect quantities of active ingredients or contain the wrong ingredients. False packaging and high level of impurities are also commonly found (WHO, 2015). Waver and Whalen (2013), stated that 76 doctors in the United States unknowingly treated cancer patients with a fake version of the drug Avastin.

Pharmaceuticals are in high demand, and the punishment for fake pharmaceutical dealing is lower than for narcotics (Sean, 2017). It is no wonder the market for counterfeit pharmaceuticals continues to grow larger than many realize. For example, Interpol's flagship pharmaceutical investigation, Operation Pangea, reports it seized 2.4 million fake and illicit pills in 2011; in 2015, the total number of medications that officials seized jumped to 20.7 million.When hospitals and clinics experience a drug shortage, they often look outside of the regular supply chain, creating opportunities for criminals to push fake pharmaceuticals (Sean, 2017).

Drug faking is a public health problem whose effects can be felt from both the manufacturing and the recipient countries although higher in some countries than others causing death, disability and injury to its consumers (WHO, 2008). According to World Health Organization (WHO, 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. The production of counterfeit drugs is affecting poorer countries and is an important cause of unnecessary mortality and morbidity, loss of public confidence in medicines and health structures, (Segun Akinyadenu, 2013).

Drug counterfeiters target medicines that are used in high volume for managing diseases of public health interest such as antimalerials, antibiotics, antihypertensives, anti-diabetic agents and life style drugs (NAFDAC Score Card, 2016).

In a 2007 report on counterfeiting and piracy, the Organization for Economic Cooperation and Development (OECD) provided an interesting list with categories of products that are subject to counterfeiting, including pharmaceuticals. This list, without being exhaustive, included medicines used for treating cancer; HIV; malaria; osteoporosis; diabetes; hypertension; cholesterol; cardiovascular disease; obesity; infectious diseases; Alzheimer's disease; prostate disease; erectile dysfunction; asthma and fungal infections; antibiotics; anti- psychotic products; steroids; anti-inflammatory tablets; pain killers; cough medicines; hormones and vitamins; and treatments for hair and weight loss 14 . Literally all kinds of medicines have been or can be counterfeited. (Turin, 2012).

Counterfeit medicines pose a very significant challenge to both the economy and public health in Nigeria. In 2009, National Agency for Food and Drug Administration and Control (NAFDAC) officers intercepted a huge consignment of almost 700,000 doses of fake clones of a popular Indian anti-malarial labelled as made in India and on further investigation was found to be made in China.

The World's Medical Supply Chain (WMSC) is riddled with counterfeit or fake drugs (Sarah, 2015). In 2012, hundreds of cancer patients took what they thought was Avastin, a monoclonal antibody cancer treatment, only to learn that the drug they obtained lacked the active ingredients. The U.S. Food and Drug Administration (FDA) received reports of fake Botox in clinics all over the country(Sean, 2017).

In 2012, the Food and Drug Administration (FDA) warned physicians and medical practices that their supplies of bevaczumab, an expensive drug used in combination with chemotheraphy to inhibit tumor growth, might be tainted. It turns out some hospitals were literally giving cancer patients cornstarch instead of anticancer meds: The FDA found that some batches of the counterfeit bevaczumab contained no active pharmaceutical ingredients at all.

Before the counterfeit bevacizumab arrived in the United States, investigators found, it traveled through Turkey, Switzerland, Denmark, U.K., and Canada. This global problem of counterfeit or fake drugs affects even legitimate sources, such as hospitals and pharmacies (Susan, 2015).

Counterfeit drugs in Nigeria include preparations without active ingredients, toxic preparations, expired drugs that are relabeled, drugs issued without complete manufacturing information and drugs that are unregistered with NAFDAC. Current estimate suggests that 10% of prescription drugs sold worldwide are counterfeits, fake or contaminated, and in parts of Africa and Asia, the figures exceed 50% (Newton et al., 2001; Cockburn, 2002).

Counterfeit pharmaceuticals remain one of the world's fastest growing industries. Recent trends suggest an increase in counterfeit drug sale to over $70 billion in 2010, an

increase of over 90% from 2005 (Finlay, 2011). A report by Pfizer, a global pharmaceutical firm, on counterfeit drugs states that profits from counterfeiting today surpasses gains made from heroin and cocaine (PGS, 2007). While the issue of counterfeit drugs has long been treated as an illicit case of intellectual property infringement, the view has often masked what is in fact a public health crisis.

In 1989, over 150 children died in Nigeria as a result of paracetamol syrup containing diethlene glycol (Gbenenee, 2016). It was so severe that neighboring countries like Ghana and Sierra Leone officially banned the sale of drugs, foods and beverages products made in Nigeria.

In an attempt to control fake drugs in Nigeria, the food and drug Act was enacted in 1974 in the form of decree which was later renamed an Act with virtually the same provisions by the civilian administrations 1979 –1983. This Act provides a large measure of protection to consumers of drug and food products. It is made up of three main parts: The first section deals with the prohibition of sale of certain food and drug items, the second forbid the sale and advertising of certain drugs as treatment for disease and the last section forbids the importation and the last section forbids the importation, exportation and distribution of some specific food and drug items.

Therefore, NAFDAC was established with the goal of eliminating counterfeit pharmaceuticals, foods and beverages products that are not manufactured in Nigeria and ensuring that available medications are safe and effective. The formation of NAFDAC was also inspired by 1986 World Health Assembly resolution requesting countries' help in combating the global health threat posed by fake or counterfeit pharmaceuticals. Thus, the mandate of NAFDAC, as established by Decree No. 15 of 1993 (as amended), is to control and regulate the manufacture, importation, exportation, distribution,

advertisement, sale and use of food, drugs, cosmetics, medical devices and packaged water including all drinks (referred to as regulated products).

In December 1992, NAFDACS's first governing council was formed as chaired by Tanimu Saulawa. In January 1993, supporting legislation was approved as legislative Decree No. 15 of 1993 and officially established on 1, January 1994 as a parastatal of the Federal Ministry of Health though replaced an earlier Federal Ministry of Health body, the Directorate of Food and Drug Administration and Control which had been deemed ineffective, partially because of lack of laws concerning fake drugs in Nigeria (NAFDAC, 2005).

The total number of impounded fake drugs in Nigeria in 2013 is worth over 886, 000, 000 million naira, 120, 000, 000 million naira worth of impounded fake drugs in 2014 and 484, 200. 420 million naira worth of impounded fake drugs in 2015 (Food and Drug Administration and Control Statistics, 2015). This means that, there is a slight increase of these fake or counterfeit drugs in the country.

According to studies conducted by NAFDAC from 2001-2012, there is a positive trend which shows a progressive decrease in the incidence of counterfeit medicines in Nigeria. This study (NAFDAC/WHO/DFID) shows that, in 2001, counterfeit stood at 40% as against 16.7% in 2005. National Survey on Quality of Medicines using Truscan shows that, counterfeits stood at 6.4% in 2012. Therefore, the need to studying the activities of NAFDAC in the control of fake drugs after the first administrative era in NAFDAC becomes necessary.

1.2 Statement of the Research Problem

The production of counterfeit drugs has and is still affecting states across Nigeria and Kaduna state is one among these states. Counterfeit drug is an important cause of unnecessary mortality and morbidity, loss of public confidence in medicines and health structures, (Akinyadenu, 2013). A disturbing aspect of the counterfeit drug menace is that the effects of consuming such drugs go unnoticed most of the times except in such cases where it results in mass deaths (Erhun, 2001).

In 1947 in Nigeria, 14 children were reported dead after being administered chloroquine phosphate injections and in 1990, 109 children died after being administered fake paracetamol syrup containing diethylene glycol (Aluko, 1994). Some people still prefer self-medication when they are ill and often times, the drugs are bought from unlicensed drug vendors, whose drug quality is not sure.

Olike (2008), stated that the government have failed as there is political setbacks in ensuring compliance with standard specification, giving adequate penal sanctions to offenders as stipulated in the drug laws. The WHO (2007) stated that, the prevalence of these fake drug is higher in countries with weak legislations and enforcement of standards as specified by the law. This has given rise to manufacturers producing drugs with insufficient active ingredients to continue to exist abusing the existing laws guiding the production of drugs.

NAFDAC ensures that drugs are registered before licenced for sale. This time for registration of drugs sometimes varies especially for drugs whose substances are relatively poor and thisslows down registration process of drugs because of the need to further inspect manufacturers of such drugs. Because of the strict evaluation and assessment process of drugs, makes producers of drugs with inactive or insufficient active ingredients not want to pass through the registration process as their drugs will be

faulted by NAFDAC. Furthermore, if a small Drug Regulatory Authority (DRA) is registering large number of generic products rapidly, the quality of the evaluation and assessment of the product may well be compromised (Hill and Johnson, 2004).

Measures have been taken to reduce the presence of fake drugs in the country such as restricting pharmaceutical imports to just two airports and two seaports, each staffed by NAFDAC officials. NAFDAC discovered several Indian and Chinese drug manufacturers suspected of producing and exporting fake drugs in Nigeria and banned the import of those products (Akunyili, 2005).

NAFDAC also established independent contacts with authorities in the two countries to regulate their exports to Nigeria. The rigorous work that has been undertaken since 2001, including meticulous borders controls; drafting of prohibition lists regarding substances' import; accompanying certification documents for imported drugs; raids to assess the quality of the medicines produced and distributed; and the boost of the national pharmaceutical industry, are strategies put in place by NAFDAC to control the proliferation of fake drugs in Nigeria. Furthermore, all medicines produced and circulated within the country started carrying a registration number to check their authenticity. NAFDAC began to wield controls to domestic pharmaceutical producers in order to make them comply with good manufacturing practices and to ensure the respect of national rules and directives. (United States Pharmacopeia, 2011).

NAFDAC have adopted other strategies to control fake drugs in Kaduna state and Nigeria and some of these strategies ranges from licensing of premises and persons, inspection of manufacturers and distributors, product registration and assessment, public awareness, etc. Also, an important short-term strategy for fighting counterfeit drugs is the development of better technologies for protecting the identity of genuine drugs such

as use of Truscan, Mobile Authentication Service (MAS), etc (Inventa International, 2017).

In 2004, three Nigerian hospitals reported cases of adverse reactions from the use of contaminated infusions produced by four Nigerian companies. Consequently, infusions and water for injection from all over the country was sampled. The results confirmed that some batches of infusions produced by the indicted companies were heavily contaminated with microorganisms. 147 of the 149 brands of water for injection screened were also not sterile (Dora Akunyili, 2005).

Counterfeit products, (drugs, food, cosmetics, medical devices, chemicals, and water including all drinks but mostly pharmaceuticals) valued at over N8.0b (US$60 million) were seized and destroyed in Nigeria by the National Agency for Food and Drug Administration and Control (NAFDAC) between April 2001 and December 2004.Also, counterfeit or fake drugs valued at over N29 billion were seized in 3 years (Frost and Sullivan, 2012) and N12 billion worth of fake drugs in 2016.These problems though dwindled especially during the period of service of prof. Mrs. Dora (Late), and studies as conducted by NAFDAC from 2001-1012, shows that in 2001, counterfeit stood at 40%as against 16.7% in 2005. Also, using Truscan shows that counterfeits stood at 6.4%in 2012 (NSQM Survey, 2012) but yet, has not solved the problem of fake or counterfeit drugs across the states.

The drug distribution network in Kaduna State, is in a state of chaos because it consists of open markets, patent medicine stores, community pharmacies, private and public hospitals, wholesalers/importers and pharmaceutical manufacturers. It is a common scene in Nigeria, to see petty traders who sell kola nuts, cigarettes, and oranges, among other items, in market kiosks, motor parks, and road sides hawking drugs that range from

over-the-counter items to antibiotics popularly called “capsules” (Adelusi and Adeluyi, 2000). This is a typical reflection of what is happening in Kaduna state today posing a threat to public health in the state. The medicines are usually left under the sun in such conditions that could facilitate the deterioration of the active ingredients while other are fake which are even more harmful to human health.

The activities of local factories in Nigeria have been controlled by NAFDAC besides being inspected at the time of product registration. Despite the fact that NAFDAC carry out inspections once in three months without prior notice, the proliferation of drugs still becomes eminent. These inspections carried out are to ensure that they are consistent with current GMP and have not deviated from the conditions under which the product was registered.It is also important to note that products from factories with poor GMP are not allowed into the country. However, the effectiveness of these inspection activities being carried out by NAFDAC remains a big question (Pharmapproach, 2019).

In Kaduna state, there are a lot of drug centres known as “Chemist’s” other than Community pharmacies who are statutorily registered with the Pharmacists Council of Nigeria. With these community pharmacies, there should not be any serious problem of the sale of fake drugs but unfortunately, there are many unregistered “pharmacies” thriving. And in such premises drugs are purchased from doubtful sources with its attendant danger to the health of the public (Erhun and Adeola, 1995).

Recently, it was recorded that NAFDAC seizes N10 million worth of fake drugs in Kaduna state (Vanguard, 2016). It also, nabbed fake drugs manufacturer in Kaduna state (www.africaprimenews.com/2016). Also, a man was arraigned over fake drugs and was charged to court for selling fake drugs in his shop in Zaria, Kaduna state (sundiatapost.com/2016).

Therefore, all these problems mentioned, shows that efforts have been made by NAFDAC and empirical data shows that the problem of faking or counterfeiting of drugs is far from being addressed, fallen short of expectations as fake drugs are still being manufactured and sold to Nigerians.

It is however against this background that the researcher assess the activities of NAFDAC in the control of fake drugs in Kaduna State so as to ascertain the extent, control and success or otherwise to the NAFDAC operation in Kaduna State.

1.3 Research Questions

The following research questions are asked to guide this research study:

i. How has standard specification by NAFDAC affected the control of fake drugs in Kaduna State?
ii. How has the process of registration of drugs by NAFDAC affected the control of fake drugs in Kaduna State?
iii. How has the inspection of imported regulated products by NAFDAC affected the control of fake drugs in Kaduna State?

1.4 Objectives of the Study

The broad objective of this study is to access the activities of NAFDAC in the control of fake drugs in Kaduna state. The specific objectives of the study are to:

i. Examine the contribution of standard specification on the control of fake drugs in Kaduna State.
ii. Examine the contribution of registration of drugs by NAFDAC on the control of fake drugs in Kaduna State.

iii. Determine the effect of the contribution of inspection of imported regulated products by NAFDAC on the control of fake drugs in Kaduna State.

1.5 Research Hypotheses

The hypotheses to be tested in this study are:

Ho_1: There is no significant effect onstandard specification on the control of fake drugs in Kaduna State.

Ho_2: There is no significant effect of the registration of drugs on the control of fake or counterfeit drugs by NAFDAC in Kaduna State.

