AN ANALYSIS OF THE IMPACT OF NAFDAC (NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL) IN DRUGS QUALITY IMPROVEMENT IN NIGERIA

Research dissertation presented in partial fulfilment of the requirements for the degree of MSc in Pharmaceutical Business and Technology (QQI)

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Candidate Declaration

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I certify that the dissertation entitled: “An Analysis of the Impact of NAFDAC (National Agency for Food and Drugs Adminstration and Control in Nigeria) in Drugs Quality Improvement in Nigeria ” submitted for MSc in Pharmaceutical Business and Technology is the result of my own work and that where reference is made to work of others, due acknowledgment is given.

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ABSTRACT

Counterfeit drugs are non-authentic drugs that have been manufactured using incorrect amounts or incorrect ingredients to either reduce or nullify the potency of the drugs. Trading and use of counterfeit drugs have been reported by WHO(World Health Organization) as one of the causes of high morbidity, mortality in the Nigerian health sector. This study aims to identify the impact of NAFDAC on drug quality control in Nigeria. A cross-sectional survey of 37 participants, including medical professionals, NAFDAC staff, pharmacists and consumers was done using a questionnaire. Results from the study revealed that the drug situation in Nigeria is not good and that the high cost of good quality drugs, inadequate laws or poor enforcement of the existing drug quality control regulations and the inadequate drug distribution monitoring system were the major factors influencing the production and distribution of low-quality drugs in Nigeria. NAFDAC has set up enforcement officers for control and routine inspection, providing mobile authentication of services to help consumers differentiate fake from original drugs to combat this issue. In conclusion, NAFDAC is trying its best to combat the drug issues in Nigeria but more efforts are needed to make it effective. This study recommends that the government should subsidise the cost of drugs, put up more stringent drug laws and punishment for defaulters to discourage production and distribution of counterfeit drugs in Nigeria.

Key Words: Counterfeit, Drug quality, NAFDAC (National Agency for Food and Drugs Administration and Control in Nigeria).

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ABBREVIATIONS

WHO	World Health Organisation
UNODC	UN Office on Drugs and Crime
NAFDAC	National Agency for Food and Drugs Administration and Control in Nigeria
ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for human use
TGA	Therapeutic Goods Administration
SAHPRA	South African Health Product Regulatory Authority
QC	Quality control
FCT	Federal Capital Territory
SON	Standard Organization of Nigeria
NIPRD	National Institute for Pharmaceutical Research and Development
PCN	President of the Pharmacists' Council of Nigeria
NDLEA	National Drug Law Enforcement Agency in Nigeria
HRM	Human Resource Management
F & A	Finance & Accounting
RSP	Research & Statistical Planning
R&R	Registration & Regulatory Affairs
LS	Laboratory Services
PID	Ports Inspection
FSAN	Food Safety & Applied Nutrition
DER	Drug Evaluation & Analysis
CER	Chemical Evaluation & Research
PV-PMS	Pharmacovigilance & Post Marketing Surveillance
VMAP	Veterinary Medicine & Allied Products
SD	Special Duties
NCS	Narcotics & Controlled Substances
ECOWAS	Economic Community of West African States
OTC	Over the Counter
INTERPOL	International Criminal Police Organisation
EID	Directorate of Establishment Inspectorate
GMP	Good Manufacturing Practice
GDP	Good Distribution Practice
DRA	Drug Registration Agency
MHRA	Medicine and Healthcare Products Regulatory Agency
GFDB	Ghana Food and Drug Board
NBA	Nigerian Bar Association
SON	Nigerian Standard Organization
NPC	National Pharmacovigilance Centre
SME	Small and Medium-sized Enterprise
MAS	Mobile Authentication Service
SMS	Short Message Service
UNTH	University of Nigeria Teaching Hospital
ESUTH	Enugu State University of Science and Technology Teaching Hospital
SPSS	Statistical Package for Social Sciences

CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

Trading and use of substandard and counterfeit drugs have been reported by WHO as one of the causes of high morbidity, mortality, and lack of public confidence in the health sector worldwide.

Reports suggest that substandard and counterfeit drugs have had side effects on users, ranging from injury, complications, paralysis, disability and treatment failure, and in some cases even death (WHO 2006).

Fake and substandard drugs are non-authentic drugs: that are manufactured using incorrect amounts of ingredients, and subsequently reducing the potency of the drugs. Fake and substandard drugs or "counterfeit drugs" was described by the World Health Organization as "a medicine intentionally and fraudulently mislabelled with respect to identity and/or source". Counterfeiting may refer to both branded and generic products, and counterfeit products can include items with the right ingredients or the wrong ingredients, with insufficient active ingredients, or with fake packaging "(WHO 2006). Thus, drug counterfeiting has been identified as a serious public health issue that has taken on global dimensions and is gaining ground rapidly daily with many new cases reported (Akinyandenu 2013). However, worldwide it has been noted that counterfeit drugs are an organized crime that gives a lot of profit to criminals. According to a survey, "in many parts of the world, criminals have discovered that drug counterfeiting is lucrative financially and of relatively low risk. As a result, organized crime has moved from drug smuggling and arms handling to drug counterfeiting "(Akunyili 2005).

In general, counterfeiting of drugs has been reported to impact various countries in different ways. Data on global and regional counterfeiting incidence are highly misleading because they are underreported or they have not been revised. Therefore, what is collected as data is pure estimates of the crime. Factsheet (2013) made this argument clearly, claiming that: counterfeiting of medical goods and related crimes impact all countries, whether as countries of origin, transit, or marketplace.

Recent figures indicate that global sales of counterfeit drugs are worth more than €57 billion, having doubled between 2005 and 2010, in just five years.

Counterfeit medicines have become a serious problem for developed countries, with a calculated effect on lives. For example, 200,000 of the one million deaths from malaria that occur each year worldwide are probably the product of counterfeit anti-malaria drugs (Karunamoorthi 2014).

However, a current meta-analysis by Ozawa et al. (2018) revealed a high prevalence of 13.6% of substandard and counterfeit drugs in underdeveloped countries. Also, WHO made an estimate of about 10% of medical products in underdeveloped countries to be of low standard and falsified, which gives a lot of burden to the health systems, destroys the confidence, and increases the illness, morbidity, and mortality risk. It suggests that 700,000 Africans die each year from the use of bogus antimalarial or tuberculosis drugs (Akinyandenu 2013). Nigeria has been reported to have one of the highest incidences of low standard and fake drugs in Sub-Saharan Africa (Spink et al., 2016). There have also been so many reports of deaths as a result of the consumption of low standard and fake drugs in Nigeria (Akinyandenu 2013).

Over recent years, these high instances of counterfeit medicines around the globe have given rise to the anti-counterfeiting epoch that dovetails the fight against the hazard. The war is gathering traction globally and the anti-counterfeiting regulatory agencies are engaged in a whirlwind of activities and initiatives to curb the threat. In 2006, the World Health Organization (WHO) launched a global policy on drugs of low quality, with a specific emphasis on the African countries (WHO 2007). The UN Office on Drugs and Crime (UNODC) followed suit in 2010 and for the first time identified illicit drugs as a major concern in its Global Crime Threat Assessment alongside cocaine trafficking, maritime piracy, and trafficking in human beings (WHO 2013). Three years later Interpol also joined these efforts by signing a landmark pharmaceutical company's agreement to expand its fight against so-called pharmaceutical crime (Interpol 2014). In the last 17 years, the issue of fake pharmaceuticals has become a major concern for international cooperation in health and law enforcement, as well as in national policy debates, especially in the global South.

However, Nigeria is not left out of this move and has set up a regulatory agency the National Agency for the Administration and Control of Food and Drugs (NAFDAC), which was at the

forefront of the war. The Federal Government of Nigeria created NAFDAC in 1993 with the task of safeguarding the nation's health by providing effective regulation of the economy's food, drug, and chemical industry. One of the agency's goals was to make sufficient supplies of drugs that are reliable, secured, accessible, and of good quality available to the Nigerian population at all times. The death of 150 children due to error in the formulation of drug syrup 'My Pikin' triggered the introduction of this agency in Nigeria (NAFDAC 2017). According to Keris (2004), the agency has the function of ensuring that all products registered by it meet the standards acceptable with respect to quality and efficiency.

One of the measures which is adopted by NAFDAC to control the production of fake drugs is drug registration of medicinal products that comes into Nigeria.

Drug registration by NAFDAC is the process of ensuring that adulterated or fake drugs are not allowed into the Nigerian drug market. WHO (2002) defined a fake drug as one which is mislabelled intentionally or fraudulently with respect to the source and/or identity. WHO stated that fake drugs are:

a. any drug or drug products which are so coated, coloured, polished or powdered in such a way that the damage is hidden, or which is made to look better or of higher therapeutic value than it actually is;
b. any drug or drug product in which the container is formed, made, or filled in such a way as to be misleading.
c. any drug or drug product in which the label does not have an appropriate direction for use or adequate caution against use under the conditions listed below :
    1. A certain pathological conditions that are contraindicated.
    2. Adequate usage dose for children.
    3. Usage dosage for adults.
    4. Certain methods for the duration of use.
    5. Side effects of the drug.

Apart from the above measures, there are so many other roles/measures adopted by NAFDAC to improve the quality of drugs produced in Nigeria.
Therefore, this study seeks to find out the various roles/measure which NAFDAC has taken to improve the quality of drugs produced and distributed in Nigeria.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for human use (ICH) is an effort bringing together regulatory authorities and the pharmaceutical industry to address the scientific and technological aspects of producing and registering pharmaceutical products. ICH put up guidelines and criteria for the registration of pharmaceutical products with the aim of fostering public health. These guidelines include quality, safety, efficacy, and multidisciplinary guidelines. They help to address and decide on the scientific issues resulting from drug registration and curtail the production and distribution of fake drugs around the world. The ICH guidelines are being used by mostly the European countries, the Japanese, and the United States. Some other countries who are members of and use the ICH guidelines include Brazil, Singapore, Canada, Republic of Korea, China, and Switzerland, etc. Some of the ICH observers include World Health Organisation (WHO), Therapeutic Goods Administration (TGA), Australia; South African Health Product Regulatory Authority (SAHPRA), South Africa; and many more (Brennan 2015).

However, NAFDAC is not among the members or observers of the ICH, and so, not regulated or affected by its guidelines.

Nigeria does not use the ICH guidelines, due to the fact that ICH was made to regulate the activities of the European, Japanese and United States, NAFDAC does not use their guideline as these guidelines were built around the activities of these countries.

1.2 Statement of the Problem

The issue of Low and wrong quality drug production in Nigeria has negatively affected the healthcare system and has brought about very harmful or even deadly effects on the consumers, leading to illness, temporary or permanent disability or even death and any individual can be affected (Akinyandenu, 2013; Foreman 2014, Iwokwagh 2013). For example, 'the use of counterfeit anti-malarial drugs alone takes the lives of over 700,000 Humans annually' (NAFDAC 2017). Scholars such as Osibo (1998) and Bamitale (2013) noted that Nigeria has more fake or counterfeit drugs in circulation than legitimate drugs. Lambo (2006) recorded that in 1990, 54 percent of drugs were fake at every major pharmacy in Lagos and that the figure rose to 80 percent in the following year. Spink et al. (2016), reported that Nigeria has one of the incidences of low quality and fake drugs in Sub-Saharan

Africa and there have also been so many reports of deaths as a result of consuming low standard and fake drugs in Nigeria (Akinyandenu 2013).

According to the World Health Organisation (2007), the prevalence of fake drugs is higher in countries with poor controls, compliance, and supply shortages of essential drugs, unregulated markets, and costs that are not affordable. Because of this, the price, safety, and effectiveness of drug products cannot be guaranteed, especially in developing countries. Fake drug dealers and their associates are constantly attempting to escape detection, and also disguising their activities. Fake drug manufacturing does not need to take place in vast infrastructures or laboratories but in ordinary homes, small cottage industries or in backyards. The high demand for drugs and low manufacturing costs are causing counterfeiters to continue because there is a shortage of effective drug-deterrent legislation. The high cost of medicines makes way for consumers to purchase medicines outside of the normal supply chain, particularly the poor. Poverty and the poor distribution network of drugs are major factors that create a market for fake circulation of drugs. The weakest point in drug control is possible in the field of implementation and compliance, according to the NAFDAC Director-General. The country's harsh socio-political interplay over thirty years has also brought some constraints and led to the weakening of drug control in Nigeria, leading to the faking and dumping of drug products across disorderly channels of drug distribution (NAFDAC customer bulletin 2003).

Drug trafficking by unskilled dealers is a popular phenomenon in the developing world. Such drug dealers are also the first point of healthcare contact by customers who support them for reasons such as ease, supply reliability, and inexpensive quality. The explanation is that most of the time customers don't find drugs in government clinics and the pharmacies licensed are often far and costly. The failure of patients to assess the quality of the drugs they are taking is a significant public health issue as these drugs can be ineffective and dangerous (Dhikav 2003). Fake drugs have the potential to deceive, particularly when replicated to make it look like the original product so consumers are unlikely to be suspicious. For a fact, the mechanism by which patients receive their medications is distinct from that for most consumer goods: they are administered by physicians or health care staff. Also if patients select their own drugs, they will lack the advanced expertise to detect if the drug they are buying is of good quality, let alone being able to detect whether or not the medication is fake (WHO 2007).

The high incidence of fake drugs in Nigeria is a result of the haphazard ways in which an import license on drugs was given in the 1980s to everyone by politicians and military leaders at the time, irrespective of the actual public health implications of their actions. In Nigeria, the epidemic of fake drugs has been a very big issue over the past two decades. Fake medications have proved to be a significant factor in leading to high mortality rates. The problem of fake drugs was so serious that the selling of drugs made in Nigeria was officially banned by neighbouring countries including Ghana and Sierra Leone. Not only did the problem of fake drugs end there, but it went to the point where drugs were hawked even in commercial buses. All of those things have affected Nigeria as a whole. On the one hand, with the launch of the "new NAFDAC" in April 2001, some accomplishments were achieved which caused a reduction in the problems (NAFDAC consumer bulletin, 2003).

The negligence of the dysfunctional judicial system and widespread corruption are major reasons why fake drugs are easy to manufacture and sell. Indiscretion in the system helps counterfeit drug manufacturers to sell their drugs cheaply to chemists who then sell to customers. As a result, the ultimate damage is seized up to not only the patients who are being treated by counterfeit medicine but also affects the credibility of the doctor who was treating patients, as well as giving a bad image to the health system (Dhikav 2003).

The cost of purchasing drugs is very high, making it very difficult to obtain the drug (Lambo 2006). The unorganised and poorly monitored drug distribution network with several illegal shops help in the rise of fake drugs (WHO 2006).

Due to the problems stated above, there is a need for individuals to understand the control measures which have been put in place to improve drug quality production and prevent individuals in the country from falling a victim of consuming low quality or fake drugs. Therefore, this research aims at analysing the impact of the improvement of dugs quality in Nigeria.

1.3 Purpose of the Study

The purpose of this study is to evaluate the impact of NAFDAC on the improvement of drug quality in Nigeria.

1.4 Research Objectives

2. To understand the perception of various group of individuals in Nigeria about the drugs produced/consumed in the country
3. To find out the preferred type of drugs (locally produced or foreign) bought by consumers or prescribed by medical practitioners in Nigeria.
4. To identify the major contributing factors to the production and distribution of low-quality drugs in Nigeria
5. To identify the control measures used by NAFDAC in ensuring the production of good quality drugs
6. To determine the degree to which the objective of drug quality improvement has been achieved in Nigeria.

1.5 Research Questions

2. What are the perceptions of Populations in Nigeria about the drugs produced/consumed in the country?
3. What type of drugs (locally produced or foreign) do Consumers/Customers prefer to use/prescribe/buy?
4. What are the major contributing factors that affect the production, distribution and consumption of low-quality drugs in Nigeria?
5. What control measures have been put up by NAFDAC to influence and improve the quality of drug production and consumption in Nigeria?
6. To what extent have NAFDAC achieved its objectives of drug quality improvement in Nigeria?

1.6 Scope/Delimitation of the Study

This study will cut across the impact of NAFDAC on the quality of medicinal products that are produced/consumed in Nigeria.

It will focus on health professionals, professionals in the drug-production industries as well as NAFDAC members and consumers across Nigeria.

