

# **An Analysis of Loopholes in the Pharmaceutical Supply Chain, and Methods for Improving Control of Counterfeit Drugs in Nigeria.**

by

Ojima Precious Yakubu

A Research thesis submitted in partial fulfillment of the requirements for  
the degree of MSc in Pharmaceutical Business and Technology (QQI)

Innopharma Faculty of Pharmaceutical Sciences  
Griffith College Dublin

Dissertation supervisor: Susanna Coghlan

August 2020

## Candidate Declaration:

Candidate Name: Ojima Precious Yakubu

I certify that the dissertation entitled:

*“An Analysis of Loopholes in the Pharmaceutical Supply Chain, and Methods for Improving Control of Counterfeit Drugs in Nigeria”* submitted for the degree of **MSc in Pharmaceutical Business and Technology** *is the result of my work* and that where reference is made to work of others, due acknowledgment is given.

Candidate signature: Ojima Precious Yakubu

Date: 28<sup>th</sup> August 2020

Supervisor Name: Susanna Coghlan

Supervisor signature:

Date: 28<sup>th</sup> August 2020

## Acknowledgments:

My earnest gratitude goes to God Almighty for the grace, wisdom, and understanding to carry out this dissertation successfully.

To all my Professors here at Griffith College who have provided their guidance throughout this master's program, I truly appreciate your seeds of knowledge sown. I would also like to express my appreciation to my supervisor Susanna Coghlan, who guided me throughout the writing of this dissertation and did not hesitate to assist me with her knowledge.

This dissertation is dedicated to my parents Mr. and Mrs. Yakubu who have constantly supported me on this journey. Thank you for always believing in me and constantly encouraging me. To my siblings, Paul and Praise Yakubu, thank you for your encouragement and support.

To all the distributors and pharmacists who spared time out of their busy schedules to respond to the interview for this research, I am sincerely grateful for your support. To all those who took out time to fill out the questionnaires, thank you.

## ABSTRACT

### **An Analysis of Loopholes in the Pharmaceutical Supply Chain, and Methods for Improving Control of Counterfeit Drugs in Nigeria.**

By

Ojima Precious Yakubu

In Nigeria, the term counterfeit drug refers to drugs that have outlived their shelf life, mislabeled drugs, drugs kept under inappropriate temperatures, and drugs produced under unfavorable conditions. The supply of counterfeit drugs is an issue of great concern for the government, regulatory bodies, and industry professionals in Nigeria. Though policies and guidelines exist to control the supply, a significant amount of operating results have not been achieved yet. In Nigeria, the drug supply system needs to be carefully managed to safeguard the flow of genuine drugs throughout the supply chain. A high level of monitoring and evaluation must be enforced at all levels of the supply chain to ensure the activities of counterfeit drug peddlers are reduced as much as possible.

The purpose of this research is to identify and analyze the current challenges which facilitate the loopholes in the pharmaceutical supply chain in Nigeria and propose methods that can reduce how counterfeit drugs enter the supply chain. This research aims to interact with distributors and pharmacists because they are directly involved in the supply chain and are important contact points before a drug reaches consumers.

**Response Rate:** A total of 20 people were scheduled to be interviewed, 10 distributors, and 10 pharmacists. A total of 13 participants responded to the interview, 7 pharmacists and 6 distributors with two responding via text, recording a response rate of 65%

The survey was distributed to a total of 370 participants. 70 pharmacists and 300 consumers. A total of 55 pharmacists responded to the survey and a total of 202 consumers responded to the survey giving a total of 257 responses. Hence, recording a response rate of 69.45%.

The loopholes facilitating the infiltration of counterfeit drugs are that the number of unqualified workers in the supply chain is greater than the number of qualified workers, the presence of open markets, and poor implementation of laws. To control the supply of counterfeit drugs more consumer awareness needs to be done and industry experts need to familiarize themselves with more anti-counterfeit technologies and to exercise greater care in sourcing drugs.

*Key Words: Counterfeit Drugs, Supply Chain Management, Nigerian Pharmaceutical Distribution Channel, NAFDAC (National Drug Law Enforcement Agency), Anti-counterfeit technology, MAS (Mobile Authentication System).*

## Table of Contents

Candidate Declaration: .....	i
Acknowledgments: .....	ii
ABSTRACT.....	iii
LIST OF FIGURES.....	vi
LIST OF TABLES.....	vii
LIST OF ABBREVIATIONS .....	viii
DEFINITIONS.....	viii
CHAPTER 1: INTRODUCTION.....	1
1.1    OVERVIEW .....	1
1.1.1.    Overview of the Supply Chain.....	2
1.1.2.    Overview of Counterfeit Drugs in Nigeria.....	5
1.1.3.    Regulatory Bodies .....	7
1.2    RESEARCH PURPOSE.....	9
1.3    RESEARCH OBJECTIVES.....	10
1.4    RESEARCH QUESTIONS.....	10
1.5    STRUCTURE OF STUDY .....	10
1.6    SIGNIFICANCE OF STUDY .....	12
1.8    CONCLUSION.....	12
CHAPTER 2: LITERATURE REVIEW .....	13
2.1    INTRODUCTION .....	13
2.2    THE CURRENT STATE OF PHARMACEUTICAL DISTRIBUTION SYSTEM IN NIGERIA .....	14
2.3    CHALLENGES OF SAFEGUARDING THE PHARMACEUTICAL SUPPLY CHAIN .....	16
2.4    KNOWLEDGE OF SUPPLY CHAIN MANAGEMENT .....	21
2.5    CHALLENGES OF IMPLEMENTING PHARMACEUTICAL LAWS AND REGULATIONS .....	22
2.6.    COUNTERFEIT DRUGS AND CONSUMER SAFETY .....	24
2.7    COMPARATIVE REVIEW: A UNITED STATE STUDY .....	27
2.8    CONCEPTUAL FRAMEWORK .....	31
CHAPTER 3: RESEARCH METHODOLOGY .....	32
3.1    OVERVIEW.....	32
3.2    RESEARCH METHODOLOGY .....	32
3.3    RESEARCH PHILOSOPHY.....	33
3.4    RESEARCH STRATEGY .....	34
3.5    COLLECTION OF PRIMARY DATA.....	35
3.6    PROCEDURE AND SAMPLE .....	36
3.7    ACCESS AND ETHICAL ISSUES.....	37
3.8    INCLUSION AND EXCLUSION CRITERIA .....	37
3.9    CONCLUSION.....	38
CHAPTER 4: FINDINGS AND ANALYSIS .....	39
4.1    OVERVIEW.....	39

4.2 FINDINGS (QUALITATIVE DATA).....	39
4.3 DISCUSSION OF THEMES.....	40
4.3.1 Open Market.....	40
4.3.2 Unskilled People.....	41
4.3.3 Greed & Corruption .....	41
4.3.4 Awareness.....	42
4.3.5 Poor Supply Chain Management System.....	42
4.3.6 Improvement of Current Anti-counterfeit Technologies.....	43
4.4 FINDINGS (QUANTITATIVE DATA).....	44
4.4.1 CONSUMER ANALYSIS DATA REPRESENTATION .....	44
4.4.2 PHARMACISTS DATA REPRESENTATION .....	48
4.5 GRAPHICAL REPRESENTATION OF DATA .....	53
4.5.1 Graphical Representation of Consumer Response .....	53
4.5.2 Graphical Representation of Pharmacists Response .....	55
CHAPTER 5: CONCLUSION.....	59
5.1 OVERVIEW.....	59
5.2 ANSWERS TO THE RESEARCH QUESTIONS.....	59
5.3 COMPARING RESULTS FROM PRIMARY DATA AND SECONDARY DATA.....	62
5.4 CONTRIBUTION & LIMITATIONS OF THE RESEARCH.....	63
5.5 RECOMMENDATIONS FOR PRACTICE .....	64
5.6 RECOMMENDATION FOR FURTHER STUDIES .....	65
5.7 FINAL CONCLUSION/REFLECTION .....	65
REFERENCE.....	67
APPENDIXES .....	1
Interview Questions for pharmacist .....	1
Interview Questions for Distributors .....	2
Survey Questions for Consumers.....	3

## LIST OF FIGURES

Figure 1: The Pharmaceutical Supply Chain (Kapoor et al., 2018)

Figure 2: Pharmaceutical Distribution System in Nigeria (UNIDO, 2011)

Figure 3: A quantitative result showing the level of corruption in each section in Nigeria's pharmaceutical system, according to Garba et al

Figure 4: Data from the study “Drug Regulation and Control in Nigeria: The Challenge of Counterfeit Drugs” by Erhun et al

Figure 5: Pharmaceutical Crimes in Different Regions of the World

Figure 6: Conceptual Framework

Figure 7: Awareness of MAS

Figure 8: Use of MAS

Figure 9: Can Consumers reduce the spread of counterfeit drugs?

Figure 10: New Technology

Figure 11: Whistle Blower Policy

Figure 12: Counterfeit Drugs Supply

Figure 13: Response to counterfeit drugs supply

Figure 14: Responsibility of reporting Counterfeit Drugs

Figure 15: Anti-counterfeit technology

Figure 16: Usefulness of anti-counterfeit technology in reducing counterfeit drugs

## LIST OF TABLES

Table 1: Research approach and Method of Data Collection.