Ho_3: There is no significant effectof the inspection of imported regulated products on the control of fake drugs by NAFDAC in Kaduna State.

1.6 Significance of the Study

The increasing rate of counterfeit or fake drugs pose an unequivocal threat to the public health of Nigerians and in Kaduna State requires corrective effort and the required effort or solution to curb this menace. The result of this increased rate of fake drugs has led to organ dysfunction or damage, worsening of chronic disease conditions and the death of many Nigerians through the consumption of these fake drugs. The situation became so bad that even when patients are later treated with genuine drugs, there is no response due to resistance caused by previous intake of fake drugs. (Akunyili, 2005).

Various researcherssuch as Akinyandenu (2013), Olike (2008), Erhun (2001), Aiwanehi et al (2015), UNICRI (2012), and etceterahave written on counterfeit drugs and the activities of NAFDAC in the control of fake drugs but are not without limitations. Hence, this study will cover the lapses and limitation of other studies. Akinyandenu

(2013), conducted a study on ‘‘Counterfeit drugs in Nigeria: A threat to public health’’ but did not look at the activities of NAFDAC especially as it relates to standard specification to the control of fake drugs. However, this study studies the contribution of NAFDAC as it relates to standard specification in the control of fake drugs in Kaduna state.

Olike (2008), conducted a study on the “the fight against fake drugs by NAFDAC in Nigeria’’ but did not review the laws and strategies adopted by NAFDAC in the control of fake or counterfeit drugs. However, this study reviews the activities and strategies adopted by NAFDAC to control fake or counterfeit drugs in Kaduna State.

The UNICRI (2012) looked at counterfeit drugs from a global perspective, as well as the implication of organized crimes in drugs counterfeiting without necessarily studying the activities of regulatory agencies in the control of this fake or counterfeit drugs. However, this study narrows its scope to NAFDAC as a regulatory agency focusing on her activities in Kaduna State.

This study (Assessment of the Activities of NAFDAC in the Control of Fake Drugs in Kaduna State) will reveal to the entire state (citizens, government and non-governmental organizations alike), the strength and weaknesses of NAFDAC, identify the effect of access to quality drugs by the public on the control of fake drugs with focus on Kaduna state and review the activities and strategies adopted by NAFDAC to control fake or counterfeit drugs in Kaduna State.

Therefore, filling these gaps will contribute immensely to the existing body of knowledge within the field of administration and enrich the existing policy, for

effectiveness in government. Also, the result of this investigation would be instructive to other regulatory bodies not just in Kaduna State, but in Nigeria as a whole.

1.7 Scope and Limitations of the Study

This research has emphasized on the Activities of NAFDAC in the control of fake or counterfeit drugs in Kaduna State. NAFDAC Kaduna was selected in the area of her activities of drug control because, it is vital to the state of human health and development; affect the lives of all members of any given society not just in Kaduna State, but Nigeria at large. As such, the choice of this area of human health and development facilitated the researcher's ability to get detail information and generated valuable data for the study.

The study covered a period of five years, 2006-2016. This is due to the fact that with the return of a new management team after the leadership of Dora Akunyili as Director-General, various strategies in relation to NAFDAC's activities, have been adopted to control fake or counterfeit drugs not just in Kaduna State. Hence, how well and effective these strategies are in relationship to the control of fake drugs in Kaduna State informed the choice of this period.Also, it is important to note that, counterfeit pharmaceuticals remain one of the world's fastest growing industries. Recent trends suggest an increase in counterfeit drug sale to over $70 billion in 2010, an increase of over 90% from 2005 (Finlay, 2011). A report by Pfizer, a global pharmaceutical firm, on counterfeit drugs states that profits from counterfeiting today surpasses gains made from heroin and cocaine (PGS, 2007). Therefore, how fast and wide the increase in counterfeit drug sale in Kaduna State informed the choice of this period.

The study purposely chose three (3) Local Governments i.e. Kaduna South, Chikun and Zaria Local Government Areas because, the faking or counterfeiting of drugs is an urban

problem since those in the rural areas believes more in herbs than drugs that are produced by pharmacists.

One of the major limitations of this study has to do with the unwillingness of both staff of NAFDAC, pharmacists and medical personnels to release documents necessary for the success of this study as reviewed. They acknowledged that this is a research; however, some information cannot be released due to their sensitive nature, tagged "classified documents" to the organizations. Similarly, some staff interviewed were nearly restrictive in giving out detailed responses on important issues raised for fear of retribution.

Against all odds, the study was able to collect relevant documents though not all as requested for; convinced interviewed respondents to release vital information, persistently visit NAFDAC, Hospitals and Pharmaceutical Centers with huge financial and health implications.

1.8 Definition of Key Concepts

i. **Fake or Counterfeit Drugs-** For the sake of this study, fake or counterfeit drugs refers to drugs with the correct ingredients but not registered or the wrong ingredients, drugs with insufficient or no active ingredients, drugs with fake packaging, drugs with active ingredients different from what is stated on the package, expired drugs relabeled with the purpose to extend the shelf-life, drugs without the name and address of the manufacturer, drugs with no expiry date and drugs which do not contain any of the specified active ingredients despite what is written on the label.

ii. **Standard Specification-** these are laws guiding the production of drugs by drug producers or manufacturers.

iii. **Product Registration**- For the purpose of this study, the product registration is where marketing authorization/certificate and product licensing are issued to pharmaceuticals that meet minimum standards of efficacy, safety and quality. 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.

iv. **Inspection of Drug Products**- For the purpose of this study, inspection of drug products refer to NAFDAC efforts in the routine check of local and imported drug products from both the producers and drug sellers in the state.

v. **Advertisement of drugs-** For the purpose of this study,advertisement of drugs has to do with the efforts of NAFDAC to enlighten or educate the general public on the need and how to identify and buy only drug products that are registered with her through electronic media, print and non-print media, religious organisations and physical presence at campaigns held at grass-root levels, etc.

vi. **Control of Fake Drugs**- In this study,control of fake drugs refers to the arrest, prosecution of fake or counterfeit drug sellers, influencing people's behavior towards the purchase and sale of drugs as well as the regulation, confiscation and prohibition of the use of certain drugs in Kaduna State.

CHAPTER TWO:
LITERATURE REVIEW AND THEORETICAL FRAMEWORK

2.1 Introduction

Drugs control is a very important role played by NAFDAC in Nigeria today because it occupies a central place in the place of human health and development. To have an in-depth understanding of issues under review, we will be reviewing literatures on fake or counterfeit drugs, the activities of NAFDAC in the control of fake drugs such as the control of fake drugs, licensing of premise and persons, inspection of manufacturers and distribution, product registration and assessment, public awareness as well as access to quality drugs.

2.2.1 Control and Regulation of Fake Drugs

The loose control system in the Nigerian economy has contributed to the circulation of fake and counterfeit drugs in the country. A major function of NAFDAC is the regulation and control of imported products. These lose control systems are exploited by counterfeiters to manufacture, import and distribute fake and adulterated products. There is therefore a need for the control of these fake drugs by NAFDAC in an attempt to build a drug free society so as to enhance public confidence in the purchase of drugs. NAFDAC have adopted a lot of measures such as cutting-edge technologies, Global Pharma Health Fund (GPHF), black eye, Mobile Authentication Service (MAS) amongst others to control the rate of fake drugs in the country (NAFDAC SCORECARD, 2016).

Various laws regulate and control the manufacture, sale and distribution of drugs in Nigeria. Sadly, empirical data shows that the situation is far from adequate (Erhun et al., 2001). The weakest point in Nigeria's drug regulation or control is in the area of implementation and enforcement. Some Nigerian drug laws conflict each other resulting in a legal framework that deter offenders, thus making it difficult to try offenders. This encourages drug counterfeiters to continue with their criminal acts. A review of the law is therefore essential to help ensure stability in the legislation and regulations guarding drug laws in Nigeria.

Drug 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).

Government intervention to prevent the sale and use of fake and illicit drugs as a tool to promoting public health in the country becomes imperative. Thus, preventing the sale of

drugs not produce under the terms and conditions of NAFDAC'S regulation. This is aimed at protecting the populace from harm due to unwholesome drug consumption.

In other to promote the control of drugs, NAFDAC ensures and oversees Good Manufacturing Practice (GMP). Good Manufacturing Practice denotes applying methods used in the production of regulated products for public use or consumption to greatly minimize human errors, avoid contamination, and ensure consistency and healthy living. GMP varies in contents and dimensions with products and the contexts, but the aim is the same in all cases – effective, consistent and safe products that guarantee sound and robust public health. Sequel to this, and in exercise of its mandate as provided in Section 5(s) of its enabling Decree No. 15 of 1993, NAFDAC as unfit for human consumption declares all products or brands found not to be consistent with this aim, and confiscates and destroys them as well.

It is essential to point out that engaging in exchange involving products such as fake drugs which have not obtained NAFDAC's registration seal of approval is unlawful and constitute a threat to public health, and attracts heavy penalties. All products found not registered with NAFDAC are seized, forfeited and dealt with in such a manner as the Honorable Minister of Health may determine (www.http/nafdacnigeria.org.com). The essence of establishing NAFDAC is to guide consumers in their purchase decision to patronize only brands with NAFDAC's approval number on their labels.

Hence, with the establishment of NAFDAC, it is apparently imperative and binding that every product brand that is covered under this law, is registered with NAFDAC, as a reflection of government's effort to safeguard the health of the generality of consumers in Nigeria. To ensure compliance NAFDAC carries out a number of regulatory activities,

some of which are but not limited to product registration, consultation with stakeholders, and public enlightenment campaigns.

Drug regulation is the totality of all measures which governments take to ensure the safety, efficacy and quality of drugs, as well as the relevance and accuracy of product information (Ratanawijitrasin, et al, 2002: 7-8). The success or failure of drug regulation however depends on implementation. The regulation of medical drugs has four dimensions, viz, administrative elements, regulatory functions, technical elements and level of regulation (Ratanawijitrasin, et al, 2002:12). The administrative components are the input factors that allow for functioning of drug regulation, including policy, legislation /regulation, organizational structures, human and financial resources and mechanism for planning, monitoring and evaluation. The regulatory functions include licensing of persons, premises, inspections of pharmaceutical establishment (market authorization), quality control, control of drug promotion/advertisement, monitoring of adverse drug reaction (ADR) and speedy redress of consumer complaints through negotiations, mediation and conciliation. The technical elements include the existence and type of standards, norms, guidelines, specifications and procedures. The level of regulation indicates level at which the various regulatory functions are performed. It should be noted that the political structure of any country determines the overall governance of drug regulation.

2.2.2 Standard Specifications, Regulations and Guidelines

These are laws guiding the production of drugs by drug producers or manufacturers. It is important to note that there are various laws that regulate and control the manufacture, sale, and distribution of drugs in Nigeria. They include:

(i) **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.

(ii) **Food and Drugs Act Cap 150 of 1990**. This Act prohibits the sale of certain foods, drugs cosmetics and devices as treatment for certain diseases. The Act prohibits the importation, exportation, distribution and sale of specified drugs. It also prohibits practices such as misleading packaging, labeling, and advertising, as well as manufacturing food and drugs in unsanitary conditions. It conveys the power to appoint inspecting officers and food and drug analysts.

(iii) **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. It also prohibits persons to sell any drug in an open market without permission from the proper authority.

(iv) **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 becomeregistered 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.

(v) **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, 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 operates within NAFDAC (NAFDAC, 2008).

(vi) **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 therein.

It is therefore important to note that, the aforementioned laws show that the government has positively responded by legislation to forestall a chaotic drug distribution situation in Nigeria. But empirical data has shown that the situation is far from adequate (Erhun, 2001).

2.2.3 Product Registration

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. NAFDAC issue guidelines to approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals. This is one of the activity of NAFDAC in the control of these fake or counterfeit drugs by employing a structured and systematic procedure for product registration at the end of which the product is assigned a NAFDAC Registration Number which is an attestation to the safety, quality and appropriateness of its intended use (NAFDAC, 2013). This is carried out by the Directorate of Registration and Regulatory which is a licencing arm of NAFDAC.

Registration 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).

NAFDAC uses product registration to establish and monitor the ownership and/or distributorship of the products it regulates, generally known as regulated products (i.e. food, drug, cosmetics, medical devices, chemicals, detergents and packaged water); their safety; quality; labelling; claims etc. NAFDAC employs a structured and systematic procedure for product registration at the end of which the product is assigned a NAFDAC Registration Number which is an attestation to the safety, quality and appropriateness for its intended use. The registration process involves:

i. **Documentation:** Documents are required such as Power of Attorney from the manufacturer authorizing an applicant to speak for his principal on all matters relating to the latter's specialties; Certificate of Manufacture and Free Sale which is an evidence that the product is manufactured and freely sold in the country of origin; Certificate of Incorporation of the representative company in Nigeria; Evidence of Trade Mark registration; Comprehensive Certificate of Analysis of the batch of product to be registered. The permit to import samples for registration purposes is issued if documentation is satisfactory.

ii. **Labelling:** Labels should be informative, clear and accurate; indicate the name of product; name and address of the manufacturer, packer, distributor, importer, exporter, or vendor; make provision for NAFDAC Registration Number; batch number, manufacturing date and expiry or best before date; net content, ingredients list in metric weight in case of solids, semi solids and aerosols and metric volume in case of liquids.

iii. **Inspection:** Good Manufacturing Practice (GMP) inspection of the production facility is carried out prior to registration of the product.

iv. **Product Approval Committee Meetings:** A three (3) tier product approval meeting is held to consider the documentation, laboratory reports, GMP inspection reports, product labels etc. of a product prior to its registration.

Once a product is satisfactory, it is assigned a NAFDAC Registration Numbers and can be freely sold or marketed within the country. Thus, the Directorate collects samples of the products to be registered from company representative and forward to appropriate unite the Registration and Regulatory for further action while sample will be sent to laboratories for analysis. When all the report are obtained from the various units with their recommendation, Registration and Regulatory would make appropriate recommendation to the product Approval committee (NAFDAC, 2013).

It is important to note that, the total number of drugs registered by NAFDAC in 2013 is 2, 906 out of which 2, 336 are imported and 570 are local drugs. In 2014, the total number of drugs registered by NAFDAC is 2, 325 out of which 2, 768 are imported and 557 are local drugs. In 2015, the total number of drugs registered by NAFDAC is 2, 789 out of which 2, 291 are imported and 498 are local drugs (Bureau of Statistics, 2016).

2.2.4 Inspection of Imported Regulated Products

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 Good Manufacturing Practice (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.

Based on the Standard Operating Procedure (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), labelling and labelling 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

For GMP and routine inspection, NAFDAC adopts the WHO guidelines for inspection visits but does not carry out 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).