1.7 Outline of the Thesis

The structure of the thesis is as follows: The thesis is divided into six chapters.

Chapter one introduced the research subject topic, explained the reason for and aim of the study as well as the significance of the study to the health and research world.

Chapter two, which is named the literature review is divided into two parts; the first part started by explaining the important concepts of drugs and drug quality, the drug situation in Nigeria as well as NAFDAC and its functions in battling fake drugs. The second section reviewed various works of literature on different works related to the study as these would help broaden the readers' knowledge of what is needed for a good understanding of the study.

Chapter three is termed the research methodology. In this chapter, the researcher explained the suitable methods and designs used in conducting the study which would help meet the research goals and address the research questions.

Chapter four reveals the results of the analysed data. It reports the individual responses to the different questions and analyses them.

Chapter five is the discussion. It discussed the entire work by discussing the results of the study and relating them to the findings from other related studies and how it addressed the research questions, it also summarizes the entire findings from the study, gave recommendations for further studies, and finally concluded the work.

1.8 Significance of the study

This study will be of great benefit to all drug users most importantly the consumers, as the number of individuals who tend to seek medical attention / treatment outside the country will be rest assured that drug products and services are of good quality in the healthcare system in Nigeria.

It will also help to boost the country's confidence and economy standards in the Nigerian pharmaceutical companies as long as they comply to the terms of NAFDAC, they will have customers to patronize them.

It would also add to the existing works of literature on drug quality and serve as reference material to the research students.

CHAPTER TWO

LITERATURE REVIEW

2.1 The Concept of Drug Quality

Medicinal products are important components of the health sector worldwide and also they are very vital to consumers, as they play an important role in patient management and in the pharmaceutical sector. Patients, caregivers, physicians, and the communities have hope that drugs being prescribed and consumed are of good quality and authentic and also meet the right standard.

Drug product quality is said to be how suitable a drug substance or product is for its intended use (International Conference of Harmonization). It involves how strong and pure the drug substance is, the process of manufacturing as well as its supervision. The issue of drug quality is mainly associated with fake and counterfeit medicines, which is seen mainly in developing countries (Ebenezer 2015). For instance, WHO received 771 confidential and public reports regarding counterfeit drugs between 1982 and 1999. About 80% of the reported were from the developing countries whereas the rest of the 20% came from wealthy countries (Ebenezer 2015). The prevalence of low-quality drugs was as well reported to be high in Nigeria and Thailand as well as Myanmar and Vietnam (WHO 1999). However, the Nigerian Government has founded the National Agency for Food, Drug Administration and Control (NAFDAC) to aid in the regulation of both local and foreign manufacturers of regulated products to help ensure that high-quality drugs are constantly produced, and also that they meet both the national and international standards.

2.1.2 Fake/Counterfeit Drugs

The definition of fake or counterfeit drugs differs from country to country (World Health Organisation, 2013) although the WHO Member States seem to share a similar definition. They emphasize deliberate and fraudulent mislabelling of drugs with respect to brand and generic products as the defining indices of fake drugs. In this sense, counterfeit products include products with correct or wrong ingredients, with or without active ingredients, inadequate quantities of ingredient(s), and with fake packaging.

Similarly, Agbaraji et al. (2012) defined counterfeited drugs as those drugs that are not fake and have been manufactured using inaccurate quantities, or inaccurate ingredients, to either

lessen the potency, or quash the potency of drugs altogether, and the same is applicable to food counterfeit. Therefore, counterfeit or fake drugs simply refer to drugs that are produced and sold in forms that deceptively represent their origin, contents, and authenticity or effectiveness.

World Health Organisation (2017) made a classification of counterfeit drugs. These classifications are;

1. Substandard medical products

These are medical products that do not meet their quality standards and are often referred to as "out of specification" products.

2. Unregistered/unlicensed medical products

These are medical products that are yet to undergo an evaluation and/or approval by the NRRA for marketing/distribution or use. The national/regional regulatory authority may or may not have issued the relevant authorization.

3. Counterfeit medical products

Counterfeit medical products are products that consciously/deceitfully falsify its identity, composition, or source. Such conscious/fraudulent misrepresentation includes any substitution, adulteration, reproduction of a certified medical product, or the manufacture of a medical product that is not authorized.

Fig 2.1 Classification of medical products to be used by WHO global surveillance and monitoring system and the Member State mechanism (WHO 2017)

2.2 Quality Control

Quality refers to a set of product characteristics that fulfill consumer expectations and adhere to the desired specifications. Quality control (QC) is the mechanism that ensures a produced product meets a set of standards and specifications for quality. The ISO 9000 addresses various aspects of quality management and establishes quality standards that serve as guidelines and tools for businesses who want to ensure consistency in the quality of the produced goods (Costigliola, et al. 2017) According to Juran and Godfrey (1999), three key tasks are required in order to achieve quality in a manufactured product. They are:

- Quality planning;
- Quality control;
- Enhancement of the standard.

Planning is reffered to the identification of quality targets, customer needs, and the implementation of appropriate manufacturing and control processes to meet the quality requirements demanded. Control refers to measuring the efficiency of the production process against quality targets. Quality improvement is the mechanism that establishes new high-quality standards criteria and procedures.

The quality assurance unit establishes and strengthens specific analytical methods for the processing of chemical compounds in drug production. Analytical chemistry is a science of measurement that develops and uses methods for the quantitative and qualitative study. A specific analytical method must be designed to recognize and measure matter, provided a certain compound. The method of identification is also called qualitative analysis. Any time there is a need to measure the mass or the concentration of a particular compound a quantitative analysis is performed (Costigliola et al. 2017)

2.3 The National Agency for Food, Drug Administration, and Control in Nigeria (NAFDAC).

NAFDAC, which is the acronym for the National Agency for Food, Drug Administration and Control, is an agency under the oversight of the Federal Ministry of Health under the Nigerian government. NAFDAC was established in 1993 by means of supporting legislation

approved in Decree No. 15 of 1993 and, on 1 January 1994, NAFDAC was formally established as a parastatal of the Federal Ministry of Health' to replace an earlier body of the Federal Ministry of Health–the Directorate of Food and Drug Administration and Control, which had been deemed ineffective, partially due to a lack of such legislation. NAFDAC currently headquartered in Abuja (Nigeria's FCT) is headed by Paul Orhii as the Director-General, who holds a Ph.D. in medicine. NAFDAC has the responsibility of regulation and control of the manufacture, import, export, advertisement, distribution, sales and use of food, drugs, cosmetics, medical devices, chemicals and packaged water (referred to as controlled products) (NAFDAC 2017)

The 1988 world health assembly influenced NAFDAC development, In that year, the resolution of the assembly called on countries to help in the fight against global health threat orchestrated by counterfeit/fake pharmaceuticals.

2.3.1 Structure and Functions of NAFDAC

Apart from the Director-General, NAFDAC has a board of governors that is not headed by a chairman. This chairman is not the director-general but a person appointed by the Nigerian president as recommended by the Hon. Minister of Health. The chairman presides over a board of governors whose membership includes:

- Permanent Secretary to the Ministry of Health
- Director-General of NAFDAC
- Standard Organization of Nigeria (SON)
- National Institute for Pharmaceutical Research and Development (NIPRD)
- President of the Pharmacists' Council of Nigeria (PCN)
- Chairman of the National Drug Law Enforcement Agency (NDLEA)
- Member of each of the Pharmaceutical and Food and Beverage Group of the Manufacturers' Association of Nigeria;
- Three people included from the general public

2.3.2 NAFDAC is sub-divided into directorates for the correct and effective division of labour and resources. They are:

- Human Resource Management (HRM)
- Finance & Accounting (F&A)
- Research & Statistical Planning (PRS)

- Registration & Regulatory Affairs (R&R)
- Laboratory Services (LS)
- Ports Inspection (PID)
- Compliance
- Food Safety & Applied Nutrition (FSAN)
- Drug Evaluation & Analysis (DER)
- Chemical Evaluation & Research (CER)
- Pharmacovigilance & Post Marketing Surveillance (PV-PMS)
- Veterinary Medicine & Allied Products (VMAP)
- Special Duties (SD)
- Narcotics & Controlled Substances (NCS)

Some prominent units are:

- Legal Unit–responsible for providing legal advice on' employee-employer relationship laws and is the custodian of legal documents and all Agency agreements.
- Public Relations Unit–headed by the Office of the Director-General. Its main function is to inform, sensitize, educate, and raise awareness about the Agency's position.
- Internal Audit Division –provides a means to measure the effectiveness of the internal control and accounting system, and performs special inquiries.

2.3.3 The Role of NAFDAC Include:

- Regulate and monitor the import, export, manufacture, marketing, distribution, selling and use of medicinal products, cosmetics, medical devices, bottled water, and chemicals
- Perform adequate tests and ensure compliance with minimum requirements developed and authorized by the Council for the successful quality control of food, medicines, cosmetics, medical devices, bottled water, and chemical products
- Ensure adequate inspection of the manufacturing sites and raw materials for food, medicines, cosmetics, medical devices, bottled water and chemicals and develop an effective quality assurance program including certification of manufacturing sites and controlled products

- Inspect imported foods, medicines, cosmetics, medical devices, bottled water and chemicals and develop an acceptable quality assurance program including certification of manufacturing sites and controlled products;
- Compile uniform requirements, legislation, and instructions for the manufacture, import, export, sale, and distribution of food, drugs, cosmetics, medical devices, bottled water and chemicals
- Register food, drugs, medical devices, bottled water and chemicals
- Export control and quality inspection of food, drugs, medical devices, bottled water and chemicals
- Establish and maintain related laboratories or other institutions in Nigeria's strategic areas as may be necessary to carry out its functions.

The restructuring of NAFDAC by the administration of Olusegun Obasanjo (former Nigerian president) (when the previous board was disbanded in August 2000 and the creation of a new board headed by Prof. Mrs. Dora Akunyili (Late) as new director-general in April 2001) brought a milestone achievement in Nigeria as a lot of food and drugs were destroyed throughout the country, especially on the Onitsha drug market. NAFDAC has registered many other accomplishments since its inception until the date (NAFDAC 2017).

2.4 Study of the Drug situation in Nigeria

With a population of approximately 167 million Nigeria represents a wide drug market. Whatever happens in the pharmaceutical market in Nigeria affects medicinal products that circulate on the ECOWAS(Economic Community of West Africa) such as this countries Nigeria, Ivory Coast, Senegal, Togo, Liberia, Ghana, Republic of Benin etc their markets. "The Nigerian industry potentially has the capacity to meet 50-75 percent of the drug needs of the country. But the actual production is below 30 percent, so 70 percent of all drugs are imported into the Nigerian market." (Okoli, 2000). Bah-Traore (2012) stated in his study that the National Agency for the Administration and Control of Food and Drugs (NAFDAC) in Nigeria has expanded the scope of counterfeit drugs to include products without the full name and address of manufacturers, products labeled "For Export Only", Expired and relabelled products designed to prolong their shelf-life, products containing controlled substances and medicines not registered with NAFDAC. NAFDAC focuses too much on registration and too little on control of the distribution system.

In 1968, fake drugs were first found in Nigeria as the situation worsened, and in 2001 Nigeria was ranked as the country with the highest incidence of fake drugs. Prior to the Akunyili's era, drug regulatory officers abused their status to rip off money from honest manufacturers while taking bribes from counterfeiters to allow access into the Nigerian medicines market Akunyili (2005). This encouraged counterfeit drug manufacturing and distribution in Nigeria as a stock-in-trade, this led to the ranking of Nigeria as the country with the highest incident of fake drugs. Akunyili (2005) reported that drug counterfeiting was first brought to light in Nigeria as early as 1968, "So people have been dying in this country from the effect of fake drugs since the early 1970s" (Akunyili, 2005). In 1995, Nigeria supposedly provided 88 000 doses of meningitis vaccine to its neighbouring country Niger, before it was realized that these vaccines were fake, about 60000 people had been "inoculated". Akunyili reported that when she assumed office in 2001 as the NAFDAC Boss, counterfeit drugs were widely circulating in Nigeria.

In 2001 an analyses was carried out on the quality of drugs from pharmacies in Nigeria, it showed that around half of the formulations had concentrations beyond the upper and lower limits of the standard pharmacopeia in the area they came from. Made-in-Nigeria products have also been banned in many West African nations (Bah-Traore 2012).

The problem of fake drugs and others takes on a new aspect as to who is responsible for averting the crisis, or not. In India, which is a big exporter of medicines to Nigeria, NAFDAC has named analysts who are now certifying drugs before they leave India for Nigeria. Nigerian medicine agency now allows importers to provide compulsory pre-shipment details for imported goods from all countries. The Agency (NAFDAC) also held a summit with the Indian authorities to raise awareness and encourage them to support Nigeria by stopping exports of low standard drugs to the country. It held another one in conjunction with House committee on Health with ambassadors of the countries described as the source of the influx of fake drugs to the country including India, Indonesia, China, Pakistan, and Egypt; a consensus was reached that they would support Nigeria in addressing the problem.

2.5 The Chain of Drug Distribution in Nigeria

According to the study by Bah-Traore (2012), the drug distribution network in Nigeria is in a state of confusion because it consists of free markets, patent medication shops, and community pharmacies run by NGOs (Non-Governmental Organizations), private and public

hospitals, wholesalers/importers, and pharmaceutical companies. The only products allowed to be marketed by vendors are drugs sold Over the Counter (OTC), but they usually sell all kinds of drugs as determined by their financial ability. Many have taken the pharmacy profession for granted as if no skills and training are needed before a person becomes a pharmacist. Patients tend to go directly to market[s] than pharmacies so they can get cheaper rates and, in effect, the medicines they often purchase are fake, obsolete, or of low quality.

These types of episodes occur on a regular basis and patients do not know because they are after cheaper drugs (due to socioeconomic conditions of countries), but they are cheated with either expired or fraudulent drugs in most cases. To maximize their profits pharmaceutical companies tend to sell their drugs across unregulated markets rather than using approved routes like hospitals or pharmacies. Thus the drugs will end up in the hands of unqualified individuals (Bah-Traore 2012).

It is a popular scene in Nigeria to see medicinal product traders selling, among other things, cigarettes, kola nuts, and oranges in market kiosks, car parking wards, and roadsides hawking drugs ranging from over the counter products to antibiotics. The drugs are typically left under the sun under such conditions that the active ingredients may deteriorate.

Therefore, NAFDAC has implemented ongoing surveillance at all sales outlets. Lists of known counterfeit/substandard drugs are regularly published in Nigerian newspapers and medical reviews. The World Health Organization (WHO) has agreed with NAFDAC's proposal to conduct a Pan-Nigerian survey to assess the extent of the goods in circulation that are not standard. New measures have been placed in place to ensure safe medicines are imported into Nigeria; these are:

- NAFDAC inspectors must inspect the manufacturing plants in the exporting country before registration or renewal of registration for any drug. In the case of medicines, to ensure good manufacturing practice, the factory must be' WHO approved.
- In the future, before drugs are imported into Nigeria even after registration, NAFDAC approved analysts will perform a pre-shipment review of the drugs in the respective countries (Bah-Traore, 2012).

2.6 Extent of Poor Quality Medicine in Nigeria

Many studies conducted in developing countries to assess the prevalence of counterfeiting medicines indicate that approximately half of the drugs examined were under the standard.

Similar findings appeared to have been obtained in selected African countries (Tanzania, Burkinafaso, Uganda, Angola, Burundi, Zimbabwe, Rwanda, Ghana, Mali, Botswana, Sudan, Mozambique, Congo, Cameroon, and Kenya). Kibwage et al. (1992) and Roy (1994) reported in former studies back in Kenya, approximately 77 percent of the various drug samples collected from the country were inferior. In recent studies, it is shown that approximately 40 percent of the medicinal products tested failed the quality assays (Amin et al. 2005).

The study conducted to assess the occurrence of non-standard medicinal products was report by Atemnkeng et al. (2006), who found out that the Republic of Congo had approximately 37.5 percent of antimalarials (artemisinin derivatives) that were randomly from pharmacies and quality testing of active ingredients was failed in Kenya.