Table 2: Demographics

Table 3: KNOWLEDGE OF EXISTING ANTI-COUNTERFEIT TECHNOLOGY

Table 4: Assessment on Response to Counterfeit Drugs

Table 5: NAFDAC Assessment

Table 6: Demographics

Table 7: Assessment of Supply Chain Management

Table 8: Evaluation of Staff Assessment

Table 9: Counterfeit Products

Table 10: Knowledge of Anti-Counterfeit Technology

Table 11: Knowledge of Pharmaceutical Distribution Laws



## LIST OF ABBREVIATIONS

UNIDO: United Nations Industrial Development Organization

GMP: Good Manufacturing Practice

GDP: Good Distribution Practice

PSI: Pharmaceutical Security Institute

UN: United Nations

WHO: World Health Organization

IOM: Institute of Medicine

NAFDAC: National Agency for Food and Drug Administration and Control

SON: Standard Organization of Nigeria

SCM: Supply Chain Management

NDLEA: National Drug Law Enforcement Agency

NDP: National Drug Policy

PCN: Pharmacists Council of Nigeria

MAS: Mobile Authentication Service

RFID: Radio-Frequency Identification

FMoH: Federal Ministry of Health

WWCV: Worldwide Commercial Venture

IoT: Internet of Things

## DEFINITIONS

**Patent Stores** are an informal community- based providers of healthcare. These are stores handled by people without formal training in pharmacy. These store sale over the counter pharmaceutical drugs on a retail basis for profit. They dispense but do not prescribe.

**Generic Drugs** are medication similar to existing branded drugs, they have the same dosage form, safety, strength, route of administration, quality, and performance characteristics.

# CHAPTER 1: INTRODUCTION

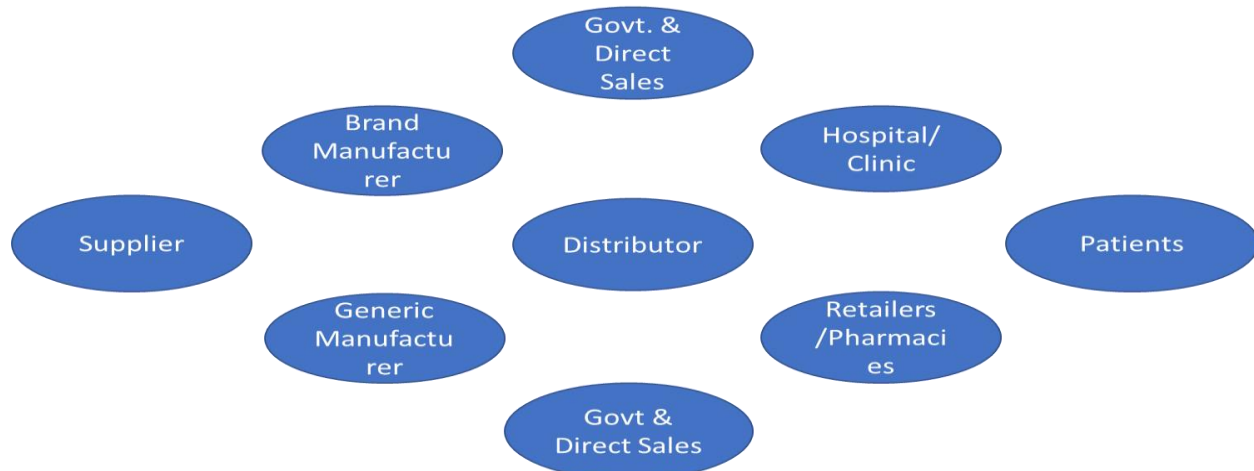
## 1.1 OVERVIEW

For every pharmaceutical supply chain, the priority is delivering safe, efficient, and quality products to the final users. The management of the supply chain has become more complex over time because most importantly it involves the life of human beings and requires the participation of an increasing range of stakeholders (Kapoor *et al.*, 2018). Due to the number of risks encountered by the pharmaceutical companies, which are vital players in the supply chain, they struggle to ensure the quantity and quality of the drugs supplied arrives at the correct location safely (Kapoor *et al.*, 2018).

Upon the successful development and production of a drug, the manufacturer prepares the drug to further dispatch it for distribution to ensure it reaches the patients for use. Some companies are solely in charge of the drug distribution, while other companies are involved to a certain extent in the distribution and then outsource the remaining phase of the distribution (Kapoor *et al.*, 2018). Unfortunately, somehow these drugs are compromised either at the point of repackaging or from open markets whereby leading to the supply of counterfeit drugs to the patients. A compromised supply chain is one-way counterfeit drugs are supplied, other ways are changing the label of an expired drug to the current date or using false or improper ingredients to produce a drug, amongst other forms in which counterfeit drugs exist. From studies, carried out by World Health Organization, International Federation of Pharmaceutical Manufacturers & Association counterfeit drugs have been a thing of concern for various countries in the world, some have made more progress than the others while others are still coming up with ways to control this threat (WHO, 2010). The author of this paper intends to analyze the loopholes in the supply chain and propose methods that can help to improve the control of the spread and supply of counterfeit drugs in Nigeria.

### 1.1.1. Overview of the Supply Chain

In the pharmaceutical industry, the supply chain is comprised of all organizational, operational, and value-adding activities to help facilitate the safe delivery of drugs from the manufacturer to the consumer (Olson, 2020). It is the combination of major business processes across the supply chain to create value for stakeholders and patients. According to the council of supply chain management professionals, supply chain management is the planning and management of all supply activities from sourcing to procurement, conversion, and all logistics activities (Kapoor *et al.*, 2018). The distribution channel is a set of interdependent marketing institutions that facilitate the marketing activities involved in the movement of goods from the manufacturer to the final consumers. The distribution channel involves the manufacturer, the distributor, the retailer, and finally the consumer (Mohanta, 2014). According to an article written in “*supply chain management global*” the distributor is also known as the wholesaler (Mhugos, 2014). The role of the distributor is to connect the manufacturer to the consumers, the distributor reduces the response time and increases the reach of a product. A distributor has the opportunity to examine usage patterns and recommend substitute products in an event of scarcity and they reduce and manage the chance of risk in the distribution channel (Mohanta, 2014). Typically, after a drug is released, the major stakeholders involved in the supply chain are the regulatory bodies, government agencies, drug distributors, hospitals, clinics, pharmacy chains, and retailers. According to Kapoor *et al.*, they stated that the pharmaceutical supply chain is a complex system, in the sense that, the same supply chain responsible for the distribution of prescription drugs, is the same supply chain used in the distribution of Over the Counter (OTC) medicines, and generics. This complexity contributes to the difficulty the pharmaceutical supply chain faces in monitoring the supply of genuine drugs (Kapoor *et al.*, 2018).



*Figure 1: The Pharmaceutical Supply Chain (Kapoor et al., 2018)*

The pharmaceutical supply chain in Nigeria has improved over the years compared to its initial state many years ago, but despite all the reforms which have been put in place, there are still loopholes that enhance the distribution of counterfeit drugs. In a survey released by UNIDO (United Nations Industrial Development Organization) reviewing the pharmaceutical profile in Nigeria, they highlighted some threats affecting the Nigerian Pharmaceutical System (UNIDO, 2011). These are the high level of poverty and how it directly affects the lack of purchasing power, which severely destabilizes the market for drugs produced within the country (UNIDO, 2011). Furthermore, the presence of informal open markets selling drugs in unauthorized premises constitutes a threat to the genuine local industry. Also, the stigma of substandard health, highly affects the exportation of drugs produced in Nigeria, hence because of the high number of counterfeit cases reported in Nigeria countries like Ghana ban the exportation of certain drugs in the country. Finally, the presence of an uncontrolled and chaotic distribution system and parallel imports is another threat to the industry (UNIDO, 2011). Furthermore, the UNIDO article stated that the Nigerian supply chain is saturated with unregistered and untrained pharmacists who are actively involved in the supply of pharmaceuticals and using unregistered sites. In rural communities, they receive supply from patent stores and vendors in open marketplaces, coupled with the absence of health facilities, these factors also contribute to the threat the pharmaceutical sector encounters (UNIDO, 2011).