2.2.5 Fake/Counterfeit Drugs

Despite the global nature of fake/counterfeit drugs, the International Community does not have a harmonized definition of fake/counterfeit drugs to reflect its global nature and capture fake/counterfeit drugs to reflect its global nature and capture its entire essence.

There are different definitions by different countries according to their perception of the problem. However, the WHO defines a counterfeit medicine as "one, which is deliberately and fraudulently mislabeled with respect to identity with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and may include products with the correct ingredients or with the wrong ingredients, without active ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake ingredients, with insufficient active ingredients or with fake packaging".

In Nigeria, NAFDAC has identified various forms of fake/counterfeit drugs, which include: Drugs with no active ingredient(s); Drugs with insufficient active ingredients; Drugs with active ingredient(s) different from what is stated on the packages; Clones of fast moving drugs -these are drugs with the same quantity of active ingredients as the

genuine original brand; Drugs without full name and address of the manufacturer; Herbal Preparations that are toxic, harmful, ineffective or mixed with orthodox medicine; Expired drugs or drugs without expiry date, or expired and re- labelled with the intention of extending their shelf - life; Drugs not certified and registered by NAFDAC.

In most developing countries, "prevalence" of 10-25% of the drugs 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).

Counterfeiting of medicines is the greatest evil of our time and the highest weapon of terrorism against public health, as well as an act of economic sabotage. It is an ill wind that blows nobody good. (Dora Akuyinli, 2005).

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).

In Kaduna state and Nigeria today, there is an influx into the market of fake drugs, fake chemicals, fake and adulterated food items, amongst many others which makes it appear that almost every existing product has a fake counterpart. The era 1985-2000 in Nigeria has heralded the regime of faking and quackery, of counterfeit drugs, illegal chemist shops and hospitals and drugs are no exception (Ohuabunwa, 2002). The menace of fake drugs became prevalent in the last decade and the present situation is alarming in the West African sub-region, including Nigeria. Empirical observations have shown that there may be more fake than genuine drugs in circulation (Osibo, 1998).

The evil of fake drugs is worse than the combined scourge of malaria, HIV/AIDS and armed robbery put together. This is because malaria can be prevented, HIV/AIDS can be avoided and armed robbery may kill a few at a time, but counterfeit/fake drugs kill in mass.

The social problem posed by hard drugs, cocaine, heroin etc. cannot also be compared with the damage done by fake drugs, because illicit drugs are taken out of choice, and by those that can afford them, but fake drugs are taken by all and anybody can be a victim.

Fake drugs have embarrassed our healthcare providers and eroded the confidence of the public on our healthcare delivery system. This development has led to treatment failures, organ dysfunction/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 antibiotics, they no longer respond positively due to resistance induced by previous intake of fake/counterfeit antibiotics.

Most of our local pharmaceutical industries that are producing genuine drugs, employing labor and boosting our economy, could not break even because of unfair competition with drug fakers, who are only paying for packaging and probably freighting without spending on active ingredients, which are the most expensive components of any drug.

In 2009, the World Health Organization (WHO) defined 'substandard' drugs (also called 'out of specification products') as 'genuine medicines produced by manufacturers authorized by the NMRA [national medicines regulatory authority] which do not meet quality specifications set for them by national standards' (WHO, 2009). A new definition was proposed by the WHO in May 2010 (UNODC, 2010): 'Each pharmaceutical product that a manufacturer produces has to comply with quality standards and specifications at release and throughout the product shelf-life required by the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable NMRA before the product is authorized for marketing. Substandard medicines are pharmaceutical products that do not meet their quality standards and specifications.'

A fake drug or counterfeit medication is any substance that is packaged or marketed in a deceptive manner. In most cases though, it involves tablets, capsules and liquids that look like the real drug or packaged to mimic the genuine item.

Drugs with no active ingredients or containing other chemicals that have no therapeutic value or relevance for the condition that is being treated may accelerate the progression of the disease. With serious conditions, this can prove fatal. It can also complicate the condition which legal pharmaceutical drugs cannot treat afterwards – for example, bacterial drug resistance by using counterfeit antibiotics.

Fake drugs have 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).

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 Olike, 2008). There are big drug manufacturing companies such as Swiss Pharma, Pfizer, Novatis etc whose drug products have been faked by unscrupulous people (Akunyili, 2005). Branding drug products is done by manufacturers to promote profits and loyalty. Though a global risk can exists 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).

Therefore from the aforementioned, one can say that, Counterfeit drugs with toxic substances can cause serious side effects or result in poisoning which may be detrimental to human health and development or even fatal. Note in this studies that the terms ‘medicine’, ‘medications’ and ‘drugs’ are used interchangeably in this studies.

Note that, NAFDAC employ some measures to educate and detect fake drugs and are as follows:

TRUSCAN Machine

Technology like the TRUSCAN machine, for example, have been deployed by the agency at the ports and entry points of the nation to carry out on the-spot-check of drugs before they are cleared into the country. The Agency's officers have also gone to the 36 states of the federation and the FCT with the TRUSCAN machine, paying unscheduled visits to medicine outlets to fish out counterfeit drugs and destroy them. NAFDAC, as the first medicine regulatory agency in the world ever to deploy the technology and its effectiveness in curbing the menace of fake drugs has not only drawn the attention of international medicine regulatory agencies, but has also made the agency's leadership the toast of the moment among foreign governments and in the industry(Durojaiye, 2012).

Mobile Authentication System (MAS)

Other technologies deployed by the agency to fight counterfeiters are the text messaging system (Mobile Authentication System) that puts the power of drug detection into the hands of the consumers who can send a direct message using the code on the drug they are about to purchase to verify whether it is genuine or fake. There are also other additional technologies like the black eye and the Radio Frequency System technology introduced by the agency to help in the detection of fake drugs.

WHO-Pre-qualification

Another strategy introduced by NAFDAC is the WHO-Pre-qualification pursued by the agency for Nigerian pharmaceutical companies. This is a paradigm shift introduced by Dr. Orhii who felt that it is just not enough condemning China and India for the importation of fake drugs into the country, but for national security reasons also, Nigeria must increase its self-sufficiency in the availability of drugs. This new approach signals NAFDAC's shift from just merely acting the policeman, to an agency that is a catalyst for national development. NAFDAC hopes through the granting of WHO-Pre-qualification to Nigerian pharmaceutical companies to increase the acceptability of Nigerian drug exports abroad so as to increase their revenue generating capacity and provide prospects for the employment of researchers, laboratory technologists etc. by the industry to drive the development of the industry at home. So far, WHO has visited Nigeria three times and six pharmaceutical companies have the prospects of getting WHO-Pre-qualification for some of their products (Durojaiye, 2012).

To further increase the chances of as many pharmaceutical companies as possible to meet the requirement of WHO for Prequalification, NAFDAC has been at the forefront of pushing for a 200 billion naira intervention fund for the pharmaceutical industry that would enable the industry to put in place all the needed infrastructure that would help them meet the best global standards. All these are further predicated on the need to enable Nigerian pharmaceutical companies to meet local demands for quality drugs which in the long run will help to effectively eradicate counterfeit drugs imported into the country.

Public Enlightenment and Awareness

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.

NAFDAC organizes public enlightenment campaigns on topical and emerging issues using the electronic media, print media, and physical presence at campaigns held at grass-root levels where the rural dwellers are invited with the cooperation and involvement of their local chiefs to inform and educate the populace. Television and radio are NAFDAC enlightenment media which NAFDAC uses. Churches are also used by NAFDAC to disseminate important safety information. Hence, public enlightenment campaigns are used in educating the public on the need and how to identify, and buy only products that are registered with NAFDAC. The Agency also uses television advertisements and radio jingles to inform and educate the public.

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. (Olike, 2008). 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.

Advertisement is one other medium of public enlightenment. Advertisement of drugs has to do with the efforts of NAFDAC to enlighten or educate the general public on the need and how to identify and buy only drug products that are registered with her through electronic media (such as the use of television advertisement, radio jingles, etc.), print and non-print media (such as T- Shirts, banners, sign boards, etc.), religious organisations and physical presence at campaigns held at grass-root levels, etc.

In the past NAFDAC spent all its energy as well as its meager resources in prosecuting hundreds of cases, which time without number turned out to be endless and frustrating. The Agency decided to effectively embark on massive enlightenment campaign, dialogue, education and persuasion in their regulatory activities because this strategy addresses the fundamental issues at stake, which is behavioural change. This method is meant to involve the public and all stakeholders in this business of safeguarding public health by ensuring provision of quality products. Enlightenment and the resultant voluntary change of heart are result-oriented and complementary to confrontation and prosecution which the Agency had used over the years with little or no results. It is gratifying to note that this strategy has yielded tremendous results. This is why it was possible for the Agency to destroy over four Billion Naira worth of drugs all over the country by February 2003. It is interesting to know that most of these drugs were voluntarily handed over by repentant traders, and a good quantity recovered on tip off by traders themselves, because it is only these traders that know these fake drug importers and their secret warehouses. NAFDAC Task Force and the general public also played a very big role(Akunyili, 2004: 9).

2.3 Review of Empirical Studies

Many researchers have carried out empirical studies on the control of fake drugs by NAFDAC. However, majority of these researchers had one lapse or the other in their studies.

Erhun, (2001) undertook a studies on "Drug Regulation and Control in Nigeria", to establish the factors that have contributed to the preponderance of counterfeit drugs in Nigeria despite the laws. Data was gathered by a combination of the use of questionnaires and oral interviews. The results suggest that drug laws were adequate falling short only in their implementation. The task forces were rated as ineffective arising from corruption, communication gaps, lack of adequate funds, lack of vehicles, etc. Unfortunately, this studies confined itself to a wider coverage as there might not be the same factors contributing to the preponderance of fake or counterfeit drugs in various states of the country unique to its enabling environment. So therefore, this study tries to discover the factors unique to Kaduna State responsible for the proliferation and availability of fake drugs in the state.

Olike, (2007) undertook a studies on "The fight against fake drugs by NAFDAC in Nigeria" to review the work of NAFDAC in the efforts made in controlling the circulation of fake drug products in an attempt 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. According to her, 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. The study finds out that, the inability to close the unmonitored, unlicensed, unregulated chaotic open drug market that forms major drug distribution center 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. 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. Having found out that there is political setback in giving adequate penal sanctions to offenders as stipulated in the drug law, the studies has not been able to proffer a solution on how to solve this problem of government interference in the implementation of the drug law. Therefore, this study intend to fill this gap by not just discovering the problem, but proffering a solution to this problem in concern.

Aiwanehi et al, (2015) also undertook a study on "The Efficiency of Government Regulatory Agencies in Nigeria," a Case of the National Agency for Food and Drugs Administration and Control as to examines business, government and society interrelationships. It eventually narrowed down to assessing the efficiency of government regulatory agencies, in fulfilling the role of government in protecting consumers from unscrupulous practices of businesses. Since the expectations of the consumers are paramount here, the stakeholder approach method was used for assessing the efficiency of NAFDAC. Literature and previous empirical studies on the topic were examined. For

representativeness, data was collected utilizing the survey research design through Questionnaire distributed to 200 respondents in some areas of Lagos Mainland in Lagos state, using the convenience sampling method. 187 copies of the questionnaire representing 93.5% were returned and usable. Descriptive statistics was used to analyze the responses to questions regarding the efficiency of NAFDAC and a hypothesis tested using a one-sample T-test. The findings ran contrary to results from some previous studies. Instead, consumer awareness of the existence of NAFDAC as a regulatory agency and its functions were established, along with a high rate of consumer education. The assessment of its efficiency also showed a high rating. Recommendations were made that the study be replicated in other states of Nigeria and further studies carried out to evaluate its efficiency under previous and current directors for improvement purposes which is one reason that prompted the researcher to carry out such a study in Kaduna State. Also, it is important to note that in assessing the efficiency of any agency, it would have been very good to consider the strategies adopted by this agency to achieving her goal than just considering consumers awareness of the existence of NAFDAC. It is one thing for consumers to be aware of your existence and another thing entirely for your strategies adopted to achieving your goal to be effective. Therefore, this study tries to look at the strategies adopted by NAFDAC in the control of fake drugs in Kaduna State.

Olusegun (2013), undertook a study on "counterfeit drugs in Nigeria: a threat to public health" discussing the prevalence of counterfeit drugs in Nigeria. It highlights factors contributing to the preponderance of counterfeit pharmaceuticals and discusses strategies that may influence policy to combat the menace of counterfeit drugs. Major factors contributing to the prevalence of counterfeit drugs in Nigeria include ineffective enforcement of existing laws, non- professionals in drug business, loose control systems, high cost of genuine drugs, greed, ignorance, corruption, illegal drug importation, chaotic

drug distribution network, demand exceeding supply amongst many others. Counterfeit drugs pose great threats to the attainment of the millennium development goals 4, 5 and 6 which hopes for a reduction in infant mortality, improved maternal health and combating human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), malaria and other diseases. Due to the complexity of the counterfeit drug problem, no single technique can eliminate the public health threat posed by counterfeit pharmaceuticals. A multi-disciplinary and cross-functional approach will help combat the prevalence of counterfeit drugs in Nigeria. He saw the production of counterfeit drugs as a broad and under reported problem particularly affecting poorer countries and an important cause of unnecessary mortality and morbidity, and loss of public confidence in medicines and health structures. Empirical observations show that there may be more fake or counterfeit drugs than genuine drugs in circulation. It is important to note that, this study focused only on secondary data. It would have been better to have used both primary and secondary data so as to access first handed data. Therefore, the researcher intends to use both primary and secondary data to enrich the study.

2.4 Theoretical Framework

In order to guide us in understanding the activities of NAFDAC in the control of Fake drugs in Kaduna state, the study adopted "Fishbein Model (Theory of Reasoned Action) and the Social Control Theory by E.A.Ross (1901), as frameworks for the study. The theories and approaches are found relevant to this study as they will explain and capture the reason behind the establishment of NAFDAC, her activities as it affects the public and how human behaviour is regulated within the society and reasons behind most delinquent behaviour as it affects the marketing of fake or counterfeit drugs in the state. They are discussed below:

Fishbein Theory (Theory of Reasoned Action)

Fishbein model (1975) proposed that a person's overall attitude toward a stimulus object is derived from his beliefs and feelings about various attributes of the object (Ahtola, 1975; Loudon and Della Bitta, 1993, Solomon, et al, 2006). The theory has to do with how attitudes influence behavior. In this theory Fishbein and Ajzen argued that "behavior results in part from intentions and from complex outcome of attitudes" (Littlejohn, 2002). In other words you behave based on your attitude and how you believe others would have you act. How each of these affects your actions is based on how much weight you give both your attitude and others opinions, that weight will often vary based on the specific situation. This theory is called the theory of reasoned action because they believe that our actions are mostly rational and based on a systematic evaluation of the information available to them. Fishbein believed that people consider the implications of their actions and act based on a reasonable assessment of those implications. According to this theory intentions are a result of the person's judgment that performing the behavior is good, their attitude toward the behavior plus the social pressure put on him to perform the behavior or the subjective norm.