These studies showed that medicinal products are of low quality in Africa; and nearly half of the samples collected in this area showing the failure of the necessary tests. This studies are similar to the findings of low-quality drugs in Nigeria, of which in most studies ranges from about 32 percent to 48 percent. Bate et al. (2009)'s study showed a smaller proportion (18 percent) fails the standard tests which is not accepted as it can't underestimate the dangers that may result from it. This decrease reported from Bate et al. (2009) can be due to the methods used to assess the medicines ' chemical constituent of the small sample size (140 treatment packs). An analysis by Bate and Hess (2010) displayed that general failure rates in Lagos dropped from around 32 percent in 2007 to around 13 percent in 2010.

However, studies shows that a small amount of sample sizes involved in 2007 and 2010 may have lead to the above and is not conclusive to observations from larger studies..

According to WHO (2011) the largest number of antimalarial samples failed of about (63.9 percent) is from Nigeria. His findings again may have been narrowed to the small sample size used in this study. Research by Taylor et al. (2001) showing that 48 percent of Nigeria's randomly sampled drugs (antibiotics and antiparasitics) did not meet the specified pharmacopeia requirements appeared to be the first to use random sampling and attempted to define the methods used appropriately (Newton et al. 2006). Certain studies that have used random sampling to minimize bias on deciding product quality include Amin and Snow (2005) and a study conducted in Laos (unpublished research cited in Newton et al., 2008). A review by Kelesidis et al. (2007) showed that in Nigeria counterfeit and under-standard types of antimalarials and antibiotics were found. This does not necessarily mean that there are no

counterfeit forms of other drugs not mentioned here in Nigeria, as there is a likelihood that they may not have been sampled for tests.

It is possible to counterfeit drugs of all clinical classes (Cockburn et al., 2005). Further demonstration by INTERPOL's current removals of drugs in Egypt and Asia, showed that counterfeits were in almost every branch of medicinal products (WHO 2010a). However, in developing countries such as Nigeria, the majority of counterfeited medicines such as antibiotics, antimalarials, and anti-infectives are life-saving (Bate et al. 2009). However, contrary to assumptions, counterfeiting are not the most costly drugs; the economies make counterfeiting attractive even for the cheapest drugs. The findings of Ofonaike et al. (2007), in which drugs such as paracetamol and chloroquine were found to be of low quality, and according to Tipke et al. (2009), chloroquine samples constituted a substantial proportion of poor quality. It could also have been that the errors found in these studies were due to poor quality control by legitimate suppliers.

It was estimated that the second-largest distributor and producer of counterfeit medicines was Nigeria with about 23 percent of falsified drugs distributed all around the world after India. It was believed that 35 percent was from India and 13.3 percent from Pakistan. (Datta, 2003 cited in Lybecker, 2004). The counterfeiting of medicines is said to be similar to the narcotics trade worldwide. In most cases, one country collects the raw materials, another formulates it into capsules and tablets, packaging is done in another country and then it ships through various countries until it gets to its final destination (Lybecker, 2007). The Safe Medicines partnership is an example, as the Spanish police discovered that counterfeit medicines were being exported to Spain from Brazil, Thailand, and Mexico; and then sold in Portugal, France and Italy (Taylor and Craig, 2009).

2.7 Sources of Poor Quality Medicine

Three of the literature review studies obtained by (Onwujekwe et al. 2009), (Tipke et al. 2009), and (Lon et al. 2006) examined sources of poor quality medicines. The study showed that drugs found in open places and streets were of low-quality because they are not well regulated. For example, patent medicine vendors accounted for 78 percent of suspect medicines in (Onwujekwe et al. 2009) and 90 percent of the medicines found to be under standard in (Tipke et al. 2009) were obtained from illicit outlets (markets, street vendors and

shops). A large proportion (100 out of 122) of samples from illegal or unlicensed outlets that did not pass quality testing were obtained (Lon et al. 2006).

In 2006, the National Agency for Food and Drug Administration and Control (NAFDAC) announced that the rate of counterfeit medicines had been decreased by as much as 70 percent to about 16.7 percent from previous values (Taylor and Craig, 2009). Nevertheless, the rise in the rate of about 40 percent on the open drug market in Onitsha, popularly known as the head bridge market, is believed to have made this figure worse (Pharmaceutical Society of Nigeria (PSN) 2007; Okoye 2007 cited in Milissa McGinnis 2010). Other open drug markets in Nigeria that contributed to the high occurrence of non-standard and counterfeit drugs include the Ariaria market (alleged to have about 75 percent of drugs in stock as fake in 2002), the Sabon Gari market, Kano (a NAFDAC review showed that about 90 percent of drugs are unregistered) and the Idumota market, Lagos (PSN 2007). With all this it is fit to ask if Nigeria should put more effort into curbing falsified medicines in areas that are supposed to be more prevalent.

2.8 Activities And Interventions Of Nafdac In The Control Of Fake Drugs

In April 2001, the " new NAFDAC' activities was introduced and will be addressed in order to analyse how initiatives were being approved to control false drugs in Nigeria legal, structured market, as well as specific successes that took about a reduction in areas and problems that needs improvement. All this will still be in comparism with other countries regulating agencies. The offices of NAFDAC are located in 36 Nigerian states and the six geopolitical zones with their national headquarters based in the federal capital territory of Abuja.

2.8.1 NAFDAC Inspection Processes to Check Fake Drugs

There are two inspection directorates involved in Nigeria. These are the Directorate of Ports Inspectorate (PID) in charge of imported products, and the Directorate of Establishment Inspectorate (EID) in charge of locally produced products. The GMP(Good manufacturing processes) has a pricinple of inspecting the finished product quality which is not just tested but built into the product. It is also perceived as a crucial component of pharmaceutical control.

NAFDAC adopts the WHO recommendations for inspection visits for GMP and routine inspection but does not carry out regular inspections abroad mainly due to financial

constraints. Overseas industrial companies are checked once during the registration of the drug. These could result in manufacturers not completely adhering to the prescribed standards. Nevertheless, for the local products, unplanned daily visits to factories are carried out by inspectors. Inspection rountines are now ongoing by The Ghana Food and Drug Board for both imported and local drug regulatory facilities, providing them with closer interaction and monitoring of drug manufacturers ' activities (Agyarko, 2006).

Channels for the sale of drugs are hard to search in Nigeria. Due to unstable and unlicensed, trade owned by illitrates with profit-oriented interests. Other countries under review have identified ways to inspect the delivery of drugs. South Africa uses the local authorities in each region, while the UK and the Netherlands follow Good Distribution Practice (GDP), where the product distribution of the inspectors from the producer to the point of dispensation after registration. The Ghana Food and Drug Board is now undertaking regular daily inspections of both imported and local drug control facilities of the manufacturers of drugs (Agyarko 2006).

Some NAFDAC Inspection Measures are

- All drug products that arrive the Nigeria's port entry are required to supply pre-shipment details.
- All banks in Nigeria are to work in accordance with the information of NAFDAC that drug importers should receive clearance from the Agency first before they process the financial documents.
- Issuance of guidelines for airlines that could lift importers ' drugs without the required authorization from the Agency.
- Unregistered and importation of drug products is subject to seizure, consequence and fine until it is registered..
- Post-marketing monitoring would be carried out according to WHO specifications.
- Procedures for mopping up counterfeit drugs already in circulation are set.
- Once in three months in local factories in Nigeria an inspection is carried out at the time of product registration without prior notice. This is to ensure that current GMP are not deviated under the criteria wew drugs are licensed.
- Weak GMP factories, their goods are not permitted into the country.
- Fake and expired drug items worth billions of naira that are seized by PID and EID officals are eventually destroyed.

2.8.2 Drug Product Registration as a Check for Fake Drugs

Registration of products is a process where the system detects drug counterfeiting and contamination. The government uses this powerful means to control the safety and good quality of goods and how products are produced and offered for sale in Nigeria. In a developing country where fake medication is of high problem, a 5-year valid license is too long; Uganda DRA only gives a one-year license that will help to track drug products more closely.

According to Nigerian drug law, drug sale, supply, and the price are one of the Agency's activities, but according to NAFDAC it is felt that regulation of products sold in companies is not among their jurisdiction and to that it is not monitored, because the high tariffs were paid by the company to obtain their license. Once a drug product is registered, sometimes, until the company returns for renewal, one does not hear about what happens with the product. There is one monitoring unit in place for other countries under study. Registration and review assistance from outside experts is unavailable. There's a lack of support from foreign experts who can come and teach the employees new ideas.

Interventions by NAFDAC in the registration of drug product

- In order for a registration to be done by NAFDAC, the drug factory must be pre-qualified by WHO or GMP before the product is approved and can be shipped to Nigeria.
- One of Nigeria's leading importers is India for drug products, NAFDAC named Indian analysts to assist in certifying every drug product before leaving India's shores to Nigeria.
- Registration number on products outer package is of high paramount by NAFDAC as they have demanded importers and their suppliers abroad that the product be registered before importation and brought to the shores of Nigeria. (NAFDAC 2007).
- Assembling of all goods with "NAFDAC Green Page" and Registered with the Agency in the Gazette to inform the public about the items registered and what to purchase.
- The Director- General of NAFDAC, made a quick registration process of a maximum of two months to help the agency solve delay problems and the companies obtain their license on time. Under the "new NAFDAC," three thousand six hundred and thirty (3,630) products were registered under one year, compared with five thousand,

seven hundred and thirty-five (5,735) products registered under the old "NAFDAC" within seven years.

2.8.3 Enforcement activities as a Check to Faking Drug

The “new NAFDAC” establishment has helped to catch wrong drug makers and to increase public trust in the Agency. Two key factors that have played a crucial role in the enforcement activities are the Surveillance and promptness, these two key factors has been useful as it has given better interventions. Nonetheless, in Nigeria there are certain parties and compliance that cause conflicts of interest by NAFDAC. In the ports ' collection of bribes from drug dealers by customs may occur, while the judiciary often averts laws and criminal penalties against violators as well as the police. This impacts policy efforts in achieving acceptable outcomes. The UK MHRA maintains close cooperation with key investors whose impact can affect the investigation, identification and prosecution of violators.

NAFDAC Enforcement Measures

- Victims of falsified medicines and health professionals reports tip-off the media and that way, fake drug dealers can be tracked and arrested.
- Regular raid on drug hawkers that confiscate and destroy the product, especially when they are unable to provide adequate location address invoices that could help the enforcement team track drug fakers and distributors.
- Warehouse leased by property owners who are aware of who uses it to store fake drugs, will be held responsible if it proves difficult to track fake drug dealers. It gave the police prompt details about drug-fakers.
- Project to create a model market for drugs in the country's six geographical zones under pharmacist control and management.

2.8.4 Program of Public Enlightenment as a Check to Faking of Drug

NAFDAC is encouraged under its enabling law section 14 to use the tools it has in advertising and supporting its activities, including a public awareness campaign that is an effective strategy that can be used in consumer awareness and the fight against the counterfeiting of goods regulated. (Consumer health, NAFDAC 2007). The use of public awareness campaigns as a strategy involves dialogues, educates as well as persuasion through various means such as use of billboards, alert notices for consumers, jingles on television,

publications of the lists of all identified fake regulated products in the media, prints and electronic media, use of Workshops, Seminars and Stakeholder Advocacy.

The U.K MHRA has a 24-hour customer hotline service which is not yet open to NAFDAC but consumer complaints are always accepted. Recently, the use of SMS text messages from mobile phones has been implemented by the Ghana Food and Drug Board (GFDB) to authenticate the drug quality a customer buys. M pedigree is what this technology is called, which tends to electronically track drugs from the original producers to the pharmacy shops where the drugs are being dispensed. It lets the drug buyer know the product's source. Because 90 percent of the population use mobile phones, this technology will be successful (Amankwah 2006)

NAFDAC Public Enlightenment Program Interventions

- An annual contests to help catch younger generations in Nigerian high schools ' clarification program on fake drug knowledge, is done to learn what their perception is about the ill effects caused by fake drug products in society.
- NAFDAC formation on high school user clubs, because it is assumed that young people pass on knowledge to their friends and others, educating young people about the dangers of fake drugs.
- Cooperation with other related participants such as NDLEA, the Nigerian Bar Association (NBA), the Nigerian Standard Organization (SON), the military, customs port authorities, etc. as contained in the enabling decree to liaise with relevant stakeholders both outside and within the country which may assist in the fight against counterfeit drugs.
- Establishment of a National Pharmacovigilance Center (NPC) which promotes the rational and safe use of medicinal products.
- Steady newspapers of the list of fake / counterfeit products identified in the quarterly newsletter and in the public newspapers of NAFDAC.
- The Agency's advocacy visits to international regulatory authorities in China and India to assist with the issue of the importation of fake drugs.
- Publication of a blueprint covering the period 2005-2010 as a guide to the Fake Drugs program.
- The "NAFDAC Green List" will be launched as a list of all licensed products to inform the public about the quality of the approved products in circulation.

- Publish warning notes for items in circulation that have public awareness issues.
- Organized seminars and workshops for SMEs, describing the NAFDAC guidelines and what is required of them.

2.9 Review of Empirical Literature

A study conducted by Chinwendu (2008) to understand the efforts made by NAFDAC in controlling fake drug circulation reviewed various works of NAFDAC to identify their strength and weaknesses in this regards, the major players in the business of fake drugs as well as factors influencing their (Fake drugs) widespread in Nigeria. Results from the study showed that the inability to give an adequate penalty to the open drug markets which are not licensed, monitored and not regulated which forms the major distribution market contribute to the proliferation of fake drugs without control; and this is due to the fact that the government does not help the situation by not giving adequate penal sanctions to the offenders as written in the drug laws. In conclusion, NAFDAC has not been able to achieve any reasonable success in fighting fake drugs in Nigeria due to inadequate support by the government, stakeholders, police, and the judiciary.

Another study by (Orga 2017), which aimed to determine the impact of NAFDAC on the quality management of the Nigerian manufacturing sectors, surveyed 315 workers using a survey questionnaire. Results from the study revealed that NAFDAC used market surveillance and routine inspection to ensure that the standard specifications are being complied with. It also revealed that the manufacturing sectors in Nigeria adopt quality management practices to a high extent. It went further to recommend that ensuring processes that incorporate quality during production is better than attempting to incorporate quality by inspection after the production process.

Anibeze (2007) conducted a descriptive study to ascertain the degree to which the NAFDAC programme has achieved success in influencing the choice of drug consumers in Nigeria using a structured questionnaire on 1,338 secondary school teachers from the five south-eastern stated of Nigeria. Findings from the study showed that secondary school teachers were very much aware of the NAFDAC registered drugs; they also agreed that there were some indigenous drug companies blacklisted by NAFDAC. The respondents further admitted that seeing or being able to view the NAFDAC registration number on the products they want to buy, brand loyalty, and the price of drugs influenced their choice of drugs to buy. The study further ascertained that many problems are still being encountered in identifying drugs

registered by NAFDAC. The study came to the conclusion that the chive of the drug was influenced very much by the drug control campaigns done by NAFDAC.

Wogu et al. (2019) also conducted a study to investigate the influence or role played by the Mobile Authentication Service (MAS) in eliminating fake drug consumption in South-east Nigeria. A cross-sectional survey of 1000 respondents from the five states of south-east Nigeria was made using a structured questionnaire. Results from the study revealed that there wasn't a good level of awareness of the MAS scheme and that MAS made no impact on the distribution and consumption of counterfeit or fake drugs. It further revealed that the reason for the ineffectiveness of the MAS scheme was attributed to the inability of people to procure appropriate phone technology, a low level of awareness of MAS scheme media, and poor network services. It finally came to the conclusion that the MAS scheme of NAFDAC has not reduced or sopped the production, distribution, and consumption of fake drugs in South-east Nigeria.

Finally, a cross-sectional survey by Oyetunde et al. (2019) which aimed to assess the acceptance of MAS by community pharmacists as well as examine what the MAS providers think are the challenges and success of developing MAS in Nigeria. They assessed 326 community pharmacists and the MAS providers using both structured questionnaires and interviews respectively and found out that both perceived reliability and awareness played an important role in the behavioural intention of the use of MAS. It further explained that the challenges encountered with MAS, which were 'no response and wrong response' were mainly as a result of contextual challenges in the Nigerian setting including incessant power outages, Global System Mobile downtime, and the limited ability of the consumers to make use of the Short Message Service (SMS). These also contributed to the limited success of MAS in Nigeria. In the conclusion of the study, the level of acceptance of MAS by the community pharmacists is moderate; also, the major determining factors influencing behavioural intentions to use MAS were awareness and reliability; finally, the reason for the limited success of MAS development is due to its interactions with the local context, where it has been deployed.