## Nigerian Pharmaceutical Industry—Distribution (continued)

Pharmaceutical Industry: Public Sector Drug Procurement—Mega Distribution Company  
Consensus Model, Nigeria, 2013

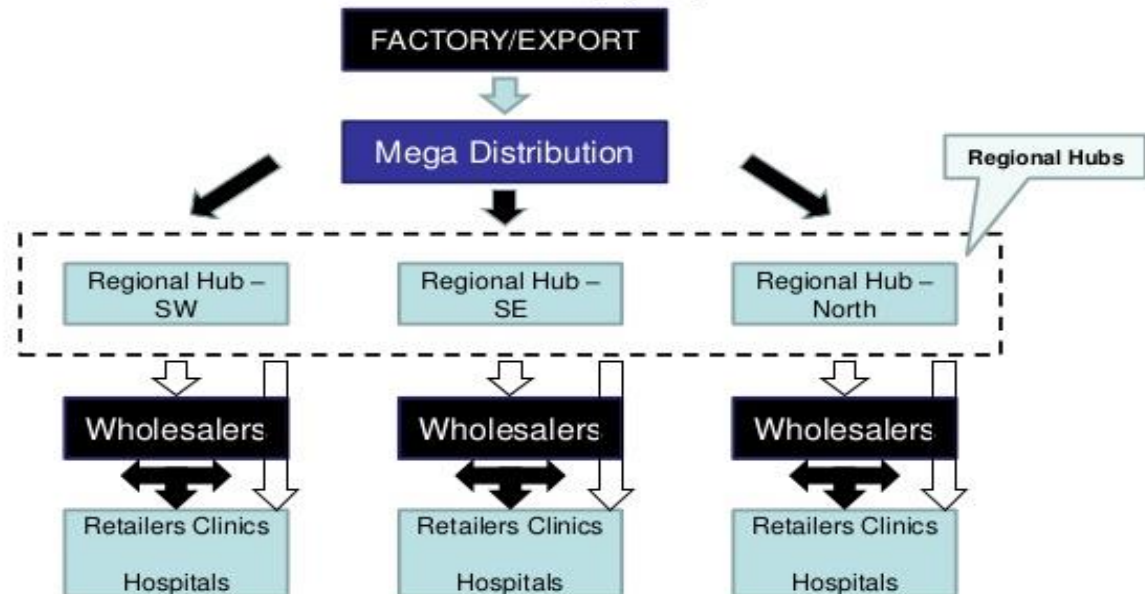


Figure 2: Pharmaceutical Distribution System in Nigeria (UNIDO, 2011)

Before any pharmaceutical product is distributed in Nigeria, there are procedures put in place, these steps are also known as the four essential functions in the Nigerian pharmaceutical sector. These procedures are *Registration*, *Procurement*, *Inspection*, and *Distribution*, they apply to both imported drugs and drugs produced within the country.

- **Registration:** at this stage, the efficacy of the drug is tested to ensure it will be efficient and effective in treating the specific disease, this is the first stage of decision making in the pharmaceutical system. The registration process includes usage, labeling, marketing, warning, and prescription requirement of the drug. Drugs that do not pass through the registration process are termed counterfeit drugs (Garuba *et al.*, 2009).
- **Procurement:** This is an interface between the public system and the drug suppliers. This involves aggregate purchasing, public bidding, managing inventory, analysis of offers, proper allocation of resources, payments, receipt of purchased drugs, and quality control checks. The purpose of procurement in the system is to obtain the appropriate number of drugs in the most cost-effective manner (Garuba *et al.*, 2009).

- Inspection: this is the inspection of goods at ports of entry and manufacturing sites within the country. According to NAFDAC's list of inspected international sites as of 2019, the majority of imported drugs in Nigeria originate from India and China. The inspection of pharmaceutical companies comprises NAFDAC ensuring all establishments adhere to all Good Manufacturing Practices (GMP) from manufacturing, sales, storage, and distribution of drugs (Garuba *et al.*, 2009).
- Distribution: this is the allocation, transportation, and appropriate storage of drugs at all times. All medications have unique storage specifications, such as refrigerators. For safe delivery of drugs, all information concerning the drug must move throughout each step of the supply chain to control inventory and deliveries (Garuba *et al.*, 2009). Two of the mega distributors, which are known as national distributors in Nigeria are Worldwide Commercial Ventures (WWCV) and Assene-Laborex, these distributors act as an intermediary between pharmaceutical companies and distributors.

#### 1.1.2. Overview of Counterfeit Drugs in Nigeria

In 1989, 150 children died due to a Paracetamol formulation error. Later, around April 1990, close to 100 infants died of kidney failure in the Central regions of Nigeria. As if that was not tragic enough, in that same year, in the Southwest of Nigeria, about 26 children experienced the same symptoms, with only 2 managing to survive (Peterson, 2014). After a thorough investigation, it was discovered that the OTC pain killers administered were manufactured under substandard conditions, and the drugs were mislabeled; as opposed to the propylene glycol mentioned on the pack, it was ethylene glycol which was used, which is known to be harmful to the kidney (Peterson, 2014). These are a few of the situations that led to the establishment of NAFDAC. NAFDAC (National Agency for Food and Drug Administration and Control) was established in 1993 to regulate the quality of all pharmaceutical products in Nigeria, ensure proper registration of drugs, lead port inspection to monitor drugs which are imported & exported in Nigeria and to investigate and ensure proper compliance with all regulatory requirements. NAFDAC which is a parastatal under Federal Ministry of Health in Nigeria, works with other government parastatal to ensure the proper enforcement of laws (NAFDAC, 2017). In terms of port inspection, NAFDAC works with NPA (Nigerian Port

Authority), to investigate proper compliance with regulations they work with PCN (Pharmacist council of Nigeria) and other government parastatals to achieve their objectives (NAFDAC, 2017).

In Nigeria, the term counterfeit drug refers to drugs that have outlived their shelf life, mislabeled drugs, drugs kept under inappropriate temperatures, drugs not registered with National Agency for Food and Drug Administration and Control (NAFDAC), drug without complete manufacturer information and drugs produced under inconducive conditions. According to WHO (World Health Organization) and IFPMA (International Federation of Pharmaceutical Manufacturers & Association), counterfeit drugs are drugs whose identity, ingredients, or even origin are labeled falsely to deceive patients. False packaging, manipulated expiration dates, and incorrect direction of dosage are all patterns which counterfeit medicine exhibit (Robles R. *et al.*, 2015). Also according to WHO, counterfeit drugs make up 25 percent of available drugs in developing countries, and 40 percent of the total supply in Nigeria - with 36.5 percent of antimalarial drugs and antibiotics in the country being substandard (Morris and Stevens, 2006). Subsequently, since 2013, WHO has received reports of 1500 cases of counterfeits drugs, with WHO Africa making up 42% of the report, and WHO America and WHO Europe having 21% respectively. This reported percentage only includes the cases which could be recorded, meaning that a large chunk of counterfeit drug cases are still unaccounted for and are not reported (Bagozzi and Lindmeier, 2017). Based on the above statistics mentioned above by Bagozzi and Lindmeier, if a large number of counterfeit drugs are yet to be accounted for, in 2013, this simply means that the life of patients is still largely at risk.

According to Felix Gillette, He likened the investigation of counterfeit drugs to that of investigating a drug cartel, because as much as these drugs are easily seen in shops and sold online, the Kingpins are difficult to source out (Gillette, 2013). Counterfeit drugs are a lucrative business, in a year counterfeiters make roughly about 200 billion dollars, which makes it even more difficult to break this criminal practice (Millar, 2020). To catch the distributors of these drugs, most investigators will have to start from the retail stores and work their way back to the

supply chain. One of the major contributors to the circulation of counterfeit drugs in Nigeria is the uncoordinated drug distribution system in Nigeria, which does not comply with the National Drug Policy. Unfortunately, attempts to minimize or eradicate the supply of counterfeit drugs do not make much progress, because Nigeria has an operative open drug market (Ojo, 2017).

The open drug market is unregulated and their locations are not a secret, but every attempt to shut them down has been futile because it is a situation of “they are aware they exist, but no concrete evidence to pull them down yet” and also because other merchandise are been sold within the same area. So hidden behind these other businesses are the counterfeit drug paddlers (Chinwendu, 2008). The notable open drug markets in Nigeria are Idumota Market in Lagos State, Sabon-Gari Market in Kano State, and Head-Bridge Market, Onitsha in Anambra State. Furthermore, Abiodun Raufu stated in an article for WHO, that every attempt to pull these markets down by taskforce has been unsuccessful (Raufu, 2006). Drugs are produced in these markets in unsterilized conditions and sold open air in corner stores, hawked on the roadside, and even alongside perishable items like vegetables (Fatokun, 2016).

### 1.1.3. Regulatory Bodies

Across the world, every country has its particular regulatory authority which deals with the safety, efficiency, effectiveness, and quality of drugs. Despite the difference in location, language, and government operation the goal of these regulatory bodies are similar across borders. Some of the goals they have in common are to provide and implement pharmaceutical laws that control the research and development, product registration, pricing, manufacturing, and distribution, market, and protection of intellectual property. At the core of all these is to ensure the consumer is safe from any form of drug-associated hazard. In relation to this research, these are the regulatory bodies that control the distribution of drugs within Nigeria;

**Federal Ministry of Health (FMoH):** this is the arm of the federal institutions in Nigeria, that is responsible for providing quality health services for Nigerians. This institution oversees the development and implementation of policies that strengthen the national health system for the



delivery of efficient, effective, affordable, and accessible health services (Federal Ministry of Health, 2020).

**NAFDAC (National Agency for Food and Drug Administration and Control):** *NAFDAC was established by Decree No. 15 of 1993 as amended by Decree No. 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004.*

NAFDAC is a department under FMOH which was officially established in 1993 to (NAFDAC, 2017);

- Regulate and control the production, importation, exportation, distribution, publication, and sales of all regulated products which are drugs, medical devices, chemicals, food, and cosmetics.
- Conduct all appropriate tests to ensure all regulated products are produced according to all required standards.
- Inspect all production sites and ensure they compile with the quality assurance system.
- Inspect all Drugs, food, etc. produced within the country and imported into the country and ensure they follow due registration process before any form of distribution or sales is authorized.