The model was developed further, and significantly extended, to not only assess attitudes, but behavior (Ajzen and Fishbein 1980; Fishbein and Ajzen 1975), and became known as the Theory of Reasoned Action (TRA). The reason behind the establishment of NAFDAC by the Federal Government of Nigeria is to ensure that people living in the country buy and use only products that are protective and harmless to their lives and well-being.

The Theory of Planned Behavior (TPB) (Ajzen, 1985), an extension of the TRA construct adds another construct – perceived behavioral control, which refers to the

extent to which a person has the skills, resources, and other prerequisites needed to perform a given behavior. Theory of Planned Behavior (TPB) has been found to be applied in a variety of behavioral domains (Shaw et al, 2000) and more significantly improve the predictive ability in specific contexts over TRA (Beck & Ajzen, 1991; Giles and Cains, 1995). The predictive ability of the TRA and TPB (Ajzen, 1985) relies on the researcher's ability to accurately identify and measure all salient attributes that are considered by the consumer in forming their attitude (Solomon et al, 2006) toward making decision to buy a particular product or brand. NAFDAC has been planned to undertake some regulatory activities that will ensure that the Federal Government goal to safeguard lives is realized.

Goal directed behavior draws heavily on the theory of planned behavior, with each of its constructs being represented and so on expects the model of goal-directed behavior to have greater predictive ability. (Perugini & Bagozzi, 2001; Bagozzi et al, 2002). This behavior is taken to be synonymous with behavioral intention, which can be derived from a combination of the consumer's attitude toward purchasing the product and the subjective norms about the behavior. Subjective norm suggests the power of other people in influencing behavior (Solomon et al, 2006). NAFDAC regulatory activities are expected to be effective in directing the consumers to comply in their buying decisions.

Consumer buying decision is the focus of consumer behavior. A number of consumer decision making scholars in consumer behavior literature are notable (Richarme, 2007; Loudon and Delala, 1993; Schiffman and Canuk, 2007; Zinkhan, 1993; Blackwell et al, 2001; Solomon et al, 2006; Foxall, 1990). Consumer behavior is the study of individuals, groups, or organizations and the processes they use to select, use, and dispose of products experiences, or ideas to satisfy needs and the impacts that these processes have on the consumer and society (Hawkins et al, 2001).

Utility theory, in economics, states that consumers, as rational decision makers, make choices based on the expected outcomes of their decisions (Schiffman and Kanuk, 2007; Zinkhan, 1992). However, contemporary research on consumer behavior are of the view that this rational decision making involves these stages; need or problem recognition, information search, evaluation of alternatives, purchase intention, evaluation and actual purchasing, consumption, post disposal (Schiffman and Kanuck, 2007; Blackwell et al , 2001; Engel, et al 1995; Bearden et al, 1995; Hawkins et al, 2001).

Consumers need information sources to get solutions for identified problem of needs or desires that are in tandem with their self-concepts and lifestyles, which are, in turn, determined by external and internal influences (Hawkins et al, 2001). In the bid to satisfy an identified need, consumers seek information from different sources including personal memory (internal sources), friends, colleagues, and family (group sources), advertisement promotion, personal selling (marketing sources), and others. However, the extent to which the consumer will be involved in the information search depends largely on level of importance or interest attached to the involvement associated with the decision (Bearden et al, 1995). High involvement decisions are made when the purchase is of high level of importance, requires thorough information processing, and substantial differences between choices. The consumer is motivated to process or learn the information. This is a case of high ticket or expensive products. On the other hand, low-involvement decisions occur when there is relatively little personal interest, relevance, or importance, attached to a purchase. The consumer has little or no motivation to process or learn the information (Huffman and Houston, 1993). Thus, it does not require extensive amount of information.

Alba and Hutchinson (1988) observe that some purchase decisions made with minimal effort and without conscious effort, involving seemingly thoughtless activity may seem

dangerous or at least stupid. This means that, the decision to buy drugs is likely of low-involvement type. Situations in which consumers are sick and are in dare need of drugs to heal them, such as in the rural areas, virtually no attention may be given to seeking information on various drug brands to know if they are approved by NAFDAC or not. This may lead to consumers' non-compliance with NAFDAC's directive that only NAFDAC's approved drug brands and other products should be bought and consumed.

Social Control Theory

The study also anchored on the Social Control theory, postulated by E.A. Ross in 1901 and further developed as Social Bonding theory by Travis Hirschi (Hirschi, 1969:18-20). The theory is concerned with how human behavior is regulated within the society. It stipulates that people are inherently motivated to deviance and due to social bonds and fear of punishment; they do not act on these instincts. It specifies that no society can afford to denounce criminal activity, without duly accepting its responsibility because most delinquent behavior is the result of "unmonitored" social control by the authorities (Borade, 2010). The Social Control theory insists that it is mostly people that have nothing to lose by conforming to delinquency or misconduct who are drawn toward the anti-social behavior of exchanging human lives for financial gains. Increasing the penalties for non-conformity may curb the inhuman activities of these nothing –to- lose people. The import of the Social Control theory is the crucial role of the society, viz, the Government (Executive, Legislature & Judiciary), regulators, operators, drug consumers, public, traditional rulers & religious leaders, in the control of unethical behavior such as in the marketing of medical drugs by NAFDAC. According to Wolpe (1988), every individual in the society must see himself as a moral entrepreneur, saddled with the responsibility to challenge definitions of deviance.

In criminology, social control theory proposes that exploiting the process of socialization and social learning builds self-control and reduces the inclination to indulge in behavior recognized as antisocial. It derives from functionalist theories of crime and was developed by Ivan Nye (1958), who proposed that there were four types of control:

i. *Direct*: by which punishment is threatened or applied for wrongful behavior, and compliance is rewarded by parents, family, and authority figures.
ii. *Internal*: by which a youth refrains from delinquency through the conscience or superego.
iii. *Indirect*: by identification with those who influence behavior, say because his or her delinquent act might cause pain and disappointment to parents and others with whom he or she has close relationships.

iv Control through needs satisfaction, i.e. if all an individual's needs are met, there is no point in criminal activity.

Relevance of the Theory and Approach to the Study

Within the framework of the theory and model which advocated for the need for planned action and later extended to the need for reasoned action, is the need for pharmaceutical crime action which has been on the increase, serving as a health threat as posed by these fake or counterfeit pharmaceuticals or drugs as the case may be. This planned action relates to the need to establishing a body such as the establishment of NAFDAC by the federal government serving as a regulatory body to ensuring that people living in the country buy and use only products that are protective and harmless to their lives and wellbeing. Thus, to ensure that food and drugs distributed and consumed in Nigeria meet specific minimum standard of quality for a healthy living.

The fishbein theory is also relevant to our study because, it improves the predictive ability of NAFDAC over the actions of drugs sellers and consumers of these drug products. Thus, there are salient attributes considered by the consumer in forming their attitudes (Solomon et al, 2006) towards making decision to buying a particular drug product or brand. This means that, NAFDAC regulatory activities are expected to be effective in directing consumers comply in their buying decisions which is the focus of consumer behavior.

Note that, these behaviors exhibited by the consumers are based on needs or problem recognition, information search, evaluation of alternatives, purchase intention, etc. (Shiffman & Kanuck, 2007). Thus, consumers are in need of information to get solution for identified problems and needs tandem with their self-concept and lifestyle as determined by internal and external influences (Hawkins et al, 2001). These consumers seek for information from different sources such as advertisement, promotion, etc. in a bid to satisfy their identified need. This means that, NAFDAC in a bid to control fake or counterfeit drugs in Kaduna state and Nigeria as a whole specifically has to put up some sensitization and awareness programs to serve as a source of information on how the public could identify fake drugs all in an attempt to preventing consumers from making the wrong buying decision.

However, the level to which the consumer would be involved in the information search will be dependent on the level of commitment and involvement of NAFDAC and the level of compliance in the absorption of these information is determined by how well the information has been spread to the consumers.

The social control theory as postulated by Ross in 1901, further developed as social bonding by Travis in 1969 is relevant in this study because, it proffer solution to

delinquent and criminal behaviors in the society. Thus, it is concern with how human behavior is regulated within the society. This is because, people are inherently motivated to deviance and due to social bonds and fear of punishment, and they do not act on these instincts. It specifies that, no society can afford to denounce criminal activity without duly accepting its responsibility because, most delinquent behavior is the result of ‘‘unmonitored’’ social control by the authorities (Borade, 2010).

Most people conforming to delinquency in Kaduna state are those who have nothing to lose drawn towards the anti-social behavior of exchanging human lives for financial gains. This means that, NAFDAC in order to control fake or counterfeit drugs in Kaduna state, should increase the level of penalties for non-conformity to drug laws as it may curb or reduce the inhuman activities of these nothing-to-lose persons. Thus, this theory clearly defined the crucial role of the society, viz the regulatory agencies such as NAFDAC in the control of unethical behaviors.

The social control theory proposed four (4) behavioral measures as against delinquencies and all forms of criminality such as direct; internal; indirect and control through need satisfaction.

The direct control measures refers to how punishment should be threatened or applied for wrongful behavior and compliance reward by the regulating body NAFDAC. The internal control measure refers to how youths in the society would refrain from delinquencies through the conscience or superego. NAFDAC through her awareness and sensitization programs could boost the mind, conscience and superego of these youths to refraining from delinquencies. Also, is the indirect measures which describes the need to identifying with those who influence behavior because, the delinquent act might cause pain and disappointment to parents and close relations. Lastly is control through need

satisfaction. This has to do with governmental responsibility to her citizens. Once these needs are not met, individuals in order to survive engage in all forms of criminality such as faking and counterfeiting of drugs in the state.

Applicability of the Theory to the Study

As mentioned hitherto, the drug market in Kaduna State has been driven by pharmaceutical crime which is caused by human attitudes as it influences human behavior and this has been a threat to public health in the state. In other words, the consumption of fake drugs is detrimental to human health leading to the death and ill health of the masses. This is in accordance with the Theory of Planned Behavior as argued by Fishbein and Ajzen who believed that intentions are a result of people's judgment that performing the behavior is good, their attitude toward the behavior plus the social pressure put on him to perform the behavior or the subjective norm (Littlejohn, 2002). In other words you behave based on your attitude and how you believe others would have you act.

As a result of this pharmaceutical crimes, the Federal Government during the period under study noticed the calamity that befell her people decided to establish the body called 'NAFDAC' across the Nigerian States and Kaduna State is not an exception. This is also in accordance with the Theory of Reason Action postulated by Fishbein and Ajzen. Thus, the reason behind the establishment of NAFDAC by the Federal Government of Nigeria is to be a regulatory body that will ensure that people living in the country buy and use only products that are protective and harmless to their lives and

well-being. Also is to ensure that food and drugs distributed and consumed in Nigeria meet specific minimum standard of quality for a healthy living.

Furthermore, is the Social Control Theory postulated by E.A. Ross and Travis Hirschi who further developed it as Social Bonding Theory which the study adopted, concerned with how human behavior is regulated within the society. Having established the fact that there is pharmaceutical fraud, is the need to proffer solution the menace. This is in accordance with the Social Control/Bonding Theory since the theory concerned itself with how human behavior is regulated in the society since it sees people as inherently motivated to deviance and due to social bonds and fear of punishment, they do not act on these instincts. Some of these control measures as derived from the functionalist theories are as follows:

Direct Control Measure: The direct control measures refers to how punishment should be threatened or applied for wrongful behavior and compliance reward by the regulating body (NAFDAC).

Internal Control Measure: The internal control measure refers to how youths in the society would refrain from delinquencies through the conscience or superego. NAFDAC through her awareness and sensitization programs could boost the mind, conscience and superego of these youths to refraining from delinquencies.

Internal Control Measure: Also, is the indirect measures which describes the need to identifying with those who influence behavior because, the delinquent act might cause pain and disappointment to parents and close relations.

Control Through Needs Satisfaction: Lastly is control through need satisfaction. This has to do with governmental responsibility to her citizens. Once these needs are not met,

individuals in order to survive engage in all forms of criminality such as faking and counterfeiting of drugs in the state.

CHAPTER THREE:
RESEARCH METHODOLOGY

3.1 Introduction

This chapter constitutes a detail plan according to which the objectives of the study were achieved in relation to the peculiarities of the study ‘‘assessment of the activities of NAFDAC in the control of fake drugs in Kaduna State’’, therefore it was paramount to have a suitable means that befits the study and ensured that the study was guided properly, based on approved research tenets. To this end, the study discussed research design, population and sample size, sampling technique, sources of data, administration of instruments and method of data presentation and analysis.

3.2 Research Design

The study adopted the survey research design which involved the use of instruments such as questionnaire and interview. The study required relatively wide range collection of opinion and judgment from professionals (NAFDAC Staff, Community Pharmacist’s, and health personnel such as Medical Doctors, Nurses/Midwives). This was to ensure that qualitative and quantitative data are generated and analyzed to come up with findings and recommendations that could be generalized in Kaduna State in respect of the activities of NAFDAC in the control of fake drugs.The survey research selects a sample

from or a subset of, the population using some techniques of sampling. The survey method is always interested in some characteristics of the population or universe of which a sample is drawn which could be used for generalization. The choice and use of this method arose from the simple fact that this study cannot cover the entire population of the study area (Kaduna state).

In addition, the documentary research design was also used to complement the survey research. This was due to the sanctity of existing scholarly contributions that are relevant to the study and in fact, constituted the root stimulant and reference points of the study.

3.3 Population and Sample Size

The population of the study comprises of NAFDAC staff (54) in Kaduna State, Pharmaceutical Council of Nigeria (PCN) Members (Community Pharmacist's) Kaduna State (125), and medical personnel's (Doctors and Nurses/Midwives) in Kaduna state (1,474) would be randomly selected in various hospitals of the state. The breakdown of the parent population is given in table 3.1

Table 3.1 Research population

S/No	Population Source	Population	Sample Size		Percentages (%)
			Questionnaire	Interview	
1	NAFDAC Staff	54	10	4	3.3
2	PCN Members	125	24	4	7.6
3	Health Personnel's (Doctors and Nurses/Midwives)	1,474	279	3	89.1
	Total	**1,653**	**313**	**11**	**100**

Source: Researcher's Survey

Note that, in arriving at the proportional sample size for each population source, the researcher divided its population source by the grand total population and multiplied by the research sample size as represented by the formula below:

$$\frac{\text{Population} \times \text{Research Sampled}}{\text{Total population}}$$

The total population of the study is one thousand, six hundred and fifty three (1,653) to draw the sample for questionnaire administration which consists of population of NAFDAC staff, PCN staff and health personnel's (Doctors and Nurses/Midwives) of Kaduna state. The sample size was drawn using Krejcie and Morgan (1970) method of determining sample size for research activities. In the Krejcie and Morgan (1970) method, no calculation is needed to use table 1 in appendix 'V' (see appendix 'V' for the Krejcie and Morgan table 1). In view of this, the value on the table for population of 1,653 is N=1,700 therefore, the sample size is S=313. However, sample size was increased by 3.5% (which is equal to eleven (11) additional respondents) who were purposively selected and interviewed by the researcher based on the data needed. This means that, the sample size for this research was adopted at 324. The medical personnel's were chosen because they have a direct contact with patient's in various primary and secondary health institutions in the state who might have been victims of this effects of fake or counterfeit drugs in Kaduna state.