CHAPTER THREE

METHODOLOGY

3.1 Method

Research Methodology is to be the major aspect of an investigation work as it helps the overall work in the proper direction to reach a suitable outcome (Harvey, Edrada-Ebel, and Quinn, 2015). When doing a study there are many approaches to choose from. Since different research studies involve various types of methods and choice behind which method considered to be the most suitable to use in this study has been carefully considered and argued for. The researcher's core consideration is to choose the most appropriate methodology to carry out the work in an appropriate manner. The investigation into actual action is based on the evaluation of analysing the impact NAFDAC has on drug quality improvement in Nigeria.

3.2 Research Philosophy

The research philosophy forms the basis for how a researcher approaches theoretical and empirical knowledge (Saunders, Thornhill, & Lewis, 2012). This means that a research's theory is that which the researcher believes in his / her thesis. There are three key philosophies of research that explain how individuals perceive their surroundings and the whole world. There are interpretive philosophies, positivism, and realism (Bryman & Bell, 2015).

Interpretivism is a theory in which people and their actions are interpreted in a complex matter. This means that this approach seeks to explain how individuals in their social environment perceive and behave around a certain phenomenon (Bryman & Bell, 2015). The theory of interpretivism further suggests that individuals behave and perceive events differently from each other, implying that generalizations regarding their individual actions are difficult to draw (Saunders et al., 2012).

In positivism, the learner is the individual who observes the research process. Positivism has been identified by Collins, H in accordance with the view of the empiricists that information comes from human expertise. It is a non-holistic, ontological world view that is composed of

distinct, measurable elements and events that behave in a measurable, normal, and decided manner. In this theory, the concepts are divided into three:

i. The research's first goal is to describe and forecast
ii. Empirical source of data, which can be measured by the human senses, is preferable. The theory must be tested while the work is ongoing.
iii. Since the research is underway, the power of common sense may be curbed.

Realism is just another form of philosophy. It should be known that the basic characteristic of realism is that anything humans would interpret as evidence should be regarded as reality. Realism emerged from an epistemology closely associated with positivism. The study of intelligence has both realism and positivism in common. These conventions make legitimate the research collection and analysis of data. For one to understand the true meaning of realism, the individual must know the two types of realism. The two styles are realism which is clear and critical. Selon Saunders (2012), is said to be simple realism

According to the pragmatism theory, the learner cannot come to a conclusion without an in-depth analysis of more than one view or idea. This means that the purpose of the philosophy of pragmatism is to figure out the realistic conclusion of the research subject. Although the purpose of this theory is to learn the various aspects of the selected subject, the work is not clearly obtained by accumulating a very large data source analysing, rather it gives credibility and validity importance.

In this study, the aim is to investigate the major reason for fake drug consumption and the impact of NAFDAC in improving drug quality in Nigeria, the researcher chose **positivism** as the subject study philosophy, after suitable valuation and consideration. Making use of positivism will enable the learner to try not to have any influence on the research findings, instead, present oneself as the person who observes and is eager to use scientific and systematic techniques for collecting data and throughout the research process.

3.3 Research Approach

The research approach is the research's means of utilizing theories. The two basic research approaches that are commonly used in the research process are the deductive approach and the inductive approach (Bryan and Bell 2015). In the deductive approach, the researcher primarily develops a theory or hypothesis, then develops a design and different research strategies based on the theory or hypothesis; whereas, in the inductive approach, the researcher basically collects all possible data and makes an analytical study on the collected data. The researcher concludes a theory, which will explain the findings in detail based on the collected data.

3.4 Research Design and Strategy

A descriptive research design would be adopted by the study. A descriptive survey centers on describing the important facts about people, their opinion, motivations, and attitudes (Osuala 2001). The researcher chose the descriptive research design because the main aim of the research is to describe the impact or role of NAFDAC in drug quality improvement or control. It will allow the researcher to get the opinions of the workers in pharmaceutical companies about their views on the role of NAFDAC in the control of drug quality in Nigeria.

The research design determines the strategy chosen and as this study follows a descriptive research style, the most suitable research strategy to implement is a quantitative strategy. In addition, implementing a quantitative approach would allow the researcher to collect data from a good number of individuals as the researcher wished to study a large population.

3.5 Research Choice

Research choice pays attention to the correct method(s) to be used during the testing process. Mono, multiple, and mixed approaches are the various types of study choices. In the mono approach, the researcher chooses a single method and methodology for data collection and analysis; while the researcher can choose two or more methods of data collection and analysis in the multiple methods, e.g. the researcher can use both observation and questionnaire to collect data. The mixed approach includes the use of quantitative as well as qualitative techniques. The researcher in this review, however, preferred to apply the mono method to the collection and analysis of data.

3.6 Time Horizon

The two major categories of time horizon in a research context are the cross-sectional and longitudinal studies. Cross-sectional studies are studies performed at a specific point in time. Most academic studies are cross-sectional studies because they are performed within a given time frame and deadlines; whereas longitudinal studies appear more like the change or development, where the individual(s) or instances are meant to be studied by the researcher by observing closely and measuring for the time duration. However, this study researcher will utilize the cross-sectional study as the study is to be done within a specific period of time.

3.7 Study Population and Sampling

The targeted population is all the health professionals, NAFDAC officials, drug producers, and consumers in Enugu. The researcher will target mainly the doctors, Nurses, NAFDAC officials, Employees in pharmaceutical companies producing drugs who have had at least two years of working experience and the drug consumers.

The sample size is said to be the number of items to be selected from a population to make a sample (Kothari 2004). The aim of sampling is to present the study population. This study will adopt a purposeful and random sampling technique. Purposeful sampling technique entails that the researcher will select the participants believed to be able to provide better and appropriate information; this means that the researcher will deliberately select the individual with the vital and reliable information required for the purpose of the study and they are the employed doctors and in UNTH and ESUTH teaching Hospitals; professionals working in Nemel Pharmaceutical and Juhel Nig. Ltd., Enugu; NAFDAC officials working in Federal Secretariat, Independence Layout, Enugu as well as the drug consumers residing in Enugu.

The random sampling technique would be used when choosing the employed professionals in the various work offices who have had at least two years of working experience. Here, the respondents would be selected randomly and each individual will have an equal chance of being part of the sample. However, the researcher will use a sample size of about 37 participants to ascertain the impact of NAFDAC on drug quality control in Nigeria.

3.8 Data Collection Method and Instrument

Data collection is a process of gathering relevant information concerning the subject matter of the study. There are different methods or techniques for data collection, including observation, interview, questionnaire, and focus group discussion methods. Selecting the appropriate data collection method id based on the research design and aims. For the purpose of this study, the questionnaire is the instrument that would be used to collect data. This is because it is can be easily used to obtain relevant information from many participants. The questionnaire will be semi-structured with open and close-ended questions as regards the subject matter of the study.

3.9 Data Analysis

The information obtained from the respondents with the questionnaire will be analysed using appropriate descriptive statistics of frequencies and percentages. The uniformity of the data collected would be assessed after which frequencies and percentages would be used to display the distribution of responses. The findings would be displayed in tables and charts and the results would be analysed using the Statistical Package for Social Sciences (SPSS).

3.10 Ethical Consideration

The research ethics includes the rules, principles, and traditions which are supposed to be followed to conduct the research. The research ethics are followed at every step of the research paper. The research paper should include the consent of participants in the research work; it means no participants are involved by cheating or by force in the research work. Participants have every right to participate or not to participate in the research work. It is important to treat the participants with the utmost dignity and dignity. The privacy and confidentiality of the information should be assured to the participants.

Research ethics involves the rules, values, and principles that should be followed in order to perform the research. At each step of the research paper, the research ethics are followed. Some of the ethical considerations which would be observed by the researcher include:

- The company management would be informed through a letter of introduction to the respondents
- Oral consent would be sought officially as well by the researcher from the company's human resource manager

- The researcher will ensure the privacy and confidentiality of the information given by the participants.
- The researcher will as well avoid making use of statements and questions that can be deceptive while conducting the research.
- The researcher will also ensure that the participants will only participate willingly and not coerced.
- The researcher will also ensure that the participants will not be exposed to any form of physical or mental hazard or injury during the study.

CHAPTER FOUR

DATA ANALYSIS AND FINDINGS

The Data used for this research was obtained through responses from the questionnaires disseminated to a different group of people ranging from Professionals working in the pharmaceutical industry, Pharmacists, NAFDAC staff to the drug consumers, to ascertain their opinions concerning the drug situation and the role of NAFDAC in the improvement of drug quality in Nigeria. The questionnaires were disseminated via Linkedin social media platform to 37 individuals, including consumers of pharmaceutical products and people from various medical professional sectors in Nigeria. The result of the findings obtained from the participants would be analysed in this chapter.

4.1 Demographic representations of the respondents

4.1.1 The various groups/ segments of the respondent

Table 4.1 The distribution of the respondent according to their respective segments

Respondents	Frequency	% Frequency
Professionals working in the Pharmaceutical industry	6	16.2%
Pharmacists	4	10.8%
Medical practitioners	4	10.8%
NAFDAC Staff	5	13.5%
Consumers	18	48.6%
Total	37	100%

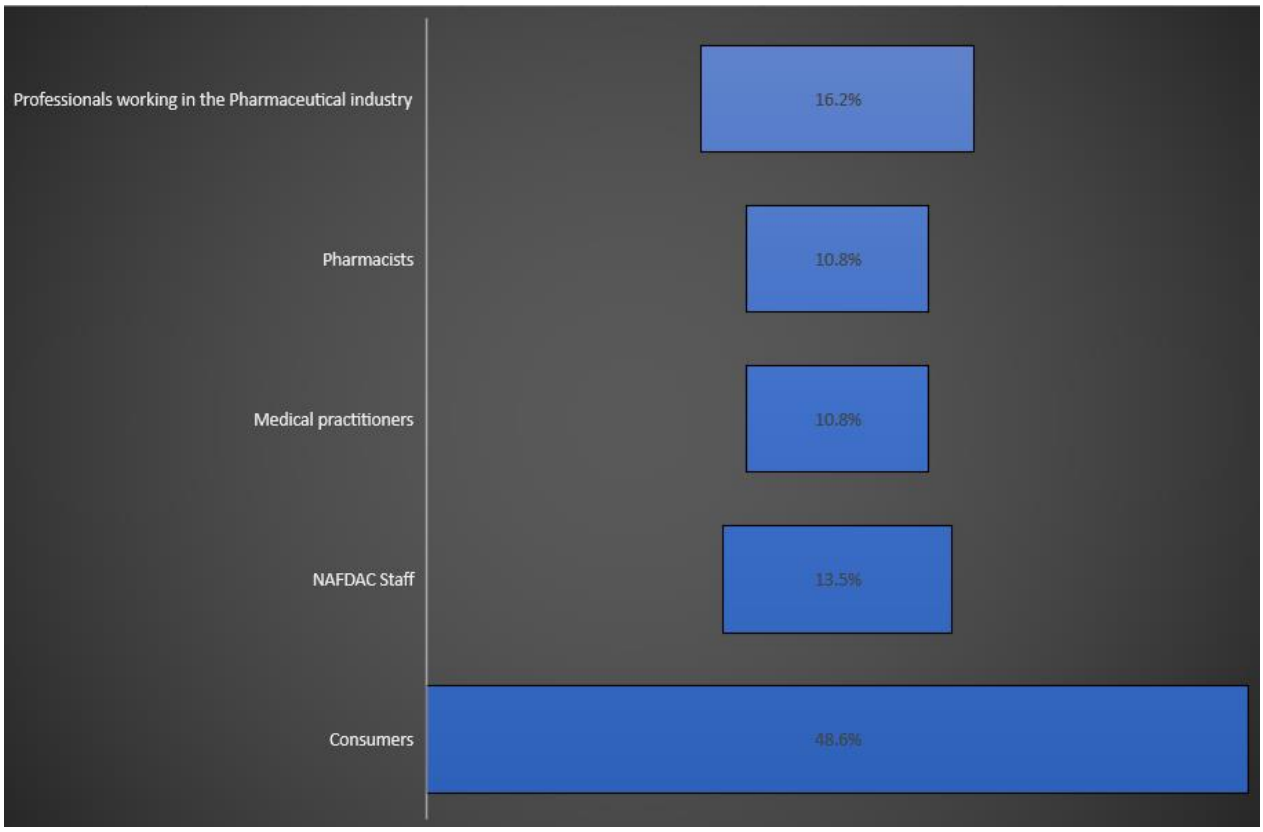

Table 4.1 A funnel chart representing the distribution percentage of the respondents according to their respective segments

Table 4.1 and Figure 4.1 show a distribution of the respondents according to the way they were grouped for this study. A total of 37 persons responded to the questionnaires. 18 (48.6%) of them were consumers, 6 (16.2%) of them were professionals working in the Pharmaceutical industry, 4 (10.8%) of them were pharmacists while the remaining 4 (10.8%) of them were medical practitioners.

4.1.2 The gender distribution of the respondents

Table 4.2 The gender distribution of the respondents according to their different segments

	Male	Female	**Total**
Professionals working in the Pharmaceutical industry	4(10.8%)	2(5.4%)	**6(16.2%)**
Pharmacists	2(5.4%)	2(5.4%)	**4(10.8%)**
Medical practitioners	2(5.4%)	2(5.4%)	**4(10.8%)**
NAFDAC Staff	3(8.1%)	2(5.4%)	**5(13.5%)**
Consumers	5(13.5%)	13(35.1%)	**18(48.6%)**
Total	**16(43.2%)**	**21(56.8%)**	**37 (100.0%)**

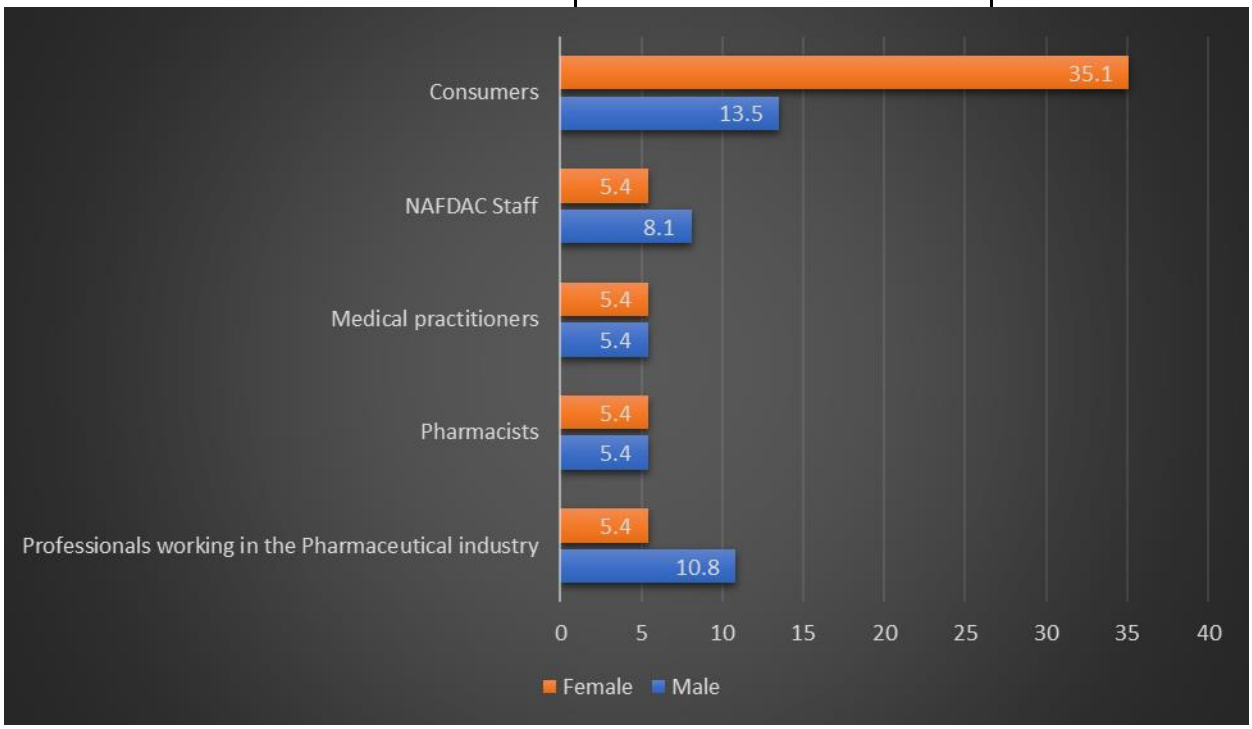

Fig 4.2 A clustered bar chart representing the gender distribution of the respondents according to their different segments

Table 4.2 and Figure 4.2 show the gender distribution of the respondents according to their various groups. A total of 16 (43.2%) males and 21 (56.8%) females responded to the questionnaire. Out of the 16 males, 5 were consumers, 4 were professionals working in the pharmaceutical industry, 3 were NAFDAC staff, 2 were pharmacists while the remaining 2 (5.4%) were medical practitioners. Out of the 21 females, 13 were consumers, 2 were professionals working in the pharmaceutical industries, another 2 were NAFDAC staff, and 2 were pharmacists whereas the remaining 2 were medical practitioners.