**NDLEA (National Drug Law Enforcement Agency):** The establishment of the National Drug Law Enforcement Agency (NDLEA) by the promulgation of Decree Number 48 of 1989, now Act of Parliament is focused on destroying illicit drugs in Nigeria. They work with the NAFDAC officials at the borders to inspect regulated products coming into the country (NDLEA, 2018).

**PCN (Pharmacist Council of Nigeria):** PCN is a Federal Government parastatal established by Act 91 of 1992 (Cap P17 LFN 2004) which is responsible for regulating and controlling pharmaceutical education, practice, and training in all aspects. It is responsible for the registration and licensing of pharmacists and pharmaceutical premises which includes manufacturing, importation, distribution, wholesale, hospital, and pharmacies). PCN is also in charge of issuing permits to pharmacy technicians, and license/registration of patent and proprietary medicine vendors (Pharmaceutical Council of Nigeria, 2020).

**NDP (National Drug Policy):** NDP Nigeria was adopted and established in 1990 to control the inadequacies in drug availability, supply/distribution. The establishment of NDP was as a result of factors such as inadequate funding of drug supply, high dependence on the supply of imported drugs, poor procurement practices, the poor performance of drug distributors, and involvement of unqualified persons in the procurement, distribution, and sales of drugs (Ogbonna *et al.*, 2015).

## 1.2 RESEARCH PURPOSE

The purpose of this research is to identify and analyze the current challenges which facilitate the loopholes in the supply chain in Nigeria and propose methods that can reduce how counterfeit drugs enter the supply chain. This research aims to interact with distributors and pharmacists because they are directly involved in the supply chain and are important contacts before it gets to the consumers. The interaction with the distributors and pharmacists is to understand the challenges they face in sourcing genuine drugs; how existing laws can be effectively implemented and gather suggestions for how the complexity and chaos associated with the supply chain system can be solved. To clamp down the supply of these counterfeit drugs the source of these counterfeit drugs must be properly investigated and cut off whereby reducing the source and manner by which counterfeit drugs enter the supply chain.

Furthermore, the researcher will use questionnaires to gauge the awareness of consumers on current anti-counterfeit technologies and how open they are to use new technologies.

The researcher will be taking conclusions and recommendations from other countries as to how they have managed the issue of the supply of counterfeit drugs. She intends to draw lessons from these countries and see how well they can fit into the current state of the Nigerian pharmaceutical supply chain and help improve the system altogether.

### 1.3 RESEARCH OBJECTIVES

The purpose of this dissertation is to achieve these objectives;

1. To study the pharmaceutical distribution system in Nigeria and the drivers that aid the infiltration of counterfeit drugs.
2. To evaluate the challenges faced with implementing Pharmaceutical Distribution laws in Nigeria, and to assess the challenges posed by the open market which facilitate the distribution of counterfeit drugs.
3. To look at supply chain reforms and recommend improvements that can facilitate control measures to minimize the distribution of counterfeit drugs in Nigeria.

### 1.4 RESEARCH QUESTIONS

1. What are the factors that challenge the effective implementation of Distribution Laws and Regulations in Nigeria, who is responsible for ensuring these laws are implemented?
2. What reforms from other countries can be recommended to improve the pharmaceutical supply chain system in Nigeria and can consumer behavior help to minimize the spread of counterfeit drugs?
3. What are the loopholes in the pharmaceutical distribution system in Nigeria that facilitate the infiltration of counterfeit drugs and what are the challenges faced with closing the open markets in Nigeria?

### 1.5 STRUCTURE OF STUDY

Using a quantitative approach (questionnaires/ surveys) and qualitative approach (phone or video interviews) these are the methods the researcher will use to source her primary data. The questioners will be administered to pharmacists and consumers. The phone interview will be done with the distributors and pharmacists. The pharmacist will participate both in the phone interview and the questioner because they are the “*middlemen*” which makes them the point of contact for both the distribution side and the consumer side.

Furthermore, as mentioned above the implementation of policies to restrict the supply of the counterfeit drug has been poor, hence during this research, lessons from other countries that have successfully managed the situation will be used as a basis to also support this study.

Patients will also be part of this study to evaluate their reaction to existing measures, their

awareness of the depth of the impact of counterfeit drugs, and their readiness to participate in reducing the spread and their acceptance to new solutions.

This study comprises of five chapters, which are the introduction, literature review, research methodology, finding & analysis, and recommendation & conclusion

**Chapter 1:** This chapter provides a brief introduction to the research study; it outlines the research questions and objectives and gives a framework of the research.

**Chapter 2:** This section examines available empirical data from relevant literature and publications on the research subject. Also, for better understanding, this chapter explores academic views on the research subject which influences the overall direction of the research methodology.

**Chapter 3:** The researcher explains the research methodology employed in this study, which is a mixed-method a combination of quantitative and qualitative methods. The use of these methods is to get an insight into the perception of industry experts on this topic and also understand the level of acceptability of current technologies by consumers.

**Chapter 4:** This section aims to analyze data gathered from the interview and questionnaire distributed. The interview was carried out via zoom and phone call with two groups of people, pharmaceutical distributors, and pharmacists. The interview was held to explore and examine the perspective of industry experts on the research study. Qualitative data gathered was analyzed using **thematic analysis** where patterns and topics are defined, analyzed, and interpreted. The questioner was distributed to consumers and pharmacists, the questioner for pharmacists was used to get basic information from a wider range of pharmacist and the questioner for consumers was used to gather information on the level of acceptability of current anti-counterfeit technology by consumers. Consumers were needed for this study because the researcher will propose areas of improvement from the data gathered from this particular sample size. To analyze the questionnaire the researcher used **Microsoft Excel** for statistical analysis and graphical representation.

**Chapter 5:** In the concluding chapter, the research questions are answered from the data gathered and the primary data is compared with the secondary data. Recommendations for further studies are highlighted and limitations during the study are stated.

## 1.6 SIGNIFICANCE OF STUDY

Counterfeit drugs are harmful to the consumer because they expose the consumer to a harmful substance and increase the risk of adverse reactions, side effects, and allergy reactions. From the current literature review, there is a gap in the study of the Nigerian pharmaceutical supply chain concerning the infiltration of counterfeit products. Previous studies have evaluated the storage of drugs for each stage of the supply chain and how improper storage of drugs can affect the quality of the pharmaceutical product. Also, previous studies have evaluated the challenges of laws implementation and how counterfeit drugs can be minimized but there is a gap in the study of how to reduce counterfeit drug infiltration into the legitimate pharmaceutical supply chain.

This study is significant because it will reveal the existing point of counterfeit drug infiltration in the Nigerian Pharmaceutical supply chain and how it can be reduced. This study will be an informative tool for the citizens of Nigeria, the regulatory bodies and health experts and the suggestions will be an instructive or directive device for the regulatory bodies and health experts.

## 1.8 CONCLUSION

An understanding of the current loopholes in the pharmaceutical supply chain will help the researcher deduce if patients' responses can help reduce the spread of counterfeit drugs. Analyzing all present technologies in place, the researcher will also identify why current laws are not as effective as they are supposed to be and propose methods that can improve on the present solutions. This study will also weigh in on the current policies and guidelines, list reasons for lack of implementation, and propose possible areas of improvement in implementing regulations.

## CHAPTER 2: LITERATURE REVIEW

### 2.1 INTRODUCTION

The pharmaceutical supply chain represents the channel through which drugs move from the manufacturer to the end-users in good condition and quality. It can further be described as the link between the laboratory and the marketplace. According to Tim K. Mackey et al, they described the legitimate supply chain as a *“path which is regulated and licensed by the ministry of health, or regulatory bodies where patients can expect to obtain authentic products supplied through a controlled supply chain (Mackey et al., 2015).”* Unfortunately, this definition is the opposite of what is facing the current supply chain of pharmaceutical products in Nigeria. The distribution of counterfeit drugs is illegal and uncontrolled supply chains such as open markets, illicit online stores, etc. have tampered with the integrity and safety of the global medicine supply chain. Also, Tim et al stated that with the proliferation of health care across the world, ensuring the safety and integrity of the medicine supply chain has turned out to be an onerous task (Mackey et al., 2015). Globally, the health system is tied to a *“strong supply chain”*, this is so because a broken supply chain can cripple the health care system, tamper with the integrity of the public health and undermine possible outcomes health-wise (Mackey et al., 2015).

According to Walter G. Chambliss et al, the impact of counterfeit medication on the legitimate global pharmaceutical market has been estimated to reach 75 billion dollars and the profit margin is greater than illicit trafficking. They also stated that the distribution of counterfeit drugs has in the past, been done through complex global networks that have been traced to terrorists and organized crime affiliates (Chambliss et al., 2012). The threat of counterfeit drugs has posed multiple challenges which have been recognized on a global level, prompting WHO to raise awareness and coordinate international law enforcement efforts against this global concern (Mackey and Liang, 2011). According to research conducted by WHO, the majority of counterfeit drug production is done in Asia, though the prevalence of counterfeit drugs is felt worldwide. In 2009, Interpol made a seizure of 20 million pills in China and Southeast Asia, 34 million pills in Europe, and millions of Dollars from counterfeit drugs in Egypt. Despite these huge seizures made, health experts fear this a minute representation of the actual scale of the

global counterfeit drug market, which is estimated to be roughly 75 billion dollars in worldwide sales as of 2010 (Mackey and Liang, 2011). Counterfeit drugs and pharmaceutical markets have created an opportunity for criminals to engage in this profitable and patient-endangering business. The globalization of counterfeit drugs is controlled by highly sophisticated criminal networks that involve multiple routes of import and export across borders and free trade zones around the world, facilitating the introduction of counterfeit drugs into the legitimate and global supply chain (Mackey and Liang, 2011).