3.4 Sampling Technique

Probability and non-probability sampling techniques employed in this study. This was such that the interview respondents were drawn through the use of purposive sampling which is a non-probability sampling technique while the questionnaire respondents were selected from among the population through the use of simple stratified random sampling

which is a probability sampling technique. Simple stratified random sampling is necessary in order to ensure that the sample is representative on the characteristics used to form the strata of the given population. This is contrary to purposive sampling which was necessary to deliberately select some persons in order to provide information that can't be gotten as well as from other choices. Questionnaires were administered to 10 NAFDAC Staff, 24 Community Pharmacist's, and 279 health personnel's who were randomly selected in Kaduna State respectively.

The purposive sampling was also used in selecting interviewees from amongst the officials – NAFDAC staff, Community Pharmacist's and Medical Doctors & Nurses/Midwives. These include State Director, Regional Director and two Heads of Departments of NAFDAC; Head of Pharmaceutical Council of Nigeria and Medical Directors of various hospitals selected within the selected Local Government Areas of Kaduna State.

The questionnaire were distributed among various local governments. Thus, 129 questionnaires were distributed within Zaria Local Government, 77 questionnaires to Chikun Local Government and 87 to Kaduna South Local Government, Kaduna State.

3.5 Sources of Data

This study adopts primary and secondary data which were used independently in some instances. In particular, interview and questionnaires were administered to NAFDAC Staff, Community Pharmacist's, and Health Personnel's in Kaduna State.

The primary data were collected through the instrument of questionnaires which was administered to respondents in Kaduna State. The questionnaires were structured in closed-ended and open-ended format for easy tabulation, coding and analysis. The questionnaire for the beneficiaries was divided into sections A, B, C and D. section A consisted of questions relating to respondents' personal data while section B, C and D of

the questionnaire addressed questions relating to the three research hypotheses respectively. The closed ended questionnaire was designed using the Likert 5 scale format (strongly agree, agree, undecided, disagree and strongly disagree). The choice of the Likert scale format assisted to determine how strongly respondents agree to a particular statement on the subject matter involved. For the interview, the structured and unstructured interview were employed in the study. The structured interview questions were contained in an interview schedule so as to ensure alignment with the objectives of the study. However, unstructured interview was used depending on the circumstances that ensued during the interview.

Secondary data were sourced from NAFDAC's Act, NAFDAC's Score Cards, NAFDAC's Campaigns, and etcetera.

3.6 Administration of Research Instruments

The study adopted three methods of data collection through the instruments of questionnaire, interviews using a check list or interview schedule, as well as documented data from different sources which were basically secondary.

a. Administration of Questionnaires

The questionnaire were self-generated subject to a reliability test.Reliability of the instrument was obtained through content validity by specialist's in the field andemploying the Cronbach's Alpha coefficient to measure the internal consistency of the instrument on the questionnaire administered to Ten (10) respondents for pilot testing. The variables were tested independently to check if the questionnaire to be used for the study is reliable enough. All variables have a figure above 0.818 which according to rule of thumb the questionnaire are suitable and relevant to the study.

The study administered 313 questionnaires on sampled respondents as indicated in table 3.1. Questionnaire administration was carried out among owners of pharmaceuticals/pharmacist council of Nigeria (PCN) and medical personnels (Doctors, Nurses/Midwives). Relevant information regarding to the study were elicited from the respondents. The various responses from the beneficiaries were measured using the five point likert scale of: Strongly agree, Agree, Undecided, Disagree and strongly disagree. The researcher employed the service of an assistant to make the administration of the questionnaire less tedious, easy and time efficient. Questionnaires were used in order to solicit responses from the respondents as their responses served as a vital input into this work for analysis. In the final analysis, chi-square non-parametric test was used to test the hypotheses. This is because the questionnaire was structured in such a way that it uses the likert scale which will be convenient to use the chi-square.

b. Interviews

The researcher adopted the structured interview for the collection of its data through a schedule so as to derive more precise generalizations in the stages. The total number of persons that were interviewed was 11. This number comprises of 4 NAFDAC Staff, 4 persons from the PCN as well as 3 Medical Doctors, Nurses/Midwives. Each interview lasted an average of 45 minutes during which the researcher took notes on relevant information. The essence of the interview was to official information about NAFDAC, PCN and their challenges in the drug business as well as Medical Doctors and Nurses/Midwives as it relates to treatment of victims of fake drugs in relation to the control of fake drugs in Kaduna State.

Interview was used because it permit the researcher to obtain firsthand information concerning the respondent's views, perceptions, experiences, attitude and beliefs on the

research subject. This method was used because it is particularly useful as an explanatory device to supplement existing literatures and questionnaires or disprove them because data to be derived using questionnaires may fail to provide insight on how to approach the research problem. The explanatory interview to be conducted gave us a wealth of details which enriched the whole research, considering the strategic nature of issues under review. The researcher employed interviews to lead the study because it permitted follow-up questions which provided clarifications that the questionnaire did not allow and because face to face interaction with the population is a particularly useful method for gaining an in-depth understanding of given the fact that most people in the state are not educated enough to read, understand and provide insightful response to questionnaire which is considered too elitist.

d. Secondary Data

The study generated secondary data such as NAFDAC's Act, NAFDAC's Score Cards, NAFDAC's Campaigns, text books and journals which were used to support data generated from primary sources (questionnaire and interview).

3.7 Methods of Data Presentation and Analysis

Data collected for this study were analyzed using both qualitative and quantitative methods where the study employed both descriptive and inferential statistical tools. The descriptive statistical tools used included frequencies, tables and percentages while chi-square cross-tabulation test was used to test the hypotheses raised for this study using the Statistical Package for Social Sciences (SPSS) version 20. However, the chi-square cross-tabulation test was calculated at 5% level of significance with 95% confidence level.

Decision Rule

The decision rule on the postulated hypotheses stated that, if p-value is less than alpha (p-value <a), we reject the null hypothesis, while if p-value is greater than alpha (p-value >a), we accept the null hypothesis. For the purpose of this study, alpha will be taken at 5% level of significance.

The study adopted simple random sampling techniques to select questionnaire respondents because it gave equal opportunity to various population of the study in the state to have equal chance of being selected or being part of the research. Thus, questionnaires were administered to 10 NAFDAC Staff, 24 Community Pharmacist's, and 279 health personnel's who were randomly selected in Kaduna State respectively. Purposive sampling technique was used because it allowed the researcher to select interview respondents based on their relevance and ability to provide invaluable and firsthand information on issues under investigation.

CHAPTER FOUR

Overview of the Activities of NAFDAC in Kaduna State

4.1 Introduction

Basically, this chapter seeks to give us an overview of NAFDAC in Kaduna State. This overview of the NAFDAC is very important to this study and it cannot be complete without the brief historical background of of the subject matter in Nigeria. Therefore, in this chapter, a brief historical development of NAFDAC will be looked at, mission statement, structure, administrative structure, location and functions of NAFDAC will be lookd at. This is geared towards exposing us to the agency for a better insight about her and her activities.

4.2 Brief Historical Development of Food and Drug Regulatory Authority in Nigeria

Prior to the establishment of NAFDAC, the Directorate of food and drug Administration and control in the federal ministry of Health was responsible for the control and regulation of food drugs, cosmetics and other regulatory products in Nigeria. Under the directorate, the regulatory structure in Nigeria had most of the necessary components expected of a regulatory authority.

Here were drug laws (with deficiencies no doubt) quality control laboratories and provision for inspection enforcement and even a fairly equipped drug – manufacturing laboratory. However, product registration was not in place, and as such drug importation and manufacturing was a free for all affair. Drug information and adverse drug reaction monitoring processes were not also in place; hence there were no effective drug recall procedures (grossarchive.com)

The paucity of enforcement of the existing drug laws can be seen from the fact that in the twenty years between the enactment of food and drug decree NO. 35 OF 1974, and the establishment of NAFDAC in 1994, there are no records of prosecution of offends despite the Ibadan and Jos Incidents in 1989 when over 150 children were reported to have died due to a formulation error.

Despite the fact that Nigeria had a relatively well – developed regulatory process, civil service bureaucracy' corruption, political instability and a host of other lapsed the averted this process. To remove these bottlenecks and ensure effectiveness, the then honourable minister of Health Prof. Olikoye Ransome kuti, directed in September 1992 that a blue print be prepared for the establishment of a food and drug regulatory agency . In the words of the pioneer director general of NAFDAC Prof. G.E. Osuide "the excision of the functions of control and regulation of foods, drug and regulated products from the main stream of civil service setting was a progressive decision in tune with what obtain in a

number of countries'' while inaugurating the pioneer governing council of NAFDAC in September 1992 the Honourable minister of Health, Prof Olikoye Ransome kuti said that the establishment of NAFDAC was, "to give a frontal attack to the health problems arising from food, chemicals, drugs medicines and similar regulated product without the inhibitions of the civil service setting" (grossarchive.com).

NAFDAC therefore was founded in 1993 under the country's health and safety law. The Administration set up her first governing council in 1992. NAFDAC was established by Decree 15 of 1993 as amended by Decree 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria, 2004. NAFDAC replaced a former Federal Ministry of Health body, the Directorate of Food and Drug Administration and Control after it was viewed as ineffectual. NAFDAC, was therefore established by Decree NO.15 OF 1993 (as amended), as a parastatal of the Federal Ministry of Health.

The National Agency for Food Drug Administration and Control a subsidiary of Federal Ministry of Health was established to put a stop to the production, advertisement, sales and use of illegitimate and fake drugs, chemicals, cosmetics, packaged water and medical devices also known as regulated products.

4.3 Mission Statement

The mission statement of the Agency is to safeguard public health by ensuring that only right quality of drugs food and other regulated products are manufactured, imported, exported, distributed, advertised sold and used NAFDAC as the foremost consumer protection and regulatory agency was therefore set up by government to ensure

that wholesome foods, efficacious medicines and safe cosmetics are made available to the consumer.

The agency protects and promotes the wellbeing of Nigerians by ensuring that hazards attendant & food consumption and medicine intake are totally eliminated. Thereby improving the quality of life "In essence, NAFDAC is the people Agency''.

4.4 Structure of NAFDAC

From inception, the Agency was structured into the following six directorates;

1. Registration and Regulatory Affairs
2. Inspectorate
3. Laboratory services
4. Narcotics
5. planning Research and statistics
6. finance and Administration

4.4.1 Administrative structure of NAFDAC

The structure of Agency has the chief Executive of NAFDAC who report to the governing council comprising of appointed member and other heads of related regulatory bodies. There are presently eight directorates in the Agency manned by full Directors in the Director General.

Director- General's office:

i. Technical services

ii. Special Duties

iii. Food and Drug information centre (FDIC)

iv. Legal Unit

v. Public Relation Unit

Directorate of Registration and Regulatory

This is the licensing arm of NAFDAC. Registration and Registration is responsible for registration of all products regulated by the Agency namely food drugs which include narcotics and controlled substances, cosmetics medical devices, detergent and packages water.

The Directorate formulates, updates and reviews relevant regulation that the Agency employ in exercising its mandate. The Directorate ensures that advertisement of regulated products is not exaggerated, unwarranted, detrimental and deceptive to consumers and other stakeholders

The Directorate collects samples of the products to be registered from company representative and forward to appropriate unite the Registration and Regulatory for further action while sample will be sent to laboratories for analysis. When all the report are obtained from the various units with their recommendation, Registration and Regulatory would make appropriate recommendation to the product Approval committee.

The Directorate is headed by a Director and each of the four broad divisions headed by Deputy Director is Regulatory Affairs, Drug Registration, food Registration and consumer affairs and Advert control.

Directorate of Laboratory Services.

This directorate is headed by a Director and each of the Laboratories is headed by Deputy Director.

The functional Laboratories of NAFDAC Kaduna is the Area Laboratory, Kaduna

Laboratory services Directorate is majorly responsible for the following functions:

i. Analyse and make pronouncement on the quality and safety of regulated products.
ii. Serve as reference laboratory for Nigeria custom service, NDLEA and other government Agencies.

Specialized units in the laboratories include the following:

i. Drug
ii. Food
iii. Sea food
iv. Organoleptic
v. Radiation
vi. Water
vii. Pesticide /Biological control
viii. Mycotoxin
ix. Vitamin Analysis

Sea food laboratory is accredited by the European Union for fish and shrimp export.

Pesticide Residue pesticide formulation and mycotoxin laboratories are affiliated with the international Atomic Energy Agency (IAEA).

The vitamin Analysis laboratory is affiliated with United Nations children find (UNICEF).

Vaccine control laboratory yaba recognized by WHO in West African region.

Ports Inspection Directorate:

The directorate take care of regulatory activities at all port of enter, border posts, airports and inland container terminals.

Functions of this Directorate

i. Control and regulate importation of regulated products
ii. Under take inspection of importation regulated products
iii. Compile guide line for the importation and exportation of regulated products.
iv. Control the exportation and issue quality certification of regulated products intended for export.

This directorates has offices in cities with seaports, airport, inland container terminals and border posts at same and Idiroko borders.

Establishment inspection Directorate (EID)

This directorate is responsible for compiling establishment inventory for production of regulated products.

The inventory state the name of establishment, its location and type regulated products it produces. The directorate responsible for the inspection of establishment for purposes, which include but not limited to:

i. Good manufacturing practices (GMP)
ii. Routine inspection

iii. Registration

iv. Surveillance e.g. survey of bakeries

v. Investigation e.g. follow –up on consumer complaints

Directorate of Narcotics and controlled substances

i. The directorate control and documents the importation, distribution and use of narcotics, psychotropic substances and chemicals.

ii. It promotes activities geared towards the reduction of demand for psychoactive drugs as well as rational use of drugs in general.

iii. It also ensures effective control on importation and distribution of chemicals

iv. It ensures Nigeria's obligation under the international Drug treaties with respect to licit transactions in Narcotic's, drug and psychotropic substances are fulfilled.