4.1.3 The age group distribution of the respondents

Table 4.3 The age group distribution of the respondents according to their different segments

	20-29yrs	30-39yrs	40-49yrs	**Total**
Professionals working in the Pharmaceutical industry	3(8.1%)	1(2.7%)	2(5.4%)	**6(16.2%)**
Pharmacists	3(8.1%)	1(2.7%)	0(0%)	**4(10.8%)**
Medical practitioners	3(8.1%)	1(2.7%)	0(0%)	**4(10.8%)**
NAFDAC Staff	2(5.4%)	2(5.4%)	1(2.7%)	**5(13.5%)**
Consumers	13(35.1%)	3(8.1%)	2(5.4%)	**18(48.6%)**
Total	**24(64.9%)**	**8(21.6%)**	**5(13.5%)**	**37 (100.0%)**

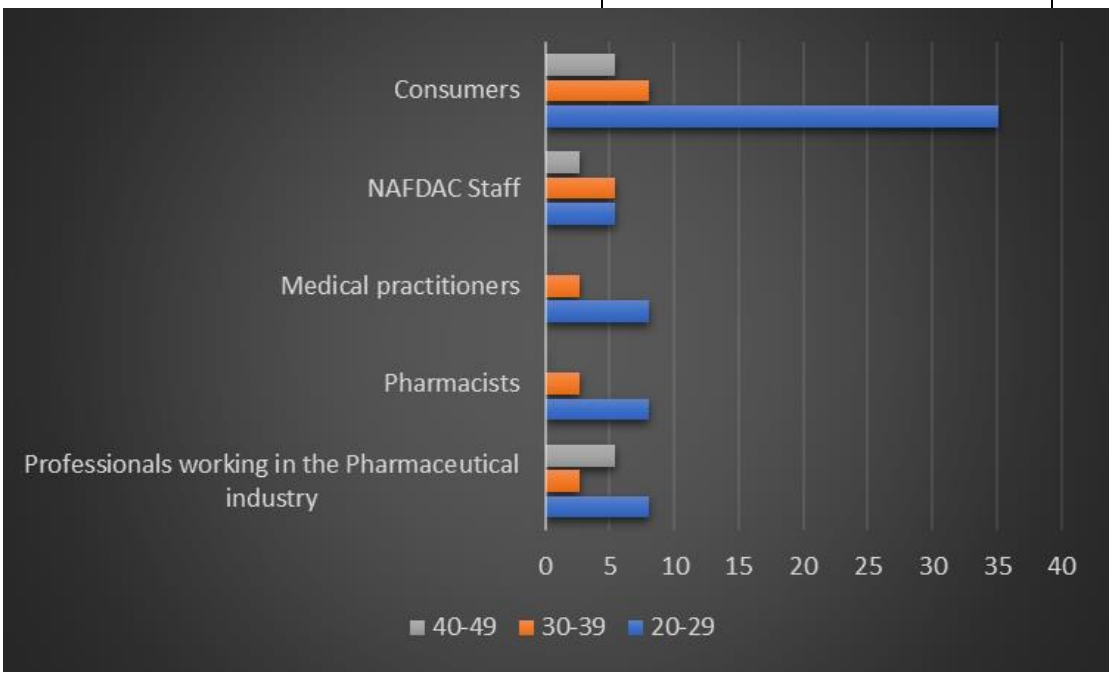

Fig 4.3 A clustered bar chart representing the age group distribution of the respondents according to their different segments

Table 4.3 and Figure 4.3 above show the age distribution of the respondents according to their various groups. Out of all the (37) respondents, 24 (64.9%) of them were between ages 20-29 years, 8 (21.6%) of them were between ages 30-39 years whereas only 5 (13.5%) of them were between ages 40-49 years. Out of the 24 respondents who were between ages 20-29 years, 13 of them were consumers, 3 were professionals working in the pharmaceutical industry, 3 were pharmacists, and another 3 were medical practitioners while the remaining 2 were NAFDAC staff. Out of the 8 respondents who were between ages 30-39 years, 3 were consumers, 2 were NAFDAC staff, 1 was a professional working in the pharmaceutical industry, and another 1 was a pharmacist, whereas the remaining 1 was a medical

practitioner. Out of the 5 respondents who were between ages 40-49 years, 2 were consumers, another 2 were professionals working in the pharmaceutical industry, and the remaining 1 person was a NAFDAC staff while none was a pharmacist nor a medical practitioner.

4.1.4 The highest educational qualification attained by the respondents

Table 4.4 The highest educational qualification attained by the respondents according to their different segments

	Certificate/Diploma	Bachelor's degree/Advanced diploma	Master's Degree	**Total**
Professionals working in the Pharmaceutical industry	0(0%)	4(10.8%)	2(5.4%)	**6(16.2%)**
Pharmacists	0(0%)	3(8.1%)	1(2.7%)	**4(10.8%)**
Medical practitioners	0(0%)	4(10.8%)	0(0%)	**4(10.8%)**
NAFDAC Staff	1(2.7%)	3(8.1%)	1(2.7%)	**5(13.5%)**
Consumers	2(5.4%)	7(18.9%)	9(24.3%)	**18(48.6%)**
Total	**3(8.1%)**	**21(56.8%)**	**13(35.1%)**	**37 (100.0%)**

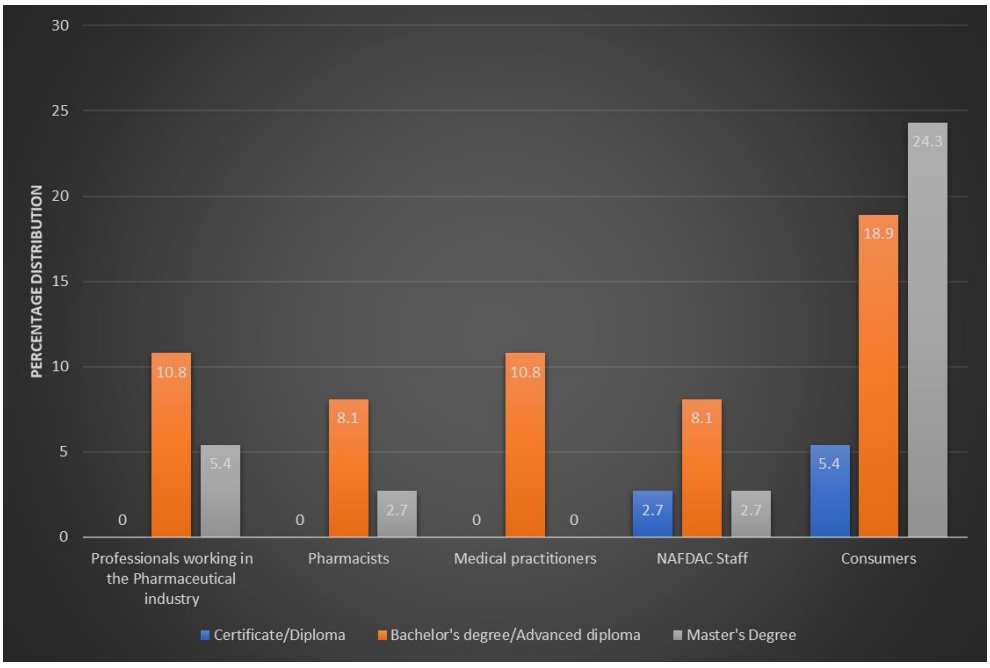

Fig 4.4 A bar chart displaying the highest educational qualification attained by the respondents according to their different segments

Table 4.4 and Figure 4.4 displayed the distribution of the highest educational qualification attained by the respondents according to their various segments. Out of all the (37) respondents, 3 (8.1%) of them had Certificate/Diploma as their highest attained educational qualification, 21 (156.8%) had bachelor's degree/advanced diploma, while the remaining 13 (35.1%) of them had master's degree as their highest attained educational qualification. Of the 3 respondents who had certificate/diploma, 2 of them were consumers, 1 of them was a NAFDAC staff whereas none was a Pharmacist, Medical practitioner, or a professional working in the pharmaceutical industry. Also, out of the 21 respondents who had bachelor's degree/advanced diploma, 7(18.9%) were consumers, 4 were professionals working in the pharmaceutical industry, another 4 were medical practitioners, 3 were pharmacists, while the remaining 3 were NAFDAC staff. Finally, out of the 13 respondents who had a Master's degree, 9 were consumers, 2 were professionals working in the pharmaceutical industry, 1 was a pharmacist, and another 1 person was a NAFDAC staff while none was a medical practitioner.

4.1.5 The distribution of the work experience of the professional respondents

Table 4.5 The distribution of the work experience of the professional respondents according to their different segments

	Less than 2Years	2- 5 years	more than 5 years
Professionals working in the Pharmaceutical industry	1(5.3%)	3(15.8%)	2(10.5%)
Pharmacists	0(0%)	1(5.3%)	3(15.8%)
Medical practitioners	1(5.3%)	2(10.5%)	1(5.3%)
NAFDAC Staff	1(5.3%)	2(10.5%)	2(10.5%)
Total	**3(15.8%)**	**8(42.1%)**	**8(42.1%)**

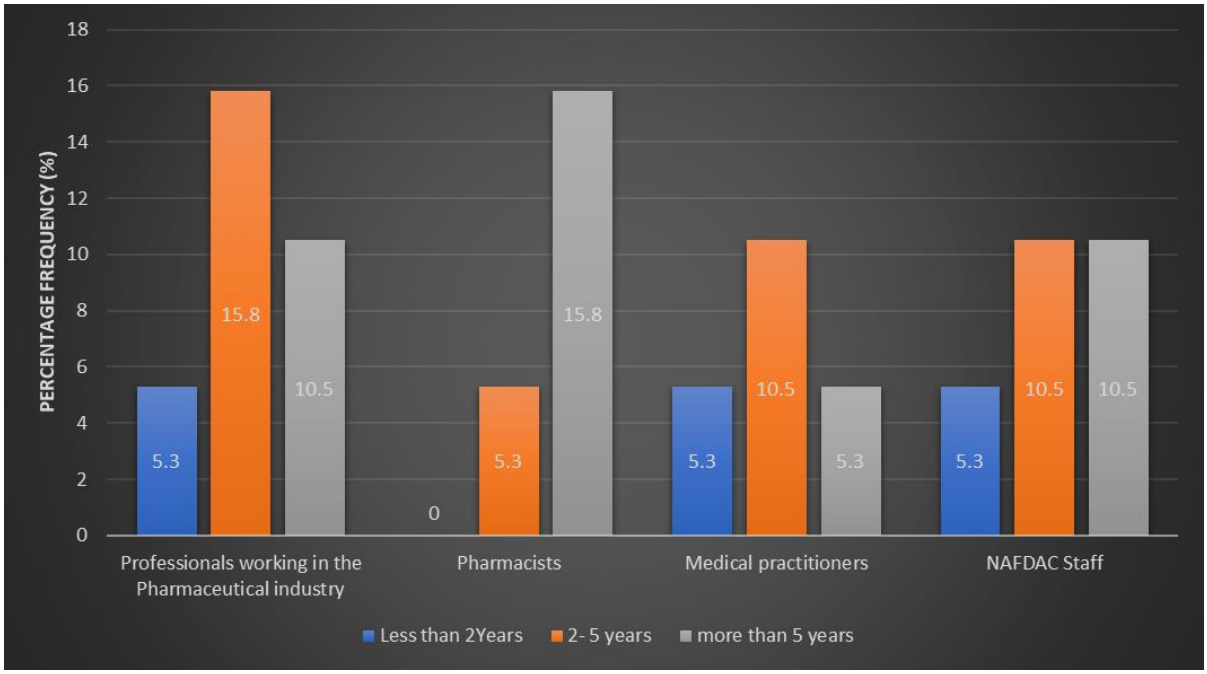

Fig 4.5 A bar chart representing the work experience of the professional respondents according to their different segments

Table 4.5 and Figure 4.5 above displayed the distribution of the work experience of the professionals according to their various segments. Out of the 19 professionals who responded to this question, only 3 (15.8%) of them have had 2 years of working experience, 8 (42.1%) of them have had 2-5 years of working experience while the remaining 8 942.2%) of them have had more than 5 years of working experience. The 3 of the professionals who have had less than two years of working experience including 1 professional working in the pharmaceutical industry, 1 medical practitioner and 1 NAFDAC staff. Also, out of the 8 respondents who have had 2-5 years of working experience, 3 of them are professionals working in the pharmaceutical industry, 1 of them is a pharmacist, and 2 of them are medical practitioners whereas the remaining 2 of them were NAFDAC staff. Lastly, out of the 8 respondents who have had more than 5 years of working experience, 2 of them are professionals working in the pharmaceutical industry, 3 of them are pharmacists, and 1 of them is a medical practitioner, while the remaining 2 of them are NAFDAC staff.

4.2 Analysis of Objective One: To understand the perception of various group of individuals in Nigeria about the drugs produced in the country

4.2.1 Do you agree or disagree with the statement that medicinal products in Nigeria are of low quality?

Table 4.6 The perception of participants on their agreement or disagreement that medicinal products are of low quality

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Professionals working in the Pharmaceutical industry	1(16.7%)	2(33.3%)	2(33.3%)	1(16.7%)	0(0%)
Pharmacists	0(0%)	2(50.0%)	1(25.0%)	1(25.0%)	0(0%)
Medical practitioners	0(0%)	2(50.0%)	0(0%)	2(50.0%)	0(0%)
NAFDAC Staff	1(20.0%)	2(40.0%)	2(40.0%)	0(0%)	0(0%)
Consumers	1(5.6%)	6(33.3%)	5(27.8%)	2(11.1%)	4(22.2%)
Total	**3(8.1%)**	**14(37.8%)**	**10(27.0%)**	**6 (16.2%)**	**4(10.8%)**

Table 4.6 shows a distribution of the extent to which the various participants believe with the statement that Nigerian medical products are of low quality. Out of all the (37) respondents, 17(45.9%) of the respondents were in agreement with the statement, 10 (27.0%) of them were neutral, while the remaining 10 (27.0%) were in disagreement with the statement. The 17 respondents in agreement with the statement were: 3 (50.0%) of the professionals working in the pharmaceutical industry, 2 (50%)) of the pharmacists, 2 (50%) of the medical practitioners, 3 (60.0%) of the NAFDAC staff, and 7 (38.9%) of the consumers. Also, the 10 respondents who were neutral to the statement include 2 (33.3%) of the professionals working in the pharmaceutical industry, 1 (25%) of the pharmacists, none (0%) of the medical practitioners, 2 (40%) of the NAFDAC staff, and 5 (27%) of the consumers. Finally, the remaining 10 respondents who were in disagreement with the statement include 1 (16.7%) of the professionals working in the pharmaceutical industry, 1 (25.0%) of the pharmacists, 2 (50%) of the medical practitioners, none (0%) of the NAFDAC staff and 6 (33.3%) of the consumers.

4.3 Analysis of Objective Two:

To find out the preferred type of drugs (locally produced or foreign) bought by consumers or prescribed by medical practitioners in Nigeria.

4.3.1 What type of drug would you prefer to recommend to your patients/customers?

Table 4.7 The distribution of the preferences of medical products made in Nigeria/abroad.