As mentioned in the introduction, drugs that are not NAFDAC registered, expired drugs that were relabeled and resold, or without an active ingredient are all tagged counterfeit drugs. In a baseline study conducted by NAFDAC in 2001, 68% of drugs available in Nigeria are not duly registered by NAFDAC and Later in 2004 NAFDAC confirmed that 40-50% of drugs in Nigeria are counterfeited (Akunyili, 2010). The majority of drugs in Nigeria are imported from countries in Asia, which are mainly India and China. As of 2009, the 92 pharmaceutical companies in Nigeria produced only 30% of internal drug supply within the country, while the remaining 70% of drugs in the country are from an external supply. These imported drugs also play a part in facilitating the distribution of counterfeit drugs, between 2001 and 2005 the supply of drugs from 30 Indian and Chinese pharmaceutical companies and 1 Pakistan company was ban because after an investigation carried out by NAFDAC these companies were confirmed to be importing counterfeit drugs to Nigeria (Morris and Stevens, 2006).

## 2.2 THE CURRENT STATE OF PHARMACEUTICAL DISTRIBUTION SYSTEM IN NIGERIA

On a global level, Nigeria is seen as a developing country, thus the pharmaceutical *supply chain* in Nigeria is seen as inadequate as is the case with many developing countries. In Nigeria, the pharmaceutical *supply chain* is grossly affected by poor management, insufficient funding, and an inadequate number of qualified workers. These discrepancies have led to the scarcity of genuine drugs giving rise to the presence of counterfeits, which has led to avoidable deaths and disabilities (Chukwu *et al.*, 2017). One of the major contributors to the circulation of

counterfeit drugs in Nigeria is the uncoordinated drug distribution system in Nigeria, which does not comply with the National Drug Policy. Unfortunately, attempts to minimize or eradicate the supply of counterfeit drugs does not make much progress, because in Nigeria open drug markets are in operation. (Chinwendu, 2008).

According to Chukwu et al, they stated that a good number of drugs in the market have been adjudged as substandard, fake and adulterated, where 30% of antimalaria and 17% of generic drugs are counterfeited. As mentioned earlier in the introduction by Kapoor et' al the pharmaceutical supply chain involves several stakeholders. The Nigerian supply chain also uses this mode of pharmaceutical supply, but the drug distribution is further handled by "too" many stakeholders which have played a part in causing the chaotic and uncoordinated supply chain system. Major pharmaceutical companies use private logistics companies, while international development partners use courier companies, and private manufacturers and importers use a separate distribution channel (Chukwu *et al.*, 2017). These numerous distribution channels have resulted in the expiration of drugs before reaching the patients, and the sales of counterfeit drugs in unregistered and unlicensed premises sold by unqualified persons.

In a publication titled "Detecting Counterfeit Drugs through Mobile Authentication Service (MAS): Users Challenges in Edo South Senatorial District" the author highlights that the Nigerian government is committed to eradicating fake drugs as one of the ways of safeguarding the health system. This need is what lead to the formulation of National Drug Policy (NDP) in 1990. The objective of NDP is to ensure that all drugs in the National Drug Distribution System are effective, efficacious, have good quality, and are safe (Eronmhonsele, 2015). Also, to minimize the spread of counterfeit drugs, other government health agencies such as Pharmaceutical Society of Nigeria, Nigeria Association of General Practice Pharmacist, Nigeria Association of Industrial Pharmacist and Pharmaceutical Manufacturers Group of the Manufacturers Association in Nigeria have organized seminars and a national symposium on counterfeit drugs. NAFDAC has also engaged several information and communication technologies to drive its regulatory processes. These technologies include an established website where information on the activities of the agency are published and relevant information for the citizens are



accessible (Eronmhonsele, 2015). NAFDAC also has a cooperate portal that makes communication of in-house information and collaborations easy and a Laboratory Information Management System (LIMS) to facilitate quality laboratory procedures and data processes, as well as E-clearance portal which allows for online electronic clearance of goods at the ports. In addition to easy the process of registration and ensure all drugs are duly registered NAFDAC also introduced the use of an Automated Product Administration and Monitoring Solution. All these are efforts implemented by NAFAC to eradicate the spread of counterfeit drugs in Nigeria (Eronmhonsele, 2015).

In Nigeria, the public sector, procurement, and distribution of drugs are both centralized and decentralized, most medical drugs are procured and stored by individual health care institutions, while drugs which are high demand such HIV, anti-malaria and tuberculosis are centrally procured and distributed from the Federal Central Medical Store (CMS) (Justine and Ilomuanya, 2016). Nigeria is divided into six geo-political zones and 36 states, each state in each zone has its own Central Medical Store and procures and stores pharmaceutical products for their public facilities (Justine and Ilomuanya, 2016). The distribution for the pharmaceutical private sector is handled via pharmaceutical distributors, although NAFDAC highlighted that unlicensed distributors play a very significant role in drug distribution at this level of the supply chain (NAFDAC and Sproxil, 2015).

### 2.3 CHALLENGES OF SAFEGUARDING THE PHARMACEUTICAL SUPPLY CHAIN

According to the European Generic Medicines Association, the most vulnerable point where counterfeit pharmaceuticals penetrate the legitimate supply chain is at the secondary distribution point and re-packagers. The presence of the secondary distributor creates an additional layer for handing over which diminishes information visibility whereby creating the opportunity for the infiltration of counterfeits in the supply chain. These multiple steps of distribution which involve series of back and forth amongst distributors generate a more complex supply chain, hence counterfeiters take advantage of this distribution complication to carry out their dealings (Enyinda and Tolliver, 2009).

According to studies carried out by Chambliss Walter, Carroll Wesley et' al, a perfect loophole which counterfeiters exploit is the "*high demand and low supply avenue*". This issue exists in the U.S, Europe, Nigeria, and other countries. In a study carried out by Chambliss Walter, Carroll et' al on "the role of the pharmacist in preventing the distribution of counterfeit medications", they described the low supply issue as a "perfect storm" because this is a situation where legitimate distributors are unable to meet the high demand of an expensive medication or unable to meet market needs. Counterfeiters take advantage of this and break into the supply chain because during these situations, there is a shortage of supply and pharmacists are in search of alternative suppliers.

In a report released by "*GAN Business Anti-corruption*," it reported that corruption has impacted the Nigerian Pharmaceutical system, this has caused a struggle to curtail the production and trafficking of substandard pharmaceuticals. Also, the report stated that bribery is common among Nigerian customs and ports authorities which makes it easy for smuggled goods to enter via the borders and seaports. In addition to bribery at ports, the import clearing procedure is difficult which makes the whole procedure poor (GAN Business Anti-corruption, 2017). Corruption is not only associated with ports clearing authority, this report further stated that the issue of corruption is also common in the Nigerian procurement sector where up to one-third of companies are expected to pay bribes before been able to secure government contracts (GAN Business Anti-corruption, 2017).

In a study titled the "Transparency in Nigeria's public pharmaceutical sector: perceptions from policymakers" the authors established that corruption is one of the reasons for the preponderance of counterfeit drugs in Nigeria, they also added inadequate legislation, poor enforcement of existing laws, un-skilled professionals in the pharmaceutical business, loose control system and high cost of drugs. The authors evaluated the level of transparency in the four essential functions (Registration, Procurement, Inspection, and Distribution) in the Nigerian pharmaceutical sector (Garuba *et al.*, 2009). The authors conducted the study from May to August 2007 based on the WHO Assessment Tool of Medicines Regulatory Systems

which provides both qualitative and quantitative data on the transparency to corruption in each stage of the four functions of the public pharmaceutical sector. Furthermore, Kanj Goyit et al highlighted that the capacity of the national, state, and local government supply chains in Nigeria for forecasting, procuring and delivering essential drugs and other medical needs is a major limitation to the smooth running of the supply chain (Goyit *et al.*, 2016).

Using standardized questionnaires which were made up of both open and closed-end questions where adapted from the WHO assessment tool for each of the four functions. In addition to the questionnaire, a semi-structured interview was carried out in person with 14 participants by one of the authors of the study. Key policymakers such as NAFDAC officials and stakeholders which represent both the public and private sectors of the pharmaceutical system were engaged during the interview. The 14 participants were selected based on their expertise and level of participation in the four functions. The data collection was mainly done to identify areas that were susceptible to corruption due to the various deficiencies in governance and institutional weakness (Garuba *et al.*, 2009).