Directorate of planning, research and statistics

This is a services directorate that is responsible for planning, researching and collating of statistical data, as well as co-ordinating and documenting the activities of all the other directorate for the efficient achievement of the goals of the agency.

i. The directorate is responsible for complication and production of NAFDAC'S Annual Reports.

ii. It ensures the development and establishment of strategies for the effective implementation of the mandates of NAFDAC.

iii. It coordinates staff trainings at all levels.

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.

4.5 Functions of NAFDAC

The Act that established the National Agency for Food and Drugs Administration Control NAFDAC has spelled out the statutory functions of the agency, and in this article, a good number of them would be explained.

Ensures Compliance to Standard

The major functions of the National Agency for Food and Drugs Administration Control NAFDAC is that of ensuring compliance to standard.

Going by this what National Agency for Food and Drugs Administration Control does is to carry out test in locally manufactured food and drugs and, sometimes, those food and the likes imported into the country with a view to ensure that these products meet specified standard.

There is standard specifications designated to every product manufactured within Nigeria or imported into the country and until these products are approved by the council, such food or drugs is not consumable.

There must be total consent by the council for the effective quality control of these goods, such as food, and drugs, and cosmetics, and medical devices, and packaged water, and chemicals, etc.

Investigates Into Production Houses

It has been primary functions of the National Agency for Food and Drugs Administration Control to ensure that premises, where these good are produced are in order and hygienic.

From time to time, the Agency will embarked on investigation tours to these places, where these good are manufactured, and its investigation into these production houses is always appropriate and proper.

Without leaving any Stone unturned, the National Agency for Food and Drugs Administration Control will investigate and inspect raw materials for these goods, be it food or be it drugs or be it cosmetics or be it chemicals or medical devices, NAFDAC would check all accurately.

The National Agency for Food and Drugs Administration Control would ensure that quality assurance is established, and this include and not limited to certification of the production premises, as well as, regulated products.

Inspects Imported Food

In this one, you cannot fool the National Agency for Food and Drugs Administration Control, it must endure that what comes into the country meets the standard and the specification.

Some of the goods imported into the country include, imported foods, imported drugs, imported cosmetics, imported medical devices, imported bottled water, and imported chemicals among others.

Just like what happened after proper investigation into the production premises, after inspection of the of the imported products, the National Agency for Food and Drugs

Administration Control would make sure that there is an establishment of the relevant quality assurance system.

NAFDAC must also ensure that, there is certification of the products and regulated products.

Compiles Standard Specification for Production, Importation, etc

National Agency for Food and Drugs Administration Control will always set standard specification to every product manufactured or imported.

The Agency carried this function by compiling the specification and the standard of every product, in such a way that will not threaten the health of Nigerians.

Apart from standard specification of products, the National Agency for Food and Drugs Administration Control would compiled guidelines, including regulations for production, and importation, and exportation, and sale, as well as, distribution of food, and drugs, and cosmetics, and medical devices, bottled water, and chemicals among others.

Registration of Food and Drug Products

No products within this sector can thrive without National Agency for Food and Drugs Administration Control knowing about such product that is why NAFDAC itself has been in the business l registering these products. I mean every product.

These products include, the aforementioned products, which falls within the powers of the National Agency for Food and Drugs Administration Control, such as food, and drugs, and medical devices, and bottled water and chemicals, and etc,etc.

Controls Exportation

Exportation control remains one of the functions of the National Agency for Food and Drugs Administration Control, so far such product for exportation is product controlled and regulated by the National Agency for Food and Drugs Administration Control NAFDAC, like food and drugs and packaged water and chemicals and medicals devices among others.

National Agency for food and Drugs Administration Control will make sure that, quality certification of all these products for export are issued.

Establishes and Maintains Laboratories

One tool that is relevant to the National Agency for Food and Drugs Administration Control is laboratories, since it is in such laboratories that products can be tested to ascertain the standard specification of such products, as well as, knowing the extent at which participants in comply efficiently to set standard, and regulations.

Apart from such relevant laboratories, the National Agency for Food and Drugs Administration Control can partner with relevant institutions in strategic areas of interest within Nigeria, and such areas of interest may be necessary in aiding NAFDAC carried out its functions.

CHAPTER FIVE

DATA PRESENTATION AND ANALYSIS

5.1 Introduction

This chapter consists of data presentation and analysis. Descriptive statistics such as frequencies and percentages were used in analyzing the data obtained. Out of the targeted sample of three hundred and thirteen (313) examined, only two hundred and ninety three (293) questionnaires were fully filled and returned, representing 93.3% rate of return. The analysis for this study was done using the two hundred and ninety three (293) questionnaires that were returned. The instrument was vetted by a group of supervisors which makes the instrument reliable for the study.

Table 5.1: The Rate of return of Questionnaire by Respondents from selected Nigerian Federal Public Service

S/N	Population Source	Total No. of Questioners Administered	Total No. of Questionnaires Returned	Percentage (%) of Questionnaires Returned

1	NAFDAC Source	3	3	3.3
2	PCN Members (Community Pharmacist's)	24	24	7.6
3	Health Personnel's (Doctors and Nurses/Midvives)	279	266	89.1
	Total	313	293	100

Source: Researcher's Survey, February 2017

As shown in table 5.1 overleaf above, 3 of the 313 questionnaires returned representing 3.3% were from staff of NAFDAC, 24 questionnaires representing 7.6% were from PCN members while 266 questionnaires represents 89.1%. Therefore, the analyses of data was based on the 293 questionnaires returned.

5.2 Personal Information

Table 5.2: Gender distribution in the sample

Option	Frequency	Percentage
Male	140	44.7
Female	173	55.3
Total	313	100.0

Source: Field survey, 2017

From table 5.2 above, response indicated that the majority of respondents were female who accounted for 55.3% and male respondents accounted for 44.7%. The females are more among the respondents. This is likely because we have more female nurses/midwives than the males among our medical personnel's.

SECTION B: 5.3Questions Related to Hypothesis One; Standard Specification

The following questions were asked based on hypothesis three; there is no significant effect ofstandard specification on the control of fake drugs in Kaduna State.

Table 5.3: NAFDAC use Test Method for Determining Quality of Drugs Produced

SS1

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	90	30.8	30.8	30.8
	Strongly Agree	202	69.2	69.2	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.3 showed that 30.8% of the respondents agree; 69.2% strongly agree; 0% disagree and 0% strongly disagree and 0% are also undecided that NAFDAC use test method for determining the quality of drugs produced in Kaduna State. This means that 100% of the respondents agreed that NAFDAC use test method for determining the quality of drugs produced in Kaduna State. In agreement to this finding,NAFDAC (2013), clearly stated that the Directorate collects samples of the products to be registered from company representative and forward to appropriate unite the Registration and Regulatory for further action while sample will be sent to laboratories for analysis. When all the report are obtained from the various units with their recommendation, Registration and Regulatory would make appropriate recommendation to the product Approval committee.

Table 5.4: On NAFDAC Engage in Public Enlightenment and Sensitizations on Required Drug Standards

SS2

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Disagree	4	1.4	1.4	1.4
	Undecided	79	27.1	27.1	28.4
	Agree	117	40.1	40.1	68.5
	Strongly Agree	92	31.5	31.5	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.4 showed that 40.1% of the respondents agree; 31.5% strongly agree; 1.4% disagree and another 0% strongly disagree; while 27.1% are undecided that NAFDAC is

actively engaged in public enlightenment and sensitization on required drug standards in Kaduna State. This means that 71.6% of the respondents agreed that NAFDAC is actively engaged in public enlightenment and sensitization on required drug standards in Kaduna State. The interview report of the owners of pharmacies and medical personnel's on the other hand also agree with the fact that NAFDAC have really tried in terms of creating awareness NAFDAC is actively engaged in public enlightenment and sensitization on required drug standards in Kaduna State through the media, prints, interactive meetings, and etcetera on the type of drugs to buy. This implies that, NAFDAC have been able to achieve this objective as a means of educating the public about fake drugs.

Table 5.5: On NAFDAC uses use Modern Technology to ensure that manufacturers meet up with drug standard in Kaduna State.

SS3

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	strongly Disagree	6	2.1	2.1	2.1
	Disagree	106	36.3	36.3	38.4
	Undecided	29	9.9	9.9	48.3
	Agree	151	51.7	51.7	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.5 showed that 51.7% of the respondents agree; 0% strongly agree; 36.3% disagree and another 2.1% strongly disagree; while 9.9% are undecided that NAFDAC uses use Modern Technology to ensure that manufacturers meet up with drug standard in Kaduna State. This means that 71.6% of the respondents agreed that NAFDAC uses use Modern Technology to ensure that manufacturers meet up with drug standard in Kaduna State. In agreement with this view, interview report of pharmacist's and NAFDAC official's states that she has succeeded in using modern technologies such as Truescan, Mobile Authentication Service, and etcetera.

Table 5.6: On NAFDAC have improved her Laboratory Services in Kaduna State.

SS4

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	strongly Disagree	3	1.0	1.0	1.0
	Disagree	27	9.2	9.2	10.3
	Agree	212	72.6	72.6	82.9
	Strongly Agree	50	17.1	17.1	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.6 showed that 72.6% of the respondents agree; 17.1% strongly agree; 9.2% disagree and another 1.0% strongly disagree; while 0% are undecided that NAFDAC have improved her laboratory services in Kaduna State.This means that, 89.7% of the respondents agreed that NAFDAC have improved her laboratory services in Kaduna State.

Table 5.7: On NAFDAC Compile Standards for the Distribution of Drugs in Kaduna State.

SS5

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	strongly Disagree	24	8.2	8.2	8.2
	Disagree	35	12.0	12.0	20.2
	Agree	90	30.8	30.8	51.0
	Strongly Agree	143	49.0	49.0	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.7 shows that, 30.8% of the respondents agree; 49% strongly agree; 12% disagree and another 8.2% strongly disagree; while 0% are undecided that NAFDAC compile standards for the distribution of drugs in Kaduna State. This means that, 79.8% of the respondents agree that, NAFDAC compile standards for the distribution of drugs in Kaduna State. Durojaiye (2012) in agreement with this finding, stated that NAFDAC grants the WHO-Prequalification to pharmaceutical companies, revealing that it was not just enough condemning drugs from China, India, etc. into Nigeria but for national

security reasons also. He further revealed that, NAFDAC hopes through the granting of the WHO-Pre-qualification to Nigerian pharmaceutical companies to increase the acceptability of the Nigerian drug export abroad so as to increase their revenue generating capacity and provide prospect for employment of researchers, laboratory technologists, etc. by the industry to drive development of the home industry. He also reveals that, presently, six (6) pharmaceutical companies have the prospects of getting WHO-Pre-qualification for some of their products.

Table 5.8: On NAFDAC Compile Standards for the Importation of Drugs

SS6

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	strongly Disagree	35	12.0	12.0	12.0
	Disagree	53	18.2	18.2	30.1
	Undecided	5	1.7	1.7	31.8
	Agree	136	46.6	46.6	78.4
	Strongly Agree	63	21.6	21.6	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.8 shows that, 46.6% of the respondents agree21.6% strongly agree; 18.2% disagree and another 12% strongly disagree; while 1.7% are undecided that NAFDAC compile standards for the importation of drugs. This means that, 68.2% of the respondents agreed that, NAFDAC compile standards for the importation of drugs. In agreement to this result, NAFDAC in addition to setting the standards by which other public establishments could be judged also maintains contact with a number of national and international organizations whose activities relate to its functions. These organizations include Consumer Protection Council of Nigeria (CPC), Standard Organization of Nigeria (SON), National Drug Law Enforcement Agency (NDLEA),

National Institute for Pharmaceutical Research and Development (NIPRD) to mention but a fewPharmapproach (2019).

SECTION C: Questions Related to Hypothesis Two; Registration of Drugs

The following questions were asked based on hypothesis one; There is no significant effect of the registration of drugs on the control of fake or counterfeit drugs by NAFDAC in Kaduna State.

Table 5.9 : NAFDAC ensures proper documentation of manufacturers and drug sellers before certification of product.

RD1

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	strongly Disagree	6	2.1	2.1	2.1
	Disagree	83	28.4	28.4	30.5
	Undecided	3	1.0	1.0	31.5
	Agree	116	39.7	39.7	71.2
	Strongly Agree	84	28.8	28.8	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.9 showed that, 39.7% of the respondents agree; 28.8% strongly agree; 28.4% disagree and another 2.1% strongly disagree; while 1.0% are undecided that NAFDAC ensures proper documentation by manufacturers and drug sellers before certification of product. This implies that most of the respondents 68.5% agreed that NAFDAC ensures proper documentation by manufacturers and drug sellers before certification of product. In agreement with this view, Ratanawijitrasin, (2002) and Olike (2011) stated in their studies that NAFDAC carry out inspection exercises on manufacturers and distributors of drugs to know if they follow the stipulated standard specification of NAFDAC and this is done by her inspectors' physical visits to drug facilities and by use of quality assurance laboratories. The interview report of the owners of pharmacies and medical personnel's

states that, NAFDAC is actively involved in inspection exercises even though, lacks adequate manpower to fully undertake this task. Thus, for this to be more effective, the government should ensure that, more hands should be recruited to the agency.

Table 5.10:On NAFDAC do not ensure clear and accurate label of drug products before full certification of the product

RD2

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	strongly Disagree	62	21.2	21.2	21.2
	Disagree	136	46.6	46.6	67.8
	Undecided	10	3.4	3.4	71.2
	Agree	53	18.2	18.2	89.4
	Strongly Agree	31	10.6	10.6	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.10 shows that, 18.2% of the respondents agree; 10.6% strongly agree; 46.6% disagree and another 21.2% strongly disagree; while 3.4% are undecided that NAFDAC do not ensure clear and accurate label of drug products before full certification of the product. This means that most of the respondents 67.8% disagreed that NAFDAC do not ensure clear and accurate label of drug products before full certification of the product. This implies that, NAFDAC is Complying with the registration process of a product.It is important to note that, the total number of drugs registered by NAFDAC in 2013 is 2, 906 out of which 2, 336 are imported and 570 are local drugs. In 2014, the total number of drugs registered by NAFDAC is 2, 325 out of which 2, 768 are imported and 557 are local drugs. In 2015, the total number of drugs registered by NAFDAC is 2, 789 out of which 2, 291 are imported and 498 are local drugsall clearly labelled (Bureau of Statistics, 2016).

Table 5.11: On NAFDAC gives certification after successful laboratory test have been carried out on a drug product.