Medical Professionals	Drugs produced in Nigeria	Drugs produced Abroad	No preference	Total
Professionals working in the Pharmaceutical industry	1(16.7%)	3(50.0%)	2(33.3%)	**6(42.9%)**
Pharmacists	1(25.0%)	1(25.0%)	2(50.0%)	**4(28.6%)**
Medical practitioners	0(0%)	2(50.0%)	2(50.0%)	**4(28.6%)**
Total	**2(14.3%)**	**6(42.9%)**	**6(42.9%)**	**14(100%)**

Table 4.7 displays the distribution of the preferences of medicinal products that are made in Nigeria or abroad. The table shows that out of the 14 professionals who responded to the question, 6 (42.9%) of them preferred to recommend drugs produced abroad to customers, 6 (42.9%) of them had no preference, while only 2 (14.3%) of them prefer to recommend drugs produced in Nigeria to customers. The 6 respondents who preferred to recommend drugs produced in abroad were 3 (50.0%) of the professionals working in the pharmaceutical industry, 1 (25.0%) of the pharmacists, and 2 (50%) of the medical practitioners prescribed drugs produced in abroad to consumers. Also, the 6 respondents who had no preference for drug recommendation include 2 (33.3%) of the professionals working in the pharmaceutical industry, 2 (50.0%) of the pharmacists and another 2 (50.0%) of the medical practitioners had no preferences to prescribe drugs to consumers. Finally, the remaining 2 respondents who preferred to recommend drugs produced in Nigeria were: 1 (16.7%) of the professionals working in the pharmaceutical industry and the remaining 1 (25.0%) of the pharmacists; none (0%) of them were medical practitioners that would prescribe drugs to consumers from Nigeria.

4.3.2 What type of drugs do you prefer to buy?

Table 4.8 A display of consumers' preferences to their choice of drugs

What type of drugs do you prefer to buy?	Frequency	% Frequency
Drugs produced abroad	14	77.8
Drugs produced in Nigeria	4	22.2
Total	**18**	**100.0**

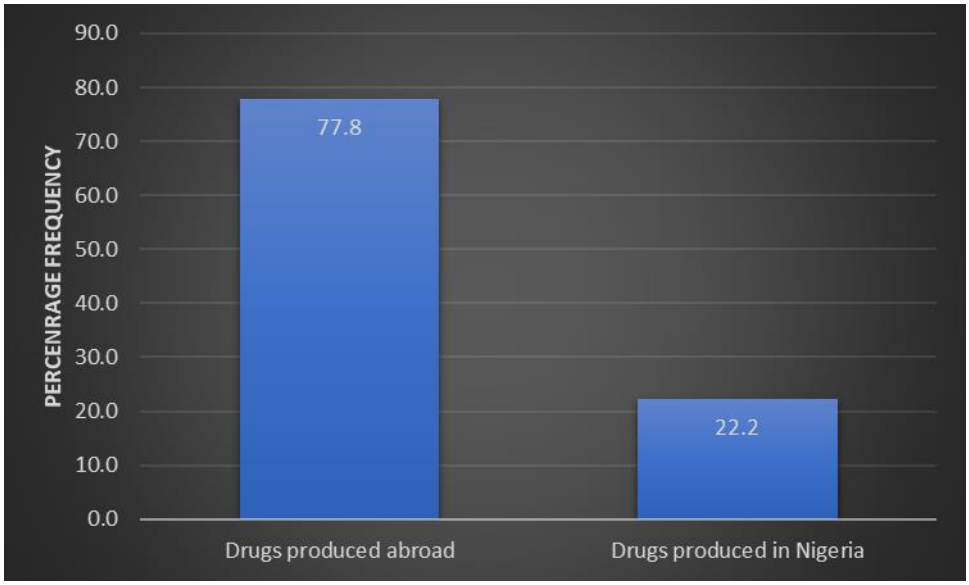

Fig 4.6 A bar chart displaying the consumers' preferences to their choice of drugs

Table 4.8 and Figure 4.6 above displayed the consumers' responses to their preference for drugs to purchase with respect to where they were produced. Out of all the consumers, 14 (77.8%) of them chose 'drugs produced abroad, indicating that they prefer purchasing drugs which were not produced in Nigeria, while the remaining 4 (22.2%) of them chose 'drugs produced in Nigeria', indicating that they prefer purchasing Nigerian produced drugs.

4.4 Analysis of Objective Three:

To identify the major contributing factors to the production and distribution of low-quality drugs in Nigeria

Table 4.9 A distribution of respondents' perception about major factors that can influence or impact on the quality of medicinal products in Nigeria

		High cost of good quality drugs	Non-health professionals in the drug business	Inadequate laws or poor enforcement of the existing drug quality control regulations	Inadequate drug distribution monitoring system	Demand exceeding supply
Professionals working in the Pharmaceutical industry	Strongly Agree	16.7	0.0	16.7	33.3	0.0
	Agree	50.0	16.7	50.0	50.0	0.0
	Neutral	33.3	16.7	33.3	16.7	33.3
	Disagree	0.0	50.0	0.0	0.0	50.0
	Strongly Disagree	0.0	16.7	0.0	0.0	16.7
Pharmacists	Strongly Agree	0.0	25.0	25.0	50.0	0.0
	Agree	75.0	75.0	75.0	50.0	0.0
	Neutral	25.0	0.0	0.0	0.0	50.0
	Disagree	0.0	0.0	0.0	0.0	25.0
	Strongly Disagree	0.0	0.0	0.0	0.0	25.0
Medical practitioners	Strongly Agree	25.0	25.0	50.0	25.0	0.0
	Agree	25.0	25.0	25.0	25.0	50.0
	Neutral	0.0	25.0	0.0	0.0	0.0
	Disagree	50.0	0.0	25.0	25.0	50.0
	Strongly Disagree	0.0	25.0	0.0	25.0	0.0
NAFDAC Staff	Strongly Agree	0.0	0.0	0.0	0.0	0.0
	Agree	20.0	0.0	0.0	0.0	0.0
	Neutral	40.0	0.0	20.0	60.0	40.0
	Disagree	40.0	40.0	60.0	40.0	40.0
	Strongly Disagree	0.0	60.0	20.0	0.0	20.0
Consumers	Strongly	16.7	22.2	33.3	27.8	11.1

Agree					
Agree	38.9	27.8	27.8	27.8	11.1
Neutral	22.2	16.7	16.7	27.8	22.2
Disagree	11.1	5.6	5.6	5.6	27.8
Strongly Disagree	11.1	27.8	16.7	11.1	27.8

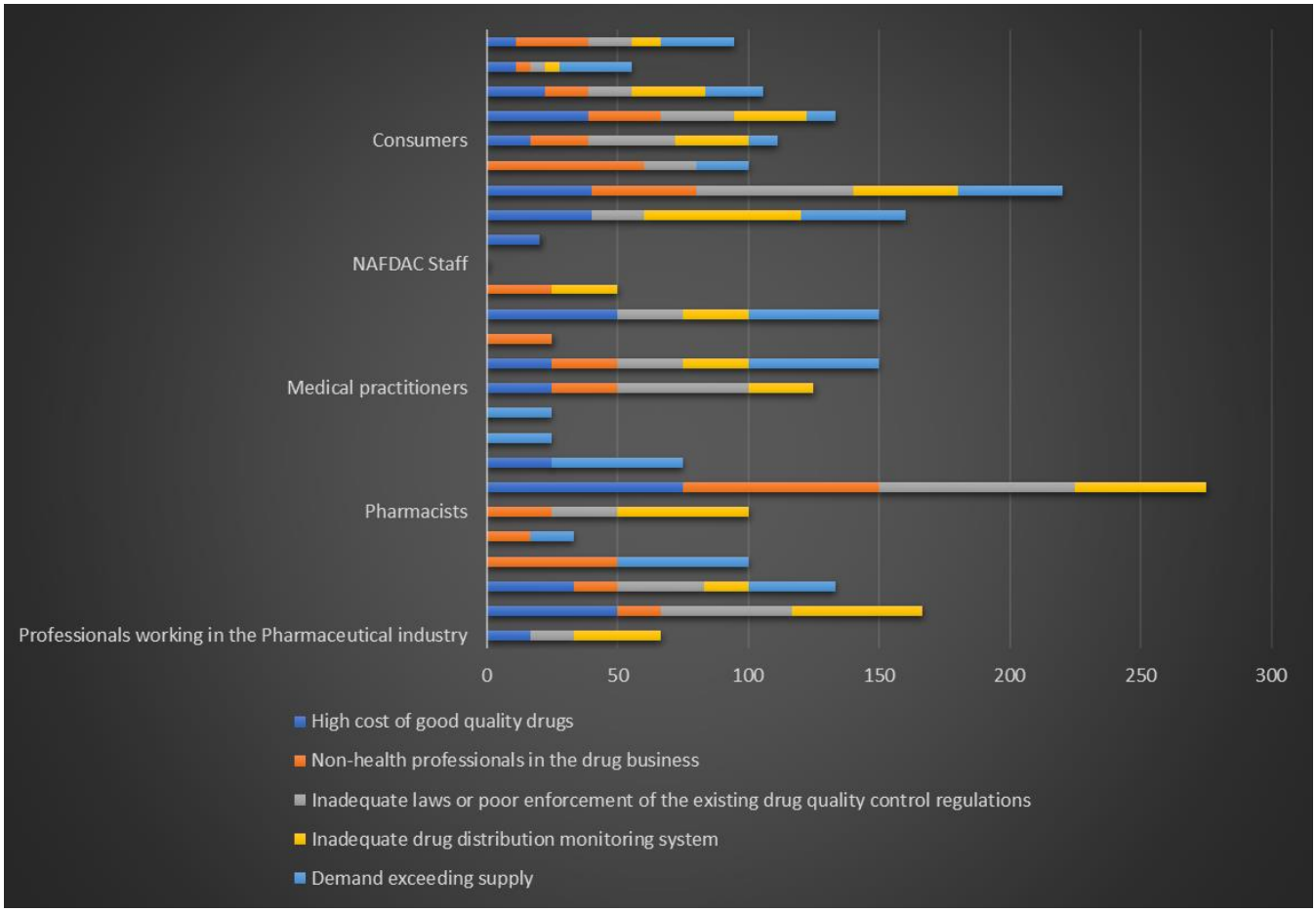

Fig 4.7 A clusterd bar of the distribution of respondents' perception about major factors that can influence or impact on the quality of medicinal products in Nigeria

Table 4.9 and Fig 4.7 above shows a distribution of the respondents' level of agreement to the major contributing factors to the production and distribution of low-quality drugs in Nigeria. With respect to the statement that the high cost of good quality drugs is a major contributing factor, 66.7% of the professionals working in the pharmaceutical industry were in agreement that it is a major contributing factor, 33.3% of them were neutral to the statement while none (0.0%) of them were in disagreement to the statement; 75% of the pharmacists were in

agreement to the statement, the remaining 25% of them were in disagreement while non (0.0%) of them disagreed to the statement; 50% of the medical practitioners agreed to the statement, none were neutral, while the remaining 50% of them disagreed to the statement; only 20% of the NAFDAC staff were in agreement with the statement, 40% were neutral whereas the remaining 40% disagreed to that; of all the consumers, 55.6% of them were in agreement, 22.2% of them were neutral, while the remaining 22.2% of them were in disagreement with the statement that high cost of good quality drugs is a major contributing factor to the production and distribution of low quality drugs in Nigeria.

With respect to the statement that Non-health professionals in the drug business are a contributing factor to the production and distribution of low-quality drugs in Nigeria, 16.7% of the professionals working in the pharmaceutical industry agreed to the statement, another 16.7% of them were neutral, while the remaining 66.7% of them were in disagreement with the statement; 100% of the pharmacists agreed to this statement, while none of them were neutral or in disagreement with it; 50% of the medical practitioners were in agreement with the statement, 25% of them were neutral while the remaining 25% of them were in disagreement with the statement; out of all the NAFDAC staff, none of them were in agreement or neutral to the statement while 100% of them disagreed to the statement; 50% of the consumers agreed to this statement, 16.7% of them were neutral while the remaining 33.4% of them were in disagreement with the statement.

With respect to the statement that the inadequate laws or poor enforcement of the existing drug quality control regulations is the major contributing factor to the production and distribution of low quality drugs in Nigeria, 66.7% of the professionals working in the pharmaceutical industry agreed to the statement, the remaining 33.3% of them were neutral to it whereas none of them were in disagreement to the statement; also, of all the pharmacists who responded to this statement, 100% of them agreed to it while none of them were neutral or in disagreement with the statement; 75% of the medical practitioner were in agreement with this statement, none of them were neutral while the remaining 25% of them disagreed with it; out of all the NAFDAC staff, none of them agreed with the statement, 20% were neutral while the remaining 80% were in disagreement with the statement; finally, 55,6% of the consumers agreed to the statement, 27.8% of them were neutral while the remaining 16.7% of them disagreed to it.

With respect to the statement that inadequate drug distribution monitoring system is a major contributing factor to the production and distribution of low-quality drugs in Nigeria, 83.3% of the professionals working in the pharmaceutical industry agreed to this statement, the remaining 16.7% of them were neutral to it while none of them disagreed to it; also, out of all the pharmacists, 100% of them were in agreement with the statement, while none was neutral or disagreed with it; 50% of the medical practitioner agreed to the statement, none was neutral while the remaining 50% were in disagreement with it; out of all the NAFDAC staff, none of them was in agreement with the statement, 60% of them were neutral, whereas the remaining 40% of them were in disagreement with it; lastly, 55.6% of the consumers were in agreement with this statement, another 27.8% of them were neutral while the remaining 16.7% of them were in disagreement with the statement.

Finally, with respect to the statement that demand exceeding supply is a major contributing factor to the production and distribution of low quality drugs in Nigeria, none of the professionals working in the pharmaceutical industry was in agreement with this statement, 33.3% of them were neutral while the remaining 56.7% of them were in disagreement with it; also, none of the pharmacists was in agreement with this statement, 50% of them were neutral while the remaining 50% of them were in disagreement with the statement; more so, 50% of the medical practitioners were in agreement with this statement, none of them was neutral while the remaining 50% were in disagreement with it; again, none of the NAFDAC staff was in agreement with this statement, 40% of them were neutral while the remaining 60% of them were in disagreement with it; finally, 22.2% of the consumers were in agreement with the statement, another 22.2% of them were neutral whereas the remaining 55.6% of them were in disagreement with the statement.

4.5 Analysis of Objective Four:
To identify and assess the control measures used by NAFDAC in ensuring the production of good quality drugs and how compliant all individuals are to them

4.5.1 What measures have been taken by NAFDAC to control the production and distribution of low-quality medicinal products in Nigeria?

The above question was directed to the NAFDAC staff. Some of the respondents who answered this question indicated that “NAFDAC agency has set up enforcement officers for control and constant routine inspection by designated inspectors”. Another response given by them was the “provision of mobile authentication of original drugs” and thirdly, “Putting in

place disciplinary measures in law against fake drug production and unlicensed drug distribution".