Based on using the WHO assessment tool the scores reflected the different levels as to which the four functions are exposed to corruption. The results from the study showed minimal vulnerability to corruption in the distribution and procurement of drugs, moderate vulnerability to corruption in drug registration, and marginal vulnerability to corruption in the inspection of goods at the port and establishments (Garuba *et al.*, 2009). On a scale of 1-10, the findings from this research showed that registration of drugs is the most vulnerable to corruption because it scored the lowest out of 10, the overall rating was 7.4 out of 10 which shows a marginal vulnerability to corruption in Nigeria's public pharmaceutical system.

Function	Score on a Scale of 1 to 10	Vulnerability to Corruption
Registration	5.8	Moderate
Procurement	8.9	Minimal
Inspection of Ports	6.4	Marginal
Inspection of Establishments	7.0	Marginal
Distribution	8.9	Minimal
<b>OVERALL</b>	<b>7.4</b>	<b>Marginal</b>

Figure 3: A quantitative result showing the level of corruption in each section in Nigeria's pharmaceutical system, according to Garba *et al*

In a study titled, “Creating reliable pharmaceutical distribution networks and supply chains in African countries: Implications for access to medicines” the author highlighted that the distributor is the most critical link in the legitimate pharmaceutical supply chain and also a point of entry for counterfeit drugs if not guarded properly (Tetteh, 2009). According to the Cambodian Ministry of Health, MoH indicated that counterfeit drugs within the region are drugs that are not registered, deliberately produced with an incorrect or wrong active ingredient, or with no active ingredient. In 2001 and 2004 the MoH in Cambodia and the WHO reported the prevalence of counterfeit drugs such as anti-malaria, antibiotics, analgesics, vitamins, and steroids. In 2001 the prevalence of counterfeit drugs was recorded at 10.43% and in 2004 it was reported to be 21.13% (Khan *et al.*, 2011). Also, a study conducted by C.T Lon *et al* between 2002-2003 reported that 92.7% of substandard aspirin were found in private outlets and in 2006 another study confirmed 58% of counterfeit anti-malaria drugs were seen in licensed outlets and 75% of counterfeit anti-malaria drugs were seen in non-licensed outlets (Lon *et al.*, 2006).

These above reports prompted the Cambodian Ministry of Health to evaluate the pharmaceutical supply chain, especially on the issue of counterfeit drugs. In collaboration with the Department of Drugs and Food (DDF) and Kanazawa University, Japan, the Ministry of Health Cambodia conducted an oral interview with pharmaceutical wholesalers to assess the level of sensitization to counterfeit issues and compliance with DDF guidelines (Khan *et al.*, 2011). The findings from this study reported 12.9% of wholesalers had encountered counterfeit

medicine, however, their perception of the issue varied. 8.1% of respondents indicated that they did not know what counterfeit drugs were. 59.7 % defined a counterfeit drug as un-registered medicine and fraudulently manufactured drugs (Khan *et al.*, 2011).

In respect to procurement, 66.1% of wholesalers consider if the product is registered in Cambodia, while 61.3% consider the reputation of the manufacturer, and 64.5% consider the credibility and quality of the product. Upon receiving a consignment 48.4% of wholesalers check the dates of production and expiration, 9.7% check for the analytical certificates, 80.6% checked the intactness of the drug, 72.6% check the specification and amount of drug, 71% check for Cambodian registration, 54.8% check for the batch and lot numbers and 56.5% check if the packaging has been tampered with. Further findings highlighted that 14.5% of the 62 wholesalers interviewed indicated they received drugs that arrived without packaging and had to be repacked before distribution and 54.8% use packing purchased from the local market (Khan *et al.*, 2011).

In conclusion, the authors of this research highlighted that a good number of wholesalers are properly informed on the issue of counterfeiting and how to handle such cases. The authors recommended that to protect the pharmaceutical supply chain from counterfeit infiltration, it is important distributors and wholesalers are properly trained on countermeasures against counterfeit drugs (Khan *et al.*, 2011).

In 2012, NDDG (National Drug Distribution Guidelines) was developed to focus on the distribution challenges in Nigeria. This was done after concluding that the pharmaceutical distribution network is “fragmented and inefficient”. The repercussions of this gap in the distribution system have led to a large infiltration of counterfeit drugs and adulterated products into the supply chain (Ojo, 2017). The major goal of the NDDG amongst other goals is to establish an organized drug distribution system in Nigeria, which will be a joint effort of all stakeholders in the health sector in the country, eliminate the preponderance of unregulated markets (open markets) in major cities in the country, crack down the informal drug distribution sector and other objectives aimed at the improvement of the distribution system.

Unfortunately, as good as these goals sound, the major problem now is implementation. Since the inception of this guideline, the implementation has been constantly stalled, as at January 2019 the implementation of the NDDG was yet to be in motion and no news has been heard since then (Ojo, 2017).

## 2.4 KNOWLEDGE OF SUPPLY CHAIN MANAGEMENT

For the proper operation of the pharmaceutical supply chain, it requires the knowledge of good governance practice because of the complexity associated with the supply chain system, if knowledge is limited, the chances of counterfeiting will be high (Enyinda and Tolliver, 2009). Ideally, pharmaceutical drugs are to be manufactured in a regulated and sterilized environment, then delivered to authorized pharmaceutical wholesalers/distributors who further distribute it to pharmacies/hospitals that dispense it to the end-users. However, in recent times, this is no longer the situation. There are now multiple steps before the end-user receives the medicine. The primary distributor may sell to the secondary distributor or the re-packer or the secondary distributor might sell to the re-packer and pharmacies before it arrives at the end-users. These multiple transactions of distribution can go back and forth for months before reaching the dispensing point, this exposes the supply chain to the penetration of counterfeit pharmaceutical (Enyinda and Tolliver, 2009).

In a publication titled “An assessment of drug supply chain system in selected facilities in Abuja and Plateau State, Nigeria” the authors indicated that poor infrastructure, limited human resources, limited materials, poor financial support and limited availability of logistics are specific challenges been faced by the public supply chain in Nigeria (Goyit *et al.*, 2016). Furthermore, the authors highlighted that the procurement of essential drugs for hospitals and primary health care facilities is managed by the state while the local government areas act autonomously to procure products and deliver the services to the delivery points (Goyit *et al.*, 2016). The authors further highlighted the attributes of a properly functioning supply chain which involves agility, quick and accurate performance of logistic functions which aids the easy

and swift movement of information via the supply chain to facilitate prompt response to customer needs (Goyit *et al.*, 2016).

Using a cross-sectional descriptive survey, the authors analyzed the current status of the drug supply chain system in selected stores in Nigeria. The survey was aimed at evaluating the knowledge of respondents on drug supply chain management. The findings from the assessment where 90% of respondents reported knowing supply chain management, 68% indicated to have a defined quality assessment system in place and 50% indicated that they have proper training in regulations, good storage procedures and safety in store (Goyit *et al.*, 2016). Also, the authors highlighted that 43% of respondents reported that precautions were not in place to prevent unauthorized people from entering storage areas and 75% indicated that the store was designed with good storage conditions in mind (Goyit *et al.*, 2016).

## 2.5 CHALLENGES OF IMPLEMENTING PHARMACEUTICAL LAWS AND REGULATIONS

According to Erhun et al in a study titled “*Drug Regulation and Control in Nigeria: the Challenge of Counterfeit Drugs*,” the authors mentioned that major concerns in health development are drug availability, distribution, and control, particularly in Nigeria where the shortage of drugs and other technologies are pervasive threats to the health system (Erhun *et al.*, 2013). The authors further stated that one of the major problems facing the Nigerian health care system is the weak drug distribution channel which has indeed posed a fractured drug supply chain of drugs from the manufacturer to the consumer. This has facilitated the sales and distribution of counterfeit drugs which have exposed Nigeria to various health risks (Erhun *et al.*, 2013).

The purpose of the study by Erhun et al was to evaluate the adequacy of the laws to minimizing the threat of counterfeit drugs and access the level of progress the task force in charge has made progress. This study was done using a questioner and an oral interview method. The participant of the study was regulatory (NAFDAC, and PCN) and non-regulatory (Nigerian Association of Industrial pharmacist, and the pharmaceutical manufacturer's group of the manufacturers association of Nigeria) staffs. On the challenge of poor implementation of laws,

100% of respondents in the research indicated that laws were not properly implemented, 60% of respondents indicated that the current penalties for drug counterfeiters were too light. The penalties which are N5,000.00 fine or two years imprisonment were seen as too light by respondents which said the current fine price should be increased and the imprisonment time should also be increased (Erhun *et al.*, 2013). Also, the authors stated that some responses suggest that, lack of proper documentation of offenders might suggest the poor implementation of laws.

Furthermore, 57% of respondents indicated that corruption is a contributory factor to the availability of counterfeit drugs because the effectiveness of some regulatory bodies is negatively affected by the corruption of some officials in the Nigerian health care system. 100% of the respondents stated that the establishment of the task force by NAFDAC was a good development but the coordination, monitoring, and control by the task force was deficient. 42.8% of these respondents attribute this deficiency to the fact that the state task force receives directives from a Military officer as suppose to the Chairman of the Federal task force (Erhun *et al.*, 2013).