AQD3

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Disagree	31	10.6	10.6	10.6
	Undecided	5	1.7	1.7	12.3
	Agree	127	43.5	43.5	55.8
	Strongly Agree	129	44.2	44.2	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.11 shows that, 43.5% of the respondents agree; 44.2% strongly agree; 10.6% disagree and another 0% strongly disagree; while 1.7% are undecided that NAFDAC gives certification after successful laboratory test have been carried out on a drug products. This means that most of the respondents 87.7 agreed that NAFDAC gives certification after successful laboratory test have been carried out on a drug products.Olike (2008), in her study titled ‘‘the fight against fake drugs by NAFDAC in Nigeria’’ agreed with the respondents view stating that NAFDAC issue marketing authorization/certificate and product licensing are issued to pharmaceuticals that meet minimum standards of efficacy, safety and quality. Also, the interview report by owners of pharmacies and medical personnel’s supported the assertion and stated that for this to be more effective, NAFDAC should ensure that Well-qualified inspectors with good knowledge of pharmacy adequately trained should be used in order to avoid deception by fakers of drugs.

Table 5.12: **On NAFDAC registration number is assigned to a product that has meet with NAFDAC standard specification and guidelines.**

RD4

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Disagree	3	1.0	1.0	1.0
	Agree	141	48.3	48.3	49.3
	Strongly Agree	148	50.7	50.7	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.12 shows that, 48.3% of the respondents agree; 50.7% strongly agree; 1.0% disagree and another 0% strongly disagreed; and 0% are undecided that NAFDAC registration number is assigned to a product that has meet with NAFDAC standard specification and guideline. This means that most of the respondents 99% of the respondents, agreed that NAFDAC registration number is assigned to a product that has meet with NAFDAC standard specification and guideline. Nebo Okwudili .G (2015),was in agreement with the respondents view in his work titled ‘‘the impact of government regulations on the marketing of food and drug products in Nigeria’’ stating that, all drugs meant for the Nigerian market, whether locally manufactured or imported into the country have to be tested by the agency and that such drugs must be registered by NAFDAC. The researcher further added that any drug that is not registered or does not have NAFDAC registration number will not be allowed into the Nigerian market. This implies that NAFDAC to a greater extent is engaged in the registration of drugs especially those that have passed through them even though, much need to be done as there are still drug in the drug market that have not been registered.

SECTION D: Inspection of Imported Regulated Drug Products

Questions Related to Hypothesis Three; Inspection of Imported Regulated Drug Products

The following questions were asked based on hypothesis one; There is no significant effect on the inspection of imported regulated products on the control of fake drugs by NAFDAC in Kaduna State.

Table 5.13: On NAFDAC staff consistently go on routine checks of pharmacies to ensure compliance with standard specification in Kaduna State.

IRD1

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	177	60.6	60.6	60.6
	Strongly Agree	115	39.4	39.4	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.13 shows that, 60% of the respondents agree; 39.4% strongly agree; 0% disagree and another 0% strongly disagree and while 0 are undecided that NAFDAC staff consistently go on routine checks of pharmacies to ensure compliance with standard specification in Kaduna State in Kaduna State. This means that 100% of the respondents agreed that NAFDAC staff consistently go on routine checks of pharmacies to ensure compliance with standard specification in Kaduna State in Kaduna State. Orga Josephine (2011), in her work titled ‘‘impact of NAFDAC on quality management of Nigerian manufacturing sector’’ agreed with the respondents assertion stating that NAFDAC undertakes these visits unannounced to assess the good manufacturing practice (GMP) status and level of compliance with standard. Samples are drawn for laboratory

evaluation at such visits. This implies that, NAFDAC have tried to carry out her duty to control the preponderance of fake drug in Kaduna State.

Table 5.14: NAFDAC staff consistently monitors the activities of drugs importers, distributors and sellers in Kaduna State.

IRD2

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	228	78.1	78.1	78.1
	Strongly Agree	64	21.9	21.9	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.14 shows that, 78.1% of the respondents agree; 21.9% strongly agree; 0% disagree and another 0% strongly disagree; and 0% are undecided NAFDAC staff consistently monitors the activities of drugs importers, distributors and sellers in Kaduna State. This means that, 100% of the respondents agree that NAFDAC staff consistently monitors the activities of drugs importers, distributors and sellers in Kaduna State. The NAFDAC Annual Reports, 2016/2017 in agreement to this finding, shows us that NAFDAC have made 323 establishment visits all in an attempt to monitor the activities of drug sellers in the state.

Table 5.15: NAFDAC inspectors seizes expired drugs and take legal actions on offenders in Kaduna State.

IRD3

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	141	48.3	48.3	48.3
	Strongly Agree	151	51.7	51.7	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.15 shows that, 48.3% of the respondents agree; 44.2% strongly agree; 51.7% disagree and another 0% strongly disagree and 0% are undecided that some drug outlets still sell expired drugs in Kaduna State. This means that, 100% of the respondents agreed

that NAFDAC inspectors seizes expired drugs and take legal actions on offenders in Kaduna State. The interview report of NAFDAC officials is in agreement with the respondents view stating that, NAFDAC have achieved huge success through mop-out of more than 300,000,000 worth of fake drugs, closed down several factories, 579 sanction actions, placement on-holds, and lots of administrative charges within the last 90 days (NAFDAC Annual Reports, 2017). This implies that NAFDAC is in the move of controlling fake drugs in Kaduna State though might be constrained by one reason or the other.

Table 5.16: On the level of inspection exercises carried out by NAFDAC staff in Kaduna State is satisfactory.

IRD4

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	117	40.1	40.1	40.1
	Strongly Agree	175	59.9	59.9	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.16 shows that, 40.1% of the respondents agree59.9% strongly agree; 0% disagree and another 0% strongly disagree and 0% are undecided that some drug outlets still sell drugs with no full address of producers or manufacturers in Kaduna State. This means that, 100% of the respondents agree that the level of inspection exercises carried out by NAFDAC staff in Kaduna State is satisfactory. Based on the interview report of NAFDAC staff, the report revealed that in assessing the level of success, I will like to say that NAFDAC have achieved huge success through mop-out of more than 300,000,000 worth of fake drugs, closed down several factories, made 323 establishment visits, 579 sanction actions, placement on-holds, and lots of administrative charges within the last 90 days (NAFDAC Annual Reports, 2016/2017). This the interviewee stated is a function of her inspection effort and added that more needs to be done since there are still cases of fake drugs in the state.

Table 5.17: NAFDAC inspectors visit drug facilities and conduct quality test through the use of their technology.

IRD5

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	strongly Disagree	2	.7	.7	.7
	Disagree	10	3.4	3.4	4.1
	Undecided	1	.3	.3	4.5
	Agree	220	75.3	75.3	79.8
	Strongly Agree	59	20.2	20.2	100.0
	Total	292	100.0	100.0	

Source: Field Study, 2017

Table 5.17 shows that, 75.3% of the respondents agree; 20.2% strongly agree; 3.4% disagree and another 0.7% strongly disagree; while 0.3% are undecided that some drugs are mislabelled and sold to consumers within Kaduna State. This means that, 95.5% of the respondents agreed that, NAFDAC inspectors visit drug facilities and conduct quality test through the use of their technology. Fortunately, Okwudile (2015) stated in his paper titled ‘‘the impact of government regulations on the marketing of food and drug products in Nigeria’’ that all drugs meant for the Nigerian market, whether locally manufactured or imported into the country is tested by NAFDAC. The interview report of NAFDAC staff support the fact that NAFDAC is employing technology such as Truescan device, Mobile Authentication System, the Black Eye and Radio Frequency System, etc. the interviewee also disclosed the fact that there were shortages of these machines to cover the entire state for effective inspection exercise to be facilitated.

5.2 Response from Interview

i. There are still a lot of fake or counterfeit drugs in Kaduna state and Nigeria though, NAFDAC have been doing her best and records has shown that there is a decrease but then, are lots of local and foreign drugs from fakers making it very different to differentiate between genuine drugs in the state today.

ii. NAFDAC have actually been monitoring the activities of drug manufacturers, distributors and pharmacist's and as a result of this effort, have carried out mop-out of more than 300,000,000 worth of fake drugs, closed down several factories, made 323 establishment visits, 579 sanction actions, placement on-holds, and lots of administrative charges between June to August 2017 (NAFDAC Annual Reports in Abuja, 2017). Furthermore, NAFDAC through information gotten from the public have been proactive through routine surveillance, investigation to find the validity of the information gotten, placing products on hold, collection and sampling of such suspected products in their laboratory, mop-out actions if drugs are out of date and fining defaulters, and handling some of them to the court of law where necessary and imposing punishments where necessary.

iii. NAFDAC have tried in terms of drug registration which is why we must see NAFDAC Registration Number in whatever genuine drug we purchase even though, much needs to be done by her because we also have a lot of fake drugs that have infiltrated the market that do not carry the NAFDAC Number but yet get into the market for sale detrimental to the health of innocent Nigerians. The effort of NAFDAC in terms of registration is captured by the ''Drug and Related Product (Registration) Decree No. 19 of 1993.

iv. NAFDAC compile standards to ensure that manufacturers produce drugs with good quality ripe enough for consumption through some laws such as the Poison and Pharmacy Act, Cap 336 of 1990, Counterfeit and Fake Drug Act Cap 73 of 1990, etcetera. In order to achieve this, NAFDAC has adopted measures such as the use of modern technologies such as cutting-edge technologies, Black Eye, Mobile Authentication Service (MAS) amongst others to checkmate the standard and genuineness of drugs by NAFDAC or consumers themselves through the

MAS.Some of the factors hindering compliance of standard specifications and guidelines compiled by NAFDAC is as follows:

a. Weak enforcement by NAFDAC since punishment on defaulters is not commensurate with crime committed.
b. People capitalize or build on the weak enforcement of laws
c. Compromises by NAFDAC staff for financial gain.
d. Shortage of personnel's or staff to monitor activities.
e. Poor power supply and lack of equipment's to carry out scientific tests and scans on drugs.
f. Poor personnel training and development.
g. Poor funding as a result of large coverage (local governments in the state).
h. Ignorance of the people despite enlightenment and also on the side of unprofessional hands since they do not have the technical knowhow to preserving even the genuine drugs, and these unprofessional only think of money and not the quality of the products they sell to the masses.
i. Poor funding of NAFDAC has demoralize officials since the agency can't even afford the money to lodge their staff when they go to various localities that require thorough checks and this automatically affect the performance of the agency.

v. The current regulatory activities of government are not adequate to protecting the interest of pharmacies in the state else, there won't be fake drugs as much as this in the state and country at large today. E.g., we have open markets for drugs in the state and today, drug is an article of trade in the state today. There are no adequate laws governing counterfeit or fake drugs in the state today. Furthermore, there is need to review our laws to some extent even though, our major problem,

lies in poor implementation of our existing drug laws and lack of respect for our existing laws.

vi. Some of these problems pharmaceutical firms encounter in adapting to NAFDAC's regulation are as follows:

   a. High cost of drug production as a result of poor power supply, bad road networks, high import duties on raw materials, etc.
   b. Competition from fakers who produce low quality drugs that tends to be cheaper in the market.
   c. Open market without proper drug distribution chain and unlicensed drug sellers like patent stores or medical stores that operate in the drugs market.

vii. Some of the possible solutions to curbing the problem of fake or counterfeit drugs in the state are as follows:

   a. The government must adequately finance NAFDAC so that it can employ more manpower to carry out routine checks, etc.; acquire modern machines and promote manpower training and development.
   b. Locally manufactured drug producers or fakers, should be granted amnesty and empowered to making them useful to promoting standards in the drug industries not just in the state but in the country at large.
   c. Ensuring strict adherence to the existing drug laws of the land.
   d. Sale of drug matters, should only be open to professionals who are licenced i.e. pharmacist's and closed to open markets, drug outlets, medical stores, drug hawkers, etc.
   e. Regular checks and inspections should be ensured at our boarders and at all local levels of the state.

f. The government should pass a bill possibly of death or life imprisonment to drug offenders as they are threats to the manpower of not just the state, but the country.

5.3 Test of Hypotheses

Ho_1: There is no significant effect of standard specificationon the control of fake drugs by NAFDAC in Kaduna State.

SS

	Observed N	Expected N	Residual
14.33	1	11.7	-10.7
15.17	23	11.7	11.3
15.33	2	11.7	-9.7
16.17	3	11.7	-8.7
16.33	2	11.7	-9.7
17.17	2	11.7	-9.7
17.33	24	11.7	12.3
17.50	2	11.7	-9.7
17.83	1	11.7	-10.7
18.50	1	11.7	-10.7
18.67	3	11.7	-8.7
18.83	2	11.7	-9.7
19.67	24	11.7	12.3
19.83	27	11.7	15.3
20.33	1	11.7	-10.7
20.67	25	11.7	13.3
20.83	3	11.7	-8.7
21.17	6	11.7	-5.7
21.33	23	11.7	11.3
21.67	25	11.7	13.3
21.83	1	11.7	-10.7
22.17	1	11.7	-10.7
22.50	2	11.7	-9.7
22.67	59	11.7	47.3
22.83	29	11.7	17.3
Total	292		

Source: Field Study, 2017

Decision Rule

The decision rule on the postulated hypotheses stated that, if p-value is less than alpha (p-value <a), we reject the null hypothesis, while if p-value is greater than alpha (p-value >a), we accept the null hypothesis. For the purpose of this study, alpha will be taken at 5% level of significance. Since our p-value is < 0.005, i.e 0.000, we reject the null hypothesis and accept the alternate hypothesis that there is a significant effectofstandard specification on the control of fake drugs by NAFDAC in Kaduna State.

Ho_2: There is no significant effect of the registration of drugs on the control of fake or counterfeit drugs by NAFDAC in Kaduna State.

RD

	Observed N	Expected N	Residual
6.00	5	13.9	-8.9
6.25	22	13.9	8.1
7.00	1	13.9	-12.9
7.25	2	13.9	-11.9
7.50	2	13.9	-11.9
8.25	8	13.9	-5.9
9.00	23	13.9	9.1
9.25	1	13.9	-12.9
10.00	26	13.9	12.1
10.25	5	13.9	-8.9
11.00	29	13.9	15.1
11.25	27	13.9	13.1
12.00	3	13.9	-10.9
12.25	29	13.9	15.1
12.50	1	13.9	-12.9
13.00	24	13.9	10.1
13.25	1	13.9	-12.9
14.00	27	13.9	13.1
14.25	27	13.9	13.1
15.00	3	13.9	-10.9
15.25	26	13.9	12.1
Total	292		

Source: Field Study, 2017

Decision Rule

The decision rule on the postulated hypotheses stated that, if p-value is less than alpha (p-value <a), we reject the null hypothesis, while if p-value is greater than alpha (p-value >a), we accept the null hypothesis. For the purpose of this study, alpha will be taken at 5% level of significance. Since our p-value is < 0.005, i.e 0.000, we reject the null hypothesis and accept the alternate hypothesis that there is a significant effect of the

registration of drugs on the control of fake or counterfeit drugs by NAFDAC in Kaduna State.