4.5.2 How often does NAFDAC inspect your drug production process?

Table 4.10 A response showing the perception of pharmaceutical professionals' to the inspection of NAFDAC on their companies' drug production process

How often does NAFDAC inspect your drug production process?	Frequency	% Frequency
Very Often	1	16.7
Often	3	50.0
No idea	1	16.7
Seldom	1	16.7
very seldom	0	0

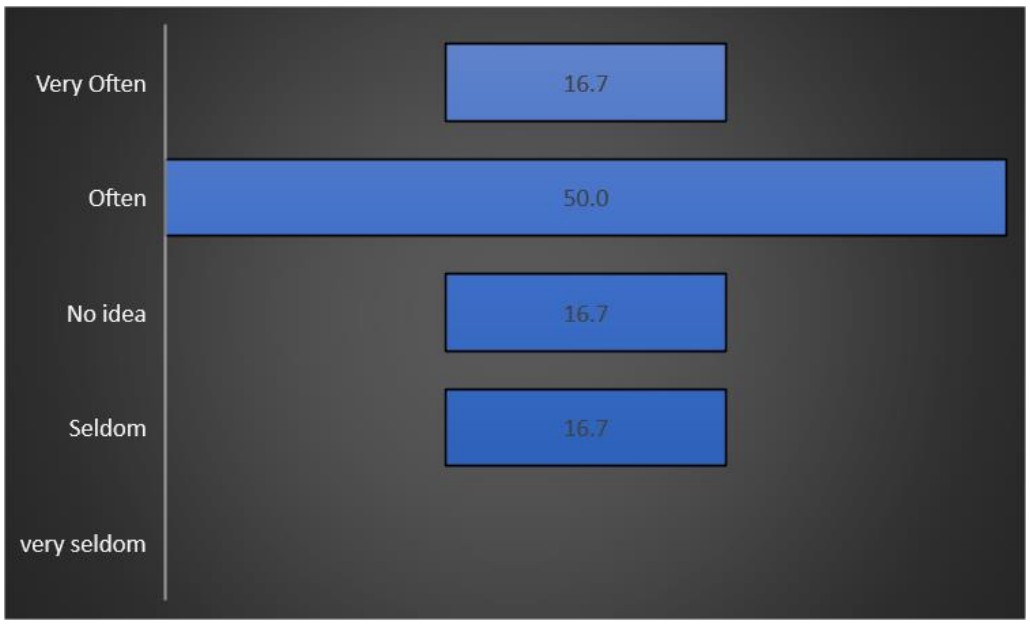

Fig 4.8 A Funnel chart showing the distribution of responses given by professionals working in the pharmaceutical industry on NAFDAC's inspection on their companies drug production process

Table 4.10 and Figure 4.8 show a distribution of the responses given by the professionals working in the pharmaceutical industry about how often the drug production process is being inspected by NAFDAC. It shows that 1 (16.7%) of them answered 'very often', 3 (50%) of them answered 'often' showing that NAFDAC often inspects their drug production process; however, 1((16.7%) of them answered 'no idea', indicating he/she cannot tell how often this

was done, the remaining 1 (16.7%) of them answered 'seldom' while none answered 'very seldom'; this shows that only one person indicated that NAFDAC does not often inspect their drug production process.

4.6 Analysis of Objective Five: To determine the degree to which the objective of drug quality improvement has been achieved in Nigeria.

4.6.1 Do you think NAFDAC is improving the quality control of the production and distribution of medicinal products in Nigeria?

Table 4.11 The Perception of Pharmacists on the improvement of the quality control of production and distribution of medicinal products in Nigeria

Do you think NAFDAC is improving the quality control of the production and distribution of medicinal products in Nigeria?	Frequency	% Frequency
Yes	3	75
No	1	25
Total	**4**	**100**

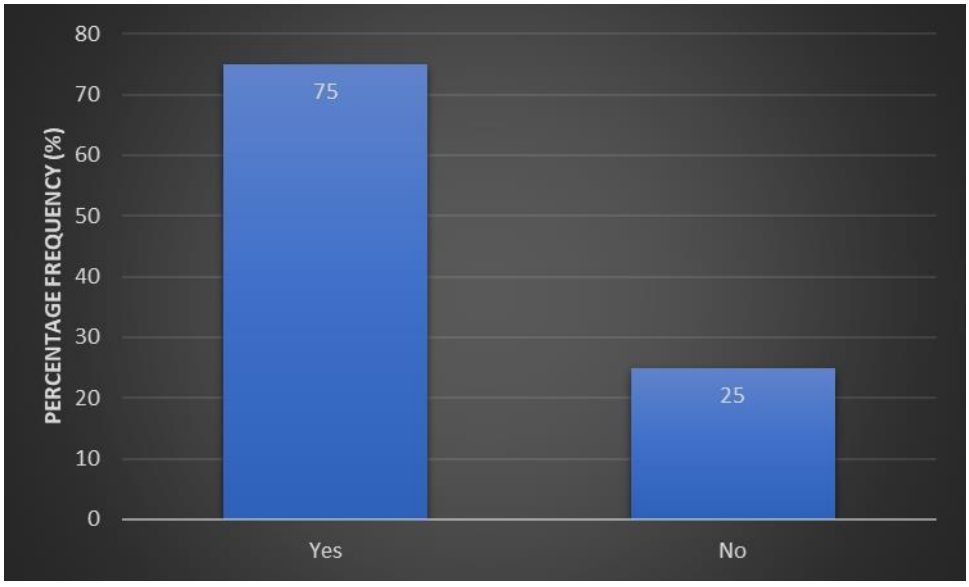

Fig 4.9 A bar chart displaying the responses of the pharmacists on the improvement of NAFDAC quality control on production and distribution of medicinal products in Nigeria

Table 4.11 and Figure 4.9 above revealed the perceptions of the pharmacists on the improvement of drug production and distribution quality control by NAFDAC. With respect to this, 3 (75.0%) of the respondents answered 'yes' indicating that they believe that

NAFDAC is improving the quality control of the production and distribution of medicinal products in Nigeria, whereas only 1 (25.0%) of them answered 'no' indicating they don't believe the statement.

4.6.2 Do you think the degree of fake drug distribution in Nigeria has reduced within the last ten years?

Table 4.12 The response of the medical professionals perception on the degree of fake drug distribution reduction in Nigeria within the last ten years

Do you think the degree of fake drug distribution in Nigeria has reduced within the last ten years?	Frequency	% Frequency
Yes	2	50.0
No	2	50.0
Total	**4**	**100.0**

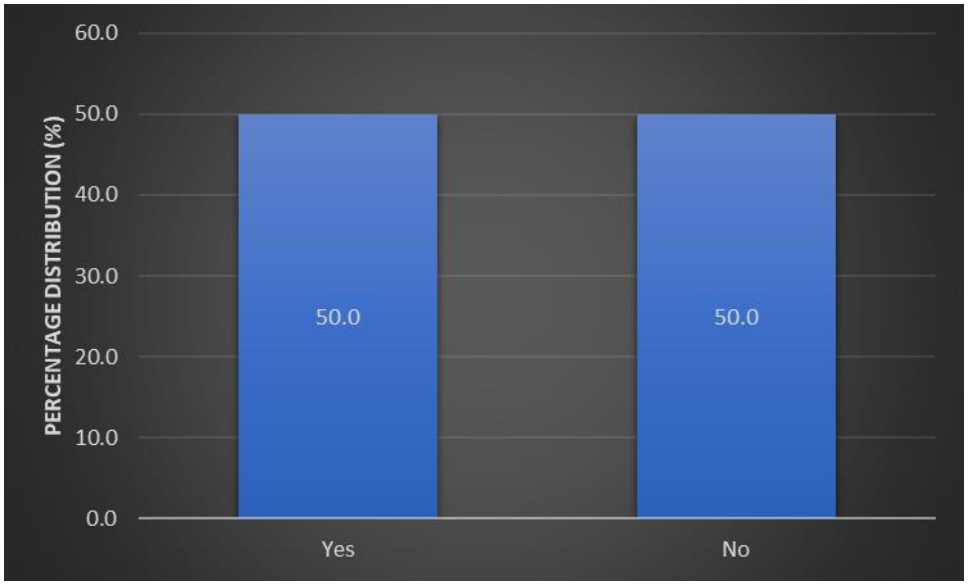

Fig 4.10 A bar chart displaying the responses of the medical professionals on their perception of the degree of fake drug distribution reduction in Nigeria within the last ten years

Table 4.12 and figure 4.10 above displayed the responses of the medical professionals perception on the degree of fake drug distribution in Nigeria has reduced within the last 10 years. 50% of them answered 'yes' to the question, indicating that they believe the degree of fake drug distribution in Nigeria has reduced within the last 10 years, while the other 50% of

them answered ‘no’ to the question indicating they don’t believe the degree of fake drug distribution in Nigeria has reduced within the last 10 years.

4.6.3 Can you identify if your purchased drugs are fake or authentic?

Table 4.13 A display of consumers responses ability to identify fake drugs

Can you identify if your purchased drugs are fake or authentic?	Frequency	% Frequency
Yes	5	27.8
No	13	72.2
Total	**18**	**100.0**

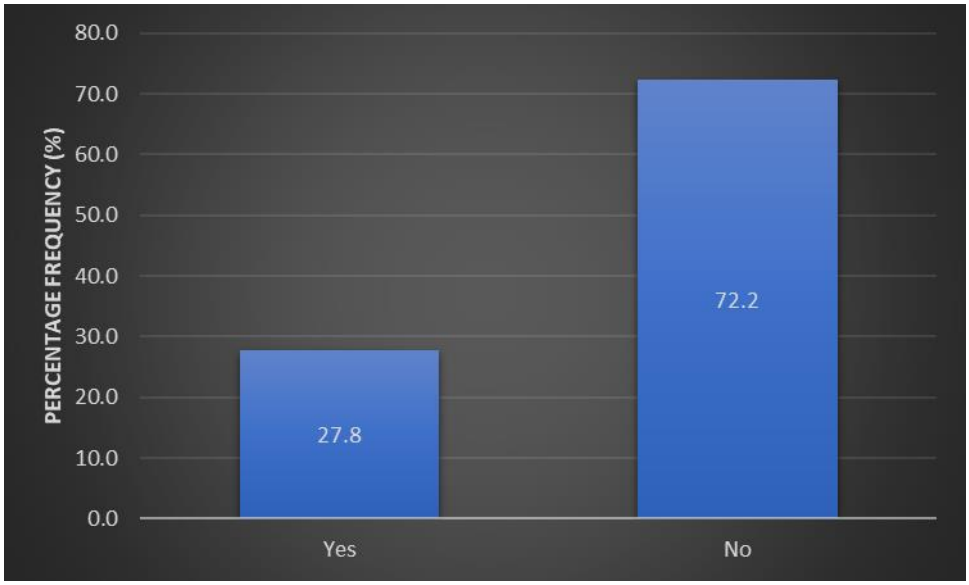

Fig 4.11 A bar chart showing the responses of consumers’ ability to identify fake drugs

Table 4.13 and figure 4.11 above showed the consumers’ responses about their ability to identify fake or authentic drugs. From the table and figure above, 5 (27.8%) of them answered ‘yes’ to the question, indicating they are able to identify if they purchased fake or authentic drugs; while 13 (72%) of them answered ‘no’ to the question, indicating they are not able to identify if they have purchased fake or authentic drugs.

RESULTS

This chapter attempts to discuss the major findings from the analysis above in relation to the objectives of this research, after which the findings from this study would be compared with that of other related studies on drug quality.

The first objective sought to outline the perception of various groups of people with different professional backgrounds that are involved in the production and distribution of medicinal products in Nigeria, as well as random consumers:

- Group A: professionals working in the pharmaceutical industry; Pharmacists; Medical professionals.
- Group B: NAFDAC – Organization that is responsible to control of Quality of Medicinal products in Nigeria.
- Group C: Consumers in Nigeria.

Findings from the analysis with respect to this objective revealed that most of the participants agreed that medical products produced in Nigeria are of low quality. Also, it was noted that a greater percentage of NAFDAC staff, pharmacists, and medical practitioners agree with the statement in comparison to others. This finding is similar to that of Ebenezer (2015), who conducted a qualitative study and reported the perceived existence of poor quality medicine in Nigeria with perceived increased level of poor quality medicine in Nigeria reported by mainly the community pharmacists and patent medicine vendor groups in comparison with other groups. According to him, the reason for this was due to their personal experiences as some of them have encountered various illegal drug hawkers on the streets and public transports, some have encountered patients who bought prescribed drugs from nearby vendors which failed to work and when checked, they noticed it had no NAFDAC registration number, etc (Ebenezer, 2015).

Secondly, the second objective sought to find out the preferred type of drugs (locally produced or foreign) bought by consumers or prescribed by medical practitioners in Nigeria. The researcher asked two questions, one to the professionals and the other to the consumers in order to ascertain this. Findings from the result revealed that majority of the professionals including the pharmacists, medical practitioners and the professionals working in the pharmaceutical industries indicated they prefer to recommend drugs produced abroad to that produced in Nigeria for their patients/customers; it also revealed that customers prefer to buy foreign drugs to that produced in Nigeria. This implies that foreign-made drugs are more

valued by Nigerians, which may probably be because many of them must have encountered a series of fake drug dealers in one way or the other. Many Nigerians do not trust drugs produced in their home country. This finding is in consensus with the findings from the first objective as the majority of the respondents has had the perception that drugs produced in Nigeria are of low quality, they will definitely prefer recommending/buying foreign drugs because the consequences of consuming fake drug products are most often costlier than purchasing original drugs.

Furthermore, the third objective sought to identify the major contributing factors to the production and distribution of low-quality drugs in Nigeria. Five factors were listed and each of the respondents was asked to specify their level of agreement or disagreement that each of the listed factors contributes majorly to the production and distribution of low-quality drugs in Nigeria. The factors include High cost of good quality drugs, non-health professionals in the drug business, inadequate laws or poor enforcement of the existing drug quality control regulations, inadequate drug distribution monitoring system, and demand exceeding supply. Findings from the results as regards this objective are: First, majority of the respondents agreed that high cost of good quality drugs is a major contributing factor to the production and distribution of good quality drugs; also, the pharmacists, professionals working in the pharmaceutical industry and the consumers had a greater percentage of agreement in comparison with the other groups. This finding is agreeable because these group of people is the ones who are directly affected by the cost of the drugs as pharmaceutical companies would spend more to produce the drug products, sell at a higher price to the pharmacists who will now dispense/sell to the consumers at the same high cost. If the cost of producing high-quality drugs are high, it would encourage the fake drug dealers to start imitating and producing fake drugs so as to sell faster; and as a good number of Nigerians live below poverty level, many drug users may not be buoyant enough to purchase good quality drugs and, therefore, would be forced to buy the affordable ones which are of lower quality.

More so, with respect to the second listed factor which is ‘non-health professionals in drug business’, overall, the majority of the respondents were in agreement with this. A greater percentage of the pharmacists, medical practitioners, and the consumers, when compared to the other groups, agreed with this statement. In Nigeria, the least required qualification for an individual to be licenced as a drug dealer in Nigeria is the first school leaving certificate. As a result of this, most of the non-health professionals in drug businesses may not be able to differentiate fake from original drugs as most of them may have not attended a higher

institution to study all about drugs (Erhun et al., 2001). This finding is in consensus with the findings of Chinwendu (2008), and Erhun et al. (2001), in whose study, the majority of the respondents indicated that non-health professionals in the drug business are a major contributing factor to the production and distribution of low-quality drugs in Nigeria. This finding is also similar to that of Ebenezer (2015), who noted that Ignorance and lack of awareness is one of the major contributing factors.

Again, most of the respondents also agreed that inadequate laws or poor enforcement of the existing drug quality control regulations are a major contributing factor to the production and distribution of low-quality drugs in Nigeria. If there are no appropriate laws governing drug production and distribution in the country, and, if the defaulters of these drug laws are not punished as appropriate, people tend to be more encouraged to produce and distribute fake drugs. This finding is in agreement with the finding of Chinwendu (2008), in which all the participants who participated in her study agreed that inadequate laws or poor enforcement of the existing drug quality control regulations are a major contributor to the production and distribution of low-quality drugs in Nigeria. However, the result revealed that none of the NAFDAC staff was in agreement with this statement. This may be because they believe that NAFDAC always does its best to enforce the drug law and punish defaulters as appropriate. Ebenezer (2015) revealed a similar finding, indicating that only a few of the respondents chose this factor as a major contributing factor to the production and distribution of low-quality drugs in Nigeria.

Lastly, a good number of the participants agreed that an inadequate drug distribution monitoring system is a major contributing factor to the production and distribution of low-quality drugs in Nigeria. This finding is also in agreement with that of Olike (2008) who also revealed that Demand exceeding supply is not a major contributing factor to the production and distribution of fake or low-quality drugs in Nigeria.

More so, the fourth objective sought to identify and assess the control measures used by NAFDAC in ensuring the production of good quality drugs. The researcher used two questions to address this objective. The first question was directed to the NAFDAC staff to ascertain their views about the control measures used by NAFDAC in ensuring production and distribution of good quality drugs, while the second question was directed to the professionals working in the pharmaceutical industry in order to ascertain how often NAFDAC inspect the drug production process in their company. Findings from the result

showed that NAFDAC uses some control measures like setting up enforcement officers for control and routine inspection, provision of mobile authentication of original drugs to help consumers identify which drugs are fake or original, and also putting in place disciplinary measures against fake drug production and unlicensed drug distribution in the law. Also, findings revealed that NAFDAC often inspects the drug production process in pharmaceutical companies. According to the findings from a study conducted by Orga (2017) on the impact of NAFDAC on quality management of Nigerian manufacturing sector, routine inspection of the pharmaceutical company was one of the measures used by NAFDAC to ensure compliance with standard specifications, which is in agreement with the finding from this study.