<b>Table 2: Suggestions on how performance of task forces could be improved upon</b>	
<b>Item</b>	<b># of Respondents (N=7)</b>
❖ Task forces should be controlled by one agency	5
❖ The structure of state and federal task forces should give way to one central task force.	5
❖ Military officers should not be part of task forces	3
❖ Membership of task forces should be exclusive to Pharmacists	6
❖ Corrupt officials should be identified and dismissed	7
❖ Seized products should be destroyed rather than being Allowed to go into circulation	7
❖ Specialized Problems facing Task Forces -	
• Lack of adequate funding	7
• Lack of vehicle and necessary equipment	7
• Shortage of manpower	5
• Inadequate training of task force personnel	5
• Inadequate security for non military members of the task forces	3

Figure 4: Data from the study "Drug Regulation and Control in Nigeria: The Challenge of Counterfeit Drugs" by Erhun *et al*

In conclusion, Erhun *et al* indicated that the pharmaceutical laws are not adequate and indeed the implementation of laws is deficient. The authors recommended that the government



urgently needs to implement existing laws, NAFDAC needs to ensure all drugs are registered and all offenders are prosecuted, and the prosecution proceedings should be documented properly (Erhun *et al.*, 2013). Also, the task force should be funded adequately and equipped with the necessary equipment for their operations, and pharmacists should be vigilant and report any suspicious counterfeiting activities to the public, colleagues and law enforcement agency (Erhun *et al.*, 2013).

## 2.6. COUNTERFEIT DRUGS AND CONSUMER SAFETY

The manufacturing and supply of counterfeit drugs have been documented as one of the major causes of high morbidity and mortality and has also facilitated the lack of confidence by the citizens in the Nigerian drug system (Uzochukwu and Chinedu- Okeke, 2017). In 2012 the counterfeit version of an expensive chemotherapy drug (Avastin) was flagged by the FDA to have not active pharmaceutical ingredient (API), instead of a cancer drug, hospital physicians who were unaware were administering corn-starch as supposed to the actual medication (Kollmorgen, 2015). The use of Mobile Authentication Service in Nigeria allows consumers to verify the Genuity of the product they are buying. This service helps consumers confirm the source of the pharmaceutical product using a mobile phone and free text message. In an instance where a drug is confirmed to be fake the consumer is given hotline number to call to report the counterfeit product directly to the appropriate authorities. The MAS feature has equipped consumers with the first-hand opportunity to report counterfeit cases whereby cutting down the previous procedure needed in reporting counterfeit drug cases (Justine and Ilomuanya, 2016).

According to a study titled “*Counterfeit Pharmaceuticals: Are the U.S Consumers Aware of the Potential Risk?*” the author stated that educating of consumers on the risk regarding counterfeit pharmaceuticals can be a driving force to reduce the purchasing of counterfeits drugs by consumers, the author also stated that if campaigns are done at grass root levels, it will also help to minimize the spread of counterfeit drugs (Willis, 2018). To create awareness, the Director-General of NAFDAC as of 2010 Dr. Paul Orhii initiated a massive public awareness campaign within Nigeria to sensitize citizens on the quality of food and pharmaceutical

products. Dr. Paul Orhii further stated the need to collaborate with all stakeholders and respondents of the Nigerian pharmaceutical supply chain to improve the quality of products been distributed within the country (Ojeme, 2010). China which is known as the center for exporting counterfeit products, established an inter-ministerial cooperative taskforce for combating the threat of counterfeit pharmaceuticals, besides the task force has initiated a public education program to raise the awareness of the public and also guide citizens on the legitimate channels to acquire medical treatments (Sun, 2012). Sun Lei highlighted that this awareness has raised consumer awareness on drug-related legal knowledge and also enabled consumers with the ability to identify counterfeit pharmaceuticals (Sun, 2012).

With the new advancement in technology, the sophistication of pharmaceutical counterfeiting has equally increased, this has compelled NAFDAC to employ technological measures in fighting against counterfeits in the market. This has led to the introduction of various anti-counterfeiting technologies to detect fake drugs. These anti-counterfeiting technologies are TruScan device (based on Raman Spectroscopy), Radio Frequency Identification (RFID), Black Eye, and Mobile Authentication Service (MAS) via the use of Short Message Service (SMS) (Justine and Ilomuanya, 2016). Through drug authentication, consumers can avoid purchasing counterfeit medication, and also play a part in reporting the counterfeit drugs. The use of the MAS feature allows consumers to anonymously and passively provide key information to law enforcement agencies regarding the location of a counterfeit product anytime the authentication process for a drug fails. The MAS feature aims to give consumers the right to know the quality of the product they are buying and improve consumer health and quality of life (Oyetunde *et al.*, 2019).

In a research paper titled “Securing the pharmaceutical supply chain: As a study of the use of Mobile Authentication Service (MAS) among the Nigerian populace utilizing antimalarials,” the authors evaluated the effectiveness of MAS in curbing the threat counterfeit antimalaria medicines. The research assessed the knowledge, attitude, and level of use of MAS technology by Nigerian citizens (Justine and Ilomuanya, 2016). Using a quantitative data approach, a total

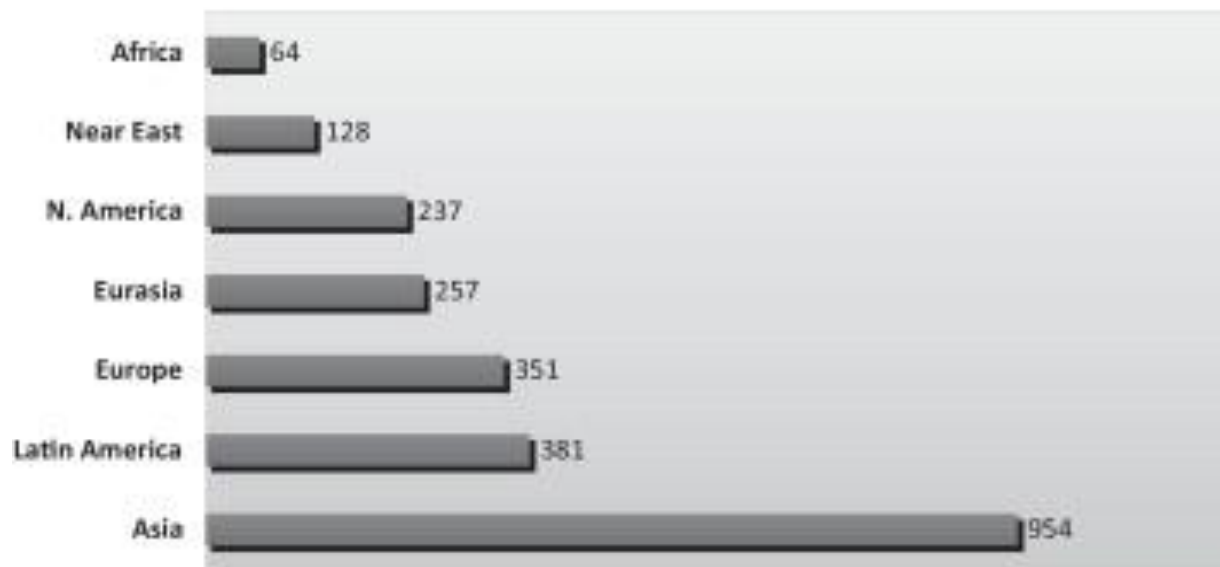
of 900 questioners were administered to assess the awareness of Nigerians on the availability of the MAS feature on anti-malaria and their knowledge of the correct use of the feature to get the necessary information about the authenticity of the product. Out of the 900 questioners the author received a total of 774 responses back. (Justine and Iloмуanya, 2016). Findings from the research indicated that over 70% of respondents were aware of the MAS feature. However, a poor response to the level of utilization was recorded; 50.1% of the respondents do not use the MAS feature at all, while 22.2% of the respondents indicated average utilization of the MAS feature and only 27.7% of the total number of respondents expressed high use of the MAS feature. Also, from the number of respondents that use the MAS feature, 48.8% of these respondents received positive feedback up send the pin, while 4.7% indicated not receiving any feedback response (Justine and Iloмуanya, 2016).

In conclusion, the authors indicated that drugs in high demand such as antimalaria medicine are targets for pharmaceutical counterfeiters, though MAS does not provide the biopharmaceutical content of the drug, it confirms the authenticity and source of the drug, whereby guarding against the infiltration of counterfeits into the supply chain (Justine and Iloмуanya, 2016). According to Job Imharobere Eronmhonsele on his assessment of the use of MAS in Edo State, Nigeria, using a qualitative and exploratory approach he indicated that the awareness of the MAS feature in the study carried out varied, but in general, the awareness of the MAS feature in the rural areas was poor. Furthermore, some of the challenges he highlighted from his research are, respondents in the rural area complained of slow response time which was mainly attributed to bad network within the area, most drugs not having a label at all, consumers purchasing unpacked drugs and conflicting message, which means receiving a text stating a drug is genuine while it was fake or vice versa. These challenges have left the resident of these areas doubting the efficacy of the MAS feature (Eronmhonsele, 2015). The author concluded that the awareness of the MAS feature within the area (rural area) of the study was low as compared to previous research carried out in the urban areas which identified a good level of awareness.