Ho_3: There is no significant effect of the inspection of imported regulated products on the control of fake drugs by NAFDAC in Kaduna State.

IRD

	Observed N	Expected N	Residual
16.20	2	26.5	-24.5
16.40	9	26.5	-17.5
16.60	1	26.5	-25.5
16.80	40	26.5	13.5
17.80	32	26.5	5.5
18.80	95	26.5	68.5
19.00	57	26.5	30.5
19.40	1	26.5	-25.5
19.80	53	26.5	26.5
20.00	1	26.5	-25.5
21.00	1	26.5	-25.5
Total	292		

Source: Field Study, 2017

Decision Rule

The decision rule on the postulated hypotheses stated that, if p-value is less than alpha (p-value <a), we reject the null hypothesis, while if p-value is greater than alpha (p-value >a), we accept the null hypothesis. For the purpose of this study, alpha will be taken at 5% level of significance. Since our p-value is < 0.005, i.e 0.000, we reject the null hypothesis and accept the alternate hypothesis that there is a significant effect of the inspection of imported regulated products on the control of fake drugs by NAFDAC in Kaduna State.

Test Statistics

	IRD	RD	SS
Chi-Square	378.397[b]	208.116[a]	444.644[d]

Df	1020	20	24
Asymp. Sig.	.000	.000	.000

Source: Field Study, 2017

5.4Major Findings

i. NAFDAC have been able to outline some standards guiding the production, importation, distribution and sale of drugs not just in Kaduna State but in Nigeria as well as penalties for not complying with those standards.

ii. NAFDAChave succeeded in drug registration which is why we must see NAFDAC Registration Number in whatever genuine drug we purchase even though, much needs to be done by her because we also have a lot of fake drugs that have infiltrated the market that do not carry the NAFDAC Number but yet get into the market for sale detrimental to the health of innocent Nigerians. Furthermore, it was discovered that there exist compromise by some NAFDAC staff for financial gains, poor implementation of laws guiding the registration of drugs and because the laws governing NAFDAC's operation are weakinadequate in terms of punishing corrupt officials, gives room for misdeeds even by these officials.

iii. Some of the factors affecting the inspection of drugs in Kaduna State ranges from shortage of personnel or inspectors to monitor drug activities in Kaduna State due to large coverage size, shortage of scan machines to enable personnel detect fake drugs easily to even chaotic drug market in the state. Also, poor funding as a result of large coverage has demoralize staff since NAFDAC can't even afford the money to lodge inspectors when they go on to various localities that requires thorough checks has affected the performance

of the agency as well as finance to acquire scan machines affects NAFDAC's effort towards inspection.

iv. NAFDAC to a greater extent have regulated and control the manufacture, advertisement and sale of drugs in Kaduna State. NAFDAC in her effort to control the proliferation of drugs in Kaduna State, have been able to seize, and destroy thousands of drugs through her mop-out of more than 300,000,000 worth of fake drugs, closed down several factories, made 323 establishment visits, 579 sanction actions, placement on-holds, and lots of administrative charges within the last 90 days (NAFDAC Annual Reports, 2017).

CHAPTER SIX

SUMMARY, CONCLUSION AND RECOMMENDATIONS

6.1 Introduction

This chapter presents as summary of findings made in the course of the study vis-à-vis what the study entails as well as the resultant conclusion and recommendation that serves as remedial elixirs that will help to tackle some of the challenges to ensure future prospect if implemented.

6.2 Summary

The drug distribution network in Kaduna State, is in a state of chaos because it consists of open markets, patent medicine stores, community pharmacies, private and public hospitals, wholesalers/importers and pharmaceutical manufacturers. It is a common scene in Nigeria, to see petty traders who sell kola nuts, cigarettes, and oranges, among other items, in market kiosks, motor parks, and road sides hawking drugs that range from over-the-counter items to antibiotics popularly called "capsules" (Adelusi and Adeluyi, 2000). This is a typical reflection of what is happening in Kaduna state today posing a threat to public health in the state. The medicines are usually left under the sun in such conditions that could facilitate the deterioration of the active ingredients while other are fake which are even more harmful to human health. This study accesses the activities of NAFDAC in the control of fake or counterfeit drugs in Kaduna state. This study adopts survey research design where the study employs both qualitative and quantitative methods, driven by the qualitative method. The survey consists of questionnaire and interview which were used to collect relevant data for this study with more emphasis on questionnaire backed by systematic interview. Chapter one forms the introductory part; this is where the main theme of the research is discussed. It comprises of the statement of the problem, objectives of the study, significance of the study, scope and limitation of the study and organization of the study. Chapter two consists of the literature review on the subject matter. Research methodology is discussed in chapter three, which consists of the research design, population and sample size, sampling technique, sources of data,

administration of instruments and method of data presentation and analysis. Chapter four consists of drug regulating agencies in Nigeria and other countries in the fight against fake drugs, Chapter five consists of the data presentation and analysis; while chapter six consists of the summary, conclusion and recommendations.

6.3 Conclusion

In Nigeria today, there is an influx of fake drugs into the market globally, nationally and in Kaduna State. It may appear that almost every existing product has a fake counterpart as the era 1985-2000 in Nigeria has heralded the regime of faking and quackery, counterfeit drugs, quack doctors, illegal chemist hospitals and drugs are no exception (Ohuabunwa, 2002). The menace of fake drugs became prevalent in the last decade and the present situation is alarming in the West African sub-region, including Nigeria. Empirical observations have shown that there may be more fake than genuine drugs in circulation (Osibo, 1998).

A disturbing aspect of the counterfeit drug menace is that, the effects of consuming such drugs go unnoticed most of the times except in such cases where it results in causing health challenges like organ dysfunction, worsening of disease conditions, generating body resistant's to treatment and mass deaths. From the data generated, it was discovered that there was poor implementation of laws guiding the registration of drugs and because the laws governing NAFDAC's operation are weak and inadequate in terms of punishing corrupt officials, gives room for misdeeds even by these officials. Also, there are generally no reliable data on the mortality or morbidity arising from the consumption of counterfeit drugs in Kaduna State and Nigeria as a whole.Furthermore,the current regulatory activities of government are not potent enough, to protecting the interest of pharmacies in the state else, there won't be fake drugs as much as this in the state and

country at large today. E.g., we have open markets for drugs in the state and today, drug is an article of trade in the state today.

Conclusively, from the data obtained in this study, there is a significant effect of the activities of NAFDAC on the control of fake drugs in Kaduna State.

6.4.1 Recommendations

In the light of the findings of this study, the following recommendations could be deducted at various levels:

i. Supervisory bodies should be secretly setup to monitor the activities of NAFDAC officials in Kaduna state against any corrupt practice in the course of registration and even inspection duty by her officials to ensure that culprits and violators of laws are adequately punished. Furthermore, the drug law should be reviewed in such a way that more stringent or capital punishments such as life imprisonment or even death sentence be imposed on those who fail to meet up with standards and drug laws than just paying fines.

ii. NAFDAC should ensure that they ensure strict adherence to standard specified for the promotion of good production practice, distribution and sale of genuine drugs in the country.

iii. The government should be willing to recruit new hands who are specialist in their various fields of endeavor having the technical-know-how to help NAFDAC in the execution of her activities and to ensure adequate coverage of the state in other to carry out routine checks, etc. Furthermore, the government should continue to empower NAFDAC to strengthen her efforts in the control of fake drugs in the state by acquiringmodern machines to upgrade the central laboratory and promote manpower training and development.

iv. More mop-out actions should be carried out by NAFDAC as well as establishment visits and closures of fake and unlicensed drug stores and factories where necessary.

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Appendixes:

Appendix I:

Interview Schedule for NAFDAC Staff

1. What can you say about NAFDAC in relation to routine checks and inspections of pharmacies in Kaduna State?
2. What can you say with regards to NAFDAC and registration of drugs?
3. What can you say in terms of the creation of public awareness and sensitizations by NAFDAC in Kaduna State?
4. Are laws governing the eradication of fake or counterfeit drugs in Kaduna state adequate?
5. How can you assess your level of success in terms of regulating and controlling the manufacture, advertisement and sale of drugs in Kaduna State?
6. What can you say about the role of NAFDAC in terms of issuingstandards and approval for the sale of drugs?
7. What is hindering compliance of standard specifications and guidelines compiled by NAFDAC in Kaduna state as well as solutions to these challenges?
8. What other factors that have encouraged the proliferation of fake or counterfeit drugs in Kaduna state?

Appendix II:

Interview Schedule for Owners of Pharmaceuticals

1. Can you briefly tell me how you perceive the problem of fake or counterfeit drugs in Kaduna state from 2001 to 2016?
2. Can you say in your own opinion that NAFDAC monitors the activities of drug distributors in Kaduna state and why?
3. What can you say about the registration of drugs by NAFDAC in Kaduna State?
4. What can u say about NAFDAC standards for the production, importation sale and distribution of drugs?
5. How has NAFDAC been able to ensure that drugs meet up to standards before they are approved for sale?
6. Are the current regulatory activities of government actually protecting the interest of pharmaceuticals in Kaduna state?
7. Are the laws governing counterfeit and fake drugs adequate to curb the menace of drug faking and counterfeiting?
8. What in your opinion are the possible suggestions to curbing the problem of fake or counterfeit drugs in Kaduna State?

Appendix III:

Questionnaire for the Projects

Department of Public Administration,

Faculty of Administration,

Ahmadu Bello University,

Zaria.

Dear Respondent,

I am a postgraduate student from the above department, faculty and institution carrying out a research on the topic "**Assessment of NAFDAC Activities in the Control of Fake or Counterfeit Drugs in Kaduna State**." The questionnaire is meant to elicit responses and gather information that will enrich the entire research. Note that any information provided will be treated confidential and used only for the purpose of this research.

Thank you.

Yours Faithfully,

Kenneth Zheihnom, KURASON

General Guidelines

The questionnaire is divided into 4 sections. You are kindly requested to answer the questions in all the sections. Give your immediate sincere impressions.

There is no right or wrong answers for each of the statements below: Please tick [□] the alphabet where applicable, the rating scaled (A) strongly disagree, to (E). Strongly agree. (A B C D and E)

SECTION A: BIO DATA

1. Sex
   a) Male [ ] (b) Female[ ]
2. Age group
   (a) 18-30 years [ ] (b) 31-40 years [ ] (c) 41-50 years [ ] (d) 51 years and above [ ]
3. Occupation
   (a) Medical Doctor [ ] (b) Nurse [ ] (c) Others [ ]
4. Local Government Area (LGA) of Resident
   (a) Kaduna South LGA [ ] (b) Chikun LGA [ ] (c) Zaria LGA [ ]

	Strongly disagree	Disagree	Undecided	Agree	Strongly agree
	A	**B**	**C**	**D**	**E**
SECTION B: INSPECTION OF IMPORTED REGULATED DRUG PRODUCTS					
5. NAFDAC staff consistently go on routine checks of pharmacies to ensure compliance with standard specification in Kaduna State?					
6. NAFDAC staff consistently monitors the activities of drugs importers and distributors in Kaduna State?					
7. The level of inspection exercises carried out by NAFDAC staff in Kaduna State is satisfactory?					
8. NAFDAC inspectors seizes expired drugs and take legal actions on offenders in Kaduna State?					
9. NAFDAC inspectors visit drug facilities and conduct quality test through the use of their technology?					
SECTION C: REGISTRATION OF DRUGS					
10. NAFDAC ensures proper documentation by manufacturers and drug sellers before certification of product?					
11. NAFDAC ensure clear and accurate label of drug products before full certification of the product?					
12. NAFDAC gives certification after successful laboratory test have been carried out on a drug product?					
13. NAFDAC registration number is assigned to a product that has meet with NAFDAC standard specification and guidelines?					
SECTION D: STANDARD SPECIFICATION					
14. NAFDAC uses test method for determining the quality of drugs produced?					
15. NAFDAC ensures standard specification by engaging in public enlightenment and sensitization of masses?					
16. NAFDAC introduces the use of modern technology to checkmate and ensure the standard of drugs?					
17. NAFDAC have improved her laboratory services to enhance the standard of					

drugs?					
18. NAFDAC compilestandards for the sale of drugs in Kaduna State?					
19. NAFDAC compile standards for the distribution of drugs?					

Appendix IV

Reliability Test

Scale: ALL VARIABLES

Case Processing Summary

		N	%
Cases	Valid	289	98.6
	Excluded[a]	4	1.4
	Total	293	100.0

a. List wise deletion based on all variables in the procedure.

APPENDIX ‘‘V’’

KREJCIE AND MORGAN’S TABLE FOR DETERMINING SAMPLE SIZE FROM A GIVEN POPULATION

N	S	N	S	N	S
10	10	220	140	1200	291
15	14	230	144	1300	297
20	19	240	148	1400	302
25	24	250	152	1500	306
30	28	260	155	1600	310
35	32	270	159	1700	313
40	36	280	162	1800	317

45	40	290	165	1900	320
50	44	300	169	2000	322
55	48	320	175	2200	327
60	52	340	186	2400	331
65	56	360	191	2600	335
70	59	380	196	2800	338
75	63	400	201	3000	341
80	66	420	205	3500	346
85	70	440	210	4000	351
90	73	460	214	4500	354
95	76	480	217	5000	357
100	80	500	226	6000	361
110	86	550	234	7000	364
120	92	600	242	8000	367
130	97	650	248	9000	368
140	103	700	254	10000	370
150	108	750	260	15000	375
160	113	800	265	20000	377
170	118	850	265	30000	379
180	123	900	269	40000	380
190	127	950	274	50000	381
200	132	1000	278	75000	382
210	136	1100	285	1000000	384

NOTE: N is population size,
S is sample size.

APPENDIX "VI"

Profile of interviewees

Sample area	Representatives	Date and time of Interview
NAFDAC	State Coordinator	01/08/2017. 11am
NAFDAC	Zonal Coordinator	01/08/2017. 12pm
NAFDAC	Staff	03/08/2017. 11am
NAFDAC	Staff	03/08/2017. 12pm
Psychiatric Hospital Kaduna	Doctor	03/08/2017. 02pm
ST. Gerald Hospital	Doctor	03/08/2017. 2:20pm
PCN	Chairperson	02/08/2017. 02pm
Aslad Pharmacy	Pharmacist	02/08/2017. 12pm
Zabaiye Pharmacy	Pharmacist	02/08/2017. 10.30am
Psychiatric Hospital Kaduna	Pharmacist	04/08/2017. 03pm
Maigari Memorial Hospital	Doctor	04/08/2017. 11am