Finally, the Fifth objective sought to determine the degree to which the objective of drug quality improvement has been achieved in Nigeria. The researcher used three questions to address this objective. The first question sought to find out if NAFDAC activity is improving the quality control of the production and distribution of drugs in Nigeria. The second question sought to find out from the participants their perception about whether fake drug production and distribution has reduced in Nigeria within the last 10 years, while the last question sought to know if the consumers were able to identify if their purchased drugs were fake or authentic. Findings from the result showed that most of the participants believe that NAFDAC activity is improving the quality control of the production and distribution of medicinal products in Nigeria. Also, there is an equal percentage of agreement and disagreement as to whether the fake drug distribution and production have reduced. Additionally, most of the consumers indicated, from the last question, that they cannot ascertain whether the drugs they purchased are fake and original. Findings from the fifth objective imply that NAFDAC has put up many measures and strategies to curtail production and distribution of low-quality drugs but some members of the public are not very familiar with how to utilize some of them like the mobile authentication service. A finding from a similar study conducted by Wogu et al. (2019) on the influence of NAFDAC mobile drugs authentication service on the use of fake drugs among Consumers in Southeast Nigeria is also in agreement with the finding from this objective, as he noted there was a low level of awareness of the Mobile authentication service by the public This may likely be one of the contributing factors to the distribution and even consumption of low-quality drugs because since consumers are not aware of this, they would find it difficult to differentiate the fake from original drug products, thereby enhancing the sales of fake drugs.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATION

This is the conclusion and recommendation chapter, of which there is a more elaborate discussion on what NAFDAC has done so far and what will be recommended they should do going forward to control the spread of counterfeit medicinal products in Nigeria.

Findings from the study have revealed how individuals from different professional backgrounds who are involved in the production and distribution of medical products in Nigeria, as well as the random consumers, perceive medical products produced in Nigeria, the factors influencing the production and distribution of low-quality drugs, the role of NAFDAC in improving drug quality, and the current situation of Nigeria with respect to drug quality. The study had five objectives that summarily boiled down to understanding the role of NAFDAC in improving drug quality in Nigeria.

From the first objective, it was concluded that the respondents, mainly the NAFDAC staff and the medical practitioners believe that drugs produced in Nigeria are of low quality. Also, findings from the second objective pointed out that the professionals, as well as the consumers, prefer to recommend and /or purchase foreign-made drugs to the locally (Nigerian) made ones.

Furthermore, it was deduced from the third objective that the high cost of good quality drugs, inadequate laws, or poor enforcement of the existing drug quality control regulations and the inadequate drug distribution monitoring system were the three major factors influencing the production and distribution of low-quality drugs in Nigeria. More so, setting up enforcement officers for control and routine inspection, provision of mobile authentication of original drugs to help consumers identify which drugs are fake or original are some of the control measures put up by NAFDAC to combat fake drug production and distribution in Nigeria; Finally, findings from the last objective revealed that there was an equal percentage of agreement and disagreement as to whether the problem of fake drug production and distribution has reduced in Nigeria in the last 10 years; it also revealed that majority of the consumers indicated they cannot ascertain whether the drugs they purchase are fake or original.

In conclusion, NAFDAC is doing its best to combat the problematic drug situation in Nigeria, but more efforts and awareness are still needed to make them more effective as to help to stop the spread of fake drugs and also to protect various group of individuals. Also, from my research in conclusion it shows that most individuals still need an awareness to the distribution and purchasing of counterfeit medicinal products and the control measures put in place by NAFDAC will need to be improved.

The researcher, therefore, recommends that the cost of producing drugs in Nigeria should be subsidised by the government as these would make good quality drugs affordable for the consumers so that they would have no reason to purchase drugs of lower quality. More stringent drug laws/policies and punishments for defaulters should also be enforced to discourage fake drug production and distribution in the country. Again, the researcher further recommends that NAFDAC should increase the awareness for the use of the mobile authentication service so as to help the consumers identify the fake drug products from the original ones. In these ways, the problem of the production and distribution of fake medical products would be reduced in Nigeria. The awareness of counterfeit medicinal products should be well known by individuals as NAFDAC work on all there control measures that have been put in place by improving on it and also they should work on the officials put in place for distribution of medicinal products to check all medicinal products are well numbered and labelled appropriately.

Also, will recommend that in future NAFDAC uses some of the guidelines from ICH, that way it will help them more on their guidelines and help improve their work in the control of low-quality medicinal products in Nigeria. The researcher would recommend that there be some form of free anti-malaria medicinal products for everyone as malaria is one of the high level of sickness and deaths in Nigeria. Futhermore, a recommendation would be that medicinal products in Nigeria should be authenticated so that individuals can appreciate medicinal products in Nigeria and not seen as low-quality drugs as long as they put all control measures in place.

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Appendix

QUESTIONNAIRE

This is a research being conducted by a student of Griffith College Dublin.

Your participation in this research study is voluntary. You may choose not to participate. If you decide to participate in this research survey, you may withdraw at any time. If you decide not to participate in this study or if you withdraw from participating at any time, you will not be penalized.

The procedure involves filling an online survey that will take approximately 4-7 minutes. Your responses will be confidential and we do not collect identifying information such as your name or email address. To help protect your confidentiality, the surveys will not contain information that will personally identify you. The results of this study will be used for scholarly purposes only.

Section A

Tick ✓ against the appropriate answer

1. Gender _____ ☐ Male ☐ Female

2. Please indicate your age ___ ☐ <20 ☐18-29yrs

   ☐30-39yrs ☐50-59yrs ☐60+yrs

3. **What is your level of education?**

   ☐Certificate/Diploma

   ☐Bachelor's degree/Advanced diploma

   ☐Master's degree

   ☐Other level (specify) _____

4. **What is your profession? _____**

5. **How long have you worked in the industry? _____**

SECTION B

MEDICAL PROFESSIONALS.

Please tick the appropriate box:

1. What is your opinion about the quality of medicinal products in Nigeria?

   Please clarify in your own words:_____
   _____

   a. Do you agree or disagree wth the statement that medicinal products in Nigeria are low quality?

   ☐Strongly Disagree

   ☐Disagree

   ☐Neutral

   ☐Agree

   ☐Strongly Agree

   b. Do you agree or disagree wth the statement that pharmaceutical companies based in Nigeria are producing and distributing low quality medicine?

   ☐Strongly Disagree

   ☐Disagree

   ☐Neutral

   ☐Agree

   ☐Strongly Agree

2. As a medical professional what is your experience (observation) in the use of medicinal products that is produced in Nigeria or medicinal products that are manufactured in different countries?

    - Preference for the use of medicines that are produced abroad.
    - Usually medicinal products that are produced by Nigerian pharmaceutical companies.
    - Use of both at any time.
    - No preference

a. What type of drug would you prefer to prescribe for your patients?

    - Drugs produced in Nigeria
    - Drugs produced Abroad
    - No preference
    - Or another product; please specify _____

b. What type of medicine do you prefer to use in your area of expertise for your patients.

    - Medicine produced in Nigeria
    - Medicine produced Abroad
    - No preference
    - Or another product; Please specify _____

3. Do you think there are certain factors that can influence or impact on the quality of medicinal product in Nigeria:

Please tick the appropriate box:

i. High cost of good quality drugs

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐ Agree
- ☐ Strongly Agree

ii. Non – qualified / non proffesionals in drug production and distributions

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐Agree
- ☐Strongly Agree

iii. Inadequate laws or poor enforcement of the existing drug quality control regulations

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐ Agree
- ☐ Strongly Agree

iv. Inadequate drug distribution monitoring system

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐Agree
- ☐Strongly Agree

v. Demand exceeding supply

- ☐Strongly Disagree
- ☐Disagree
- ☐Neutral
- ☐Agree
- ☐Strongly Agree

vi. Or other other factors, please specify _____

4. Do you think drugs produced in Nigeria are of better quality than that produced abroad?

☐ Yes

☐ No

5. Do you think the degree of fake drug distribution in Nigeria has reduced within the last ten years?

☐ Yes

☐ No

6. As per your expertise – who are the distributors of Vaccine in your country?

☐ WHO – World Health Organization
☐ NAFDAC

☐ Or another distributor /supplier. Please specify

_____

7. Do you think NAFDAC is improving quality control of production and distribution of medicinal products in Nigeria?

☐ Yes
☐ No

SECTION B

PHARMACISTS

Please tick the appropriate box:

1. What is your opinion about the quality of medicinal products in Nigeria?

   Please Specify: _____

   _____

   _____

   a. Do you agree or disagree wth the statement that medicinal products in Nigeria are low quality?

      ☐Strongly Disagree

      ☐Disagree

      ☐Neutral

      ☐Agree

      ☐Strongly Agree

   b. Do you agree or disagree wth the statement that pharmaceutical companies based in Nigeria are producing and distributing low quality medicine?

      ☐Strongly Disagree

      ☐Disagree

      ☐Neutral

      ☐Agree

      ☐Strongly Agree

2. As a professional what is your experience / observation of your castomers/ consumers: What type of medicinal product they are prefer:

Please mark suitable box below:

- Customers select medicines that are produced abroad.
- Customers prefer medicinal products that are produced by Nigerian pharmaceutical companies.
- Use of both at any time.
- No preference

- Or other. Please specify _____

_____

_____

3. Do you think there are certain factors that can influence or impact on the quality of medicinal product in Nigeria:

Please tick the appropriate box:

i. High cost of good quality drugs

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐ Agree
- ☐ Strongly Agree

ii. Non – qualified / non proffesionals in drug production and distributions

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐Agree
- ☐Strongly Agree

iii. Inadequate laws or poor enforcement of the existing drug quality control regulations

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐ Agree
- ☐ Strongly Agree

iv. Inadequate drug distribution monitoring system

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐ Agree
- ☐ Strongly Agree

v. Demand exceeding supply

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐ Agree
- ☐ Strongly Agree

vi. Or other other factors, please specify _____

_____

_____

3. What type of medicinal products would you advise to your consumers / customers to purchase?

Please tick the appropriate box:

- ☐ Medicine produced in Nigeria
- ☐ Medicine produced abroad
- ☐ No preference

☐ Or another product; Please specify _____

4. Do you advise your consumers / customers to scratch and send the certification pin when you issue drugs to them?

☐Yes
☐No

5. Do you think that medicine produced abroad have better quality than medicine produced in Nigeria.

☐Yes
☐No

6. Do you think NAFDAC is improving quality control of production and distribution of medicinal products in Nigeria?

 Yes
 No

SECTION B

NAFDAC OFFICIALS

1. Do you agree or disagree with the statement that production and distribution of drugs in Nigeria are of low quality ?
   Please tick the appropriate box:

   ☐Strongly Disagree

   ☐Disagree

   ☐Neutral

   ☐Agree

   ☐Strongly Agree

2. What is your opinion about major factors that can influence or impact on the quality of medicinal products in Nigeria:
   Please tick the appropriate box:

   i. High cost of good quality drugs
      ☐Strongly Disagree
      ☐Disagree
      ☐Neutral
      ☐Agree
      ☐Strongly Agree

   ii. Non- professionals in drug business
      ☐Strongly Disagree
      ☐Disagree
      ☐Neutral
      ☐Agree
      ☐Strongly Agree

   iii. Inadequate laws and poor enforcement of the existing procedures:
      ☐Strongly Disagree
      ☐Disagree
      ☐Neutral
      ☐Agree
      ☐Strongly Agree

iv. Inadequate drug distribution monitoring system

- ☐Strongly Disagree
- ☐Disagree
- ☐Neutral
- ☐Agree
- ☐Strongly Agree

v. Demand exceeding supply

- ☐Strongly Disagree
- ☐Disagree
- ☐Neutral
- ☐Agree
- ☐Strongly Agree

vi. Or other other factors, please specify _____

_____

3. What measures have been taken by NAFDAC to control the production and distribution of low quality medicinal products in Nigeria.

Please specify _____

---

4. Do you agree or disagree that the fake drug production in Nigeria has reduced by up to 85% within the last ten years?

- ☐Yes Agree
- ☐No Disagree

- ☐ Or other other, please specify _____

_____

SECTION B

PROFESSIONALS WORKING IN THE PHARMACEUTICAL INDUSTRY

Please tick the appropriate box:

1. What is your opinion about the quality of medicinal products in Nigeria?

Please Specify: _____

_____

a. Do you agree or disagree wth the statement that medicinal products in Nigeria are low quality?

☐Strongly Disagree

☐Disagree

☐Neutral

☐Agree

☐Strongly Agree

b. Do you agree or disagree wth the statement that pharmaceutical companies based in Nigeria are producing and distributing low quality medicine?

☐Strongly Disagree

☐Disagree

☐Neutral

☐Agree

☐Strongly Agree

c. What type of drug would you prefer to recommend for your consumers?

- □ Drugs produced in Nigeria
- □ Drugs produced Abroad
- □ No preference
- □ Or another product; please specify _____

d. What type of medicine do you prefer to use in your area of expertise:

- □ Medicine produced in Nigeria
- □ Medicine produced Abroad
- □ No preference
- □ Or another product; Please specify _____

2. What is your opinion about major factors that can influence or impact on the quality of medicinal products in Nigeria:

Please tick the appropriate box below:

i. High cost of good quality drugs
- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐ Agree
- ☐ Strongly Agree

ii. Non – qualified / non proffesionals in drug production and distributions
- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐Agree
- ☐Strongly Agree

iii. Inadequate enforcement of the existing drug quality control regulations

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐ Agree
- ☐ Strongly Agree

iv. Inadequate drug distribution monitoring system

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐ Agree
- ☐ Strongly Agree

v. Demand exceeding supply

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neutral
- ☐ Agree
- ☐ Strongly Agree

vi. Or other factors, please specify _____

3. To what extent have your company adopted the following quality management practices?

Please tick the appropriate box:

i. Employee participation in the overall quality management. ☐

ii. Every sector of the company is involved in the quality management process of their products ☐

iii. Senior managers define the organisation's quality objectives and ensure its continuous communication to the employees. ☐

iv. Or other factors, please specify _____

_____

4. Do your company ensure the distribution of drugs to only licensed distributors?
Please tick the appropriate box:

Yes ☐
No☐

5. How often does NAFDAC inspect your drug production process
Please tick the appropriate box:

☐Very Often
☐ Often
☐ Undecided
☐ Seldom
☐ Very Seldom

SECTION B

CONSUMERS

1. Do you agree or disagree with the statement that production and distribution of drugs in Nigeria are of low quality ?
   Please tick the appropriate box below:

   ☐Strongly Disagree

   ☐Disagree

   ☐Neutral

   ☐Agree

   ☐Strongly Agree

2. What is your opinion about major factors that can influence or impact on the quality of medicinal products in Nigeria:

Please tick the appropriate box:

i. The high cost of good quality drugs
   - ☐Strongly Disagree
   - ☐Disagree
   - ☐Neutral
   - ☐Agree
   - ☐Strongly Agree

ii. Non-health professionals in the drug business
   - ☐Strongly Disagree
   - ☐Disagree
   - ☐Neutral
   - ☐Agree
   - ☐Strongly Agree

iii. Inadequate laws and poor enforcement of the existing ones
   - ☐Strongly Disagree
   - ☐Disagree
   - ☐Neutral
   - ☐Agree
   - ☐Strongly Agree

iv. Loose control system
- ☐Strongly Disagree
- ☐Disagree
- ☐Neutral
- ☐Agree
- ☐Strongly Agree

v. Demand exceeding supply
- ☐Strongly Disagree
- ☐Disagree
- ☐Neutral
- ☐Agree
- ☐Strongly Agree

vi. Or other factors, please specify _____

_____

3. What type of drugs do you prefer to buy?

Please tick the appropriate box:

☐Drugs produced in Nigeria

☐Drugs produced abroad

4. Do you think that drugs produced in Nigeria are of better quality than that produced abroad?

Please tick the appropriate box:

☐Yes

☐No

5. Where do you prefer to purchase your drugs?

Please tick the appropriate box:

☐Pharmacy stores

☐Chemist stores

☐Roadside stores

☐ Or other, please specify _____

6. Can you identify if your purchase drugs are fake or authentic?

□ If Yes Please specify _____

_____

_____

□ If No Please specify _____

_____

_____