In conclusion, the author recommended that further research be carried in other areas of the state and more awareness should be done to enlighten the public on the use of the MAS feature. In a bid to confirm the challenges related to the wrong text message and the slow response, the author interviewed the NAFDAC regional head of the area and he confirmed the challenges but could not give a concrete response on when the challenge will be resolved. The author indicated the need for this to be sorted on time so the implementation of the MAS feature especially in rural areas does not fade out (Eronmhonsele, 2015).

## 2.7 COMPARATIVE REVIEW: A UNITED STATE STUDY

According to the Pharmaceutical Security Institute (PSI), a non-profit organization which constitutes pharmaceutical companies' security directors, between 2005 to 2010, a 66% increase in pilfering and diversion of pharmaceuticals was recorded. During this same period, the number of counterfeit activities increased by 122% (Pharmaceutical Security Institute, 2019). Subsequently, other international bodies such as the United Nations Office of Drugs and Crime, WHO, Institute of Medicine (IOM) and National Association of Boards of Pharmacy, also reported the need to protect the global medicine supply chain because of the upsurge in the challenges constantly faced. Despite these reports and investigations done, the exact depth of the problem is still elusive (Mackey *et al.*, 2015).



Source: Adapted from the Pharmaceutical Security Institute (2012)

*Figure 5: Pharmaceutical Crimes in Different Regions of the World*

The increase in the prevalence of counterfeit drugs is a problem for pharmacists, pharmaceutical companies, and patients as well. According to Lakeisha Williams and Ellen McKnight, they stated that the magnitude of the problem cannot be gauged properly because, the production and selling of counterfeit drugs are only known when the preparator has been caught, which makes the gathering of data difficult. The World Health Organization (WHO) estimated that 10 percent of the global pharmaceutical commerce contains counterfeit drugs (Williams and McKnight, 2014). The issue of drug counterfeiting has provoked great concerns across borders. In a study done by WHO, 48.7 percent of drug counterfeiting cases were reported in countries of the Western Pacific particularly China, Philippines, and Vietnam, followed by developing countries in Africa which accounted for 18.7 percent. In Europe, the industrialized areas accounted for 13.6 percent of reported counterfeiting cases, and approximately 1% of counterfeit medications are sold in the US, although these numbers increase annually (Williams and McKnight, 2014).

In the United States, patient safety issues and deaths have been reported as a result of counterfeit drugs. As the world's largest market for pharmaceutical sales, the United States is targeted by counterfeit manufacturers as its most lucrative market. Blockbuster drugs are not

exempted from the threats of counterfeiting, blockbuster drugs such as Lipitor had to be recalled due to the discovery of their counterfeit versions on sale (Mackey and Liang, 2011). Furthermore, in 2010, the FDA had discovered the counterfeited version of generic Tamiflu, which was never certified by the FDA as a generic product. To make matters worse, independent consumers are not the only victims of these counterfeit drugs; they have also been discovered in hospitals and pharmacies in the U.S. A relevant discovery Mackey and Liang shows that the major source of these counterfeits was through “gray markets” (Mackey and Liang, 2011). Gray markets in the United States are secondary markets that take advantage of the loopholes in the distribution supply chain to slip counterfeit drugs. Additionally, these counterfeiters may also use stolen drugs which can be diverted to criminal parties for illegal sales (Mackey and Liang, 2011).

To control the distribution of counterfeit medication, the FDA and pharmaceutical industry use two major fronts: packaging and dosage form authentication systems. In addition to these authentication systems, pharmacists are advised to closely and carefully examine all pharmaceutical products. Also, in addition to the present measures to reduce how counterfeit drugs enter the supply chain, a total of 18 states in the United States have adopted a regulatory approach by using the “normal distribution” model for the distribution of pharmaceutical products. This model requires wholesalers to purchase prescription drugs from an “established customary supply chain” i.e. purchasing drugs solely from the manufacturer or an authorized agent by the manufacturer as defined by law (Chambliss et al., 2012). In a case whereby the wholesaler does not obtain the pharmaceutical products from these sources, the wholesaler is expected to provide the buyer with a document known as a pedigree. A pedigree is a document that documents the movement of products through the normal distribution channel. The pedigree document requires that every person involved in the distribution of a drug, which is not an authorized distributor or the manufacturer, is required to present a pedigree to the next person on the supply chain, till it reaches the final consumer.

To secure the pharmaceutical supply chain in the United States, the White House Counterfeit Pharmaceutical Inter-Agency Working Group has recommended that the track and trace system should be adopted to monitor all pharmaceutical products and related products. In line with this, the USFDA (United States Food and Drug Administration), issued guidance on the use of standardized “numeric identifiers” to create a unique “license plate” to monitor individual drug packages in the supply chain (Chambliss et al., 2012). Also, to reduce the sales of counterfeit drugs, the Institute for Safe Medication Practices recommends the use of a “standardized prescription verification process” in all pharmacies. This was recommended because reports also showed that pharmacies that used imaging and scanning technologies as part of the prescription verification process made fewer medication errors (Chambliss et al., 2012). To ensure the credibility of distributors, (National Association Board of Pharmacy) NABP in the United States has an accreditation program for distributors. The criteria reviewed during the accreditation process are licensure verification, operating procedure, an inspection of facilities, screening of clearinghouse, and background checks. Facility accreditation is done every year while the site survey is done every 3 years (Chambliss et al., 2012).

According to Boumil et al in a publication titled “ *Whistleblowing in the Pharmaceutical Industry in the United States, England, Canada, and Australia*”, Since 2000 via the implementation of the whistleblower policy in the pharmaceutical industry in the US, the Department of Justice has investigated dozens of major cases involving allegations of fraud and abuse on the part of pharmaceutical manufactures related to specific drugs (Boumil *et al.*, 2010). Furthermore, the authors stated that the implementation of the whistleblower policy in the pharmaceutical sector exposed an illegal market scheme that promotes off-label (unapproved) use of an approved drug by a pharmaceutical company. This is against the Food, Drug, and Cosmetics Act which states drugs approved for specific (‘intended’) uses and thereafter physicians can prescribe them for any use, including those ‘off-label’. In this case, the manufacturers are not allowed to market or promote the drug directly or indirectly. Boumil et al concluded that the use of the Whistleblower policy has proved to be a significant tool in exposing false claims and fraudulent activities in the pharmaceutical Industry (Boumil *et al.*, 2010).

## 2.8 CONCEPTUAL FRAMEWORK

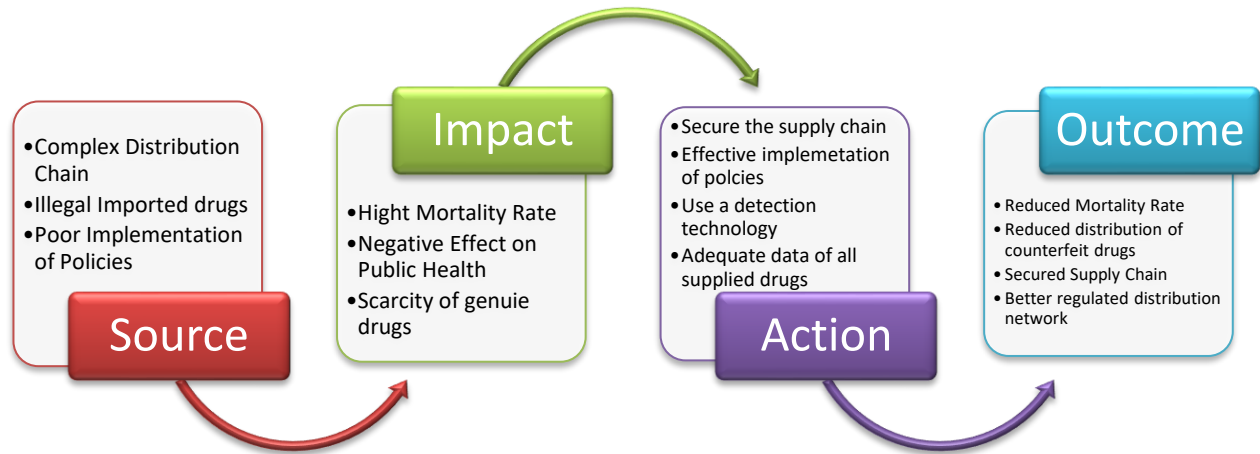


Figure 6: Conceptual Framework

This conceptual framework is developed based on the recurring subject and themes in the literature review. This framework shows the sources of counterfeit drugs in the supply chain, the impact of these counterfeit drugs, the reason why much progress has not been made in controlling the distribution channel, and possible solutions that can help fight the threat.



## CHAPTER 3: RESEARCH METHODOLOGY

### 3.1 OVERVIEW

Section	Primary Data	Part A	Part B
1.	Method	Qualitative Analysis	Quantitative Analysis
2.	Philosophy	Pragmatism	Pragmatism
3.	Source	Zoom/phone Interviews	Questionnaire: Google generated forms distributed online
4.	Structure	10-25 minutes of Interview	Consumers: 5 sections made up of 20 questions Pharmacist: 6 sections made up of 21 questions
5.	Subjects	Pharmaceutical Distributors (6) Pharmacist (7)	Consumers (202) Pharmacists (55)

*Table 1: Research approach and Method of Data Collection.*

### 3.2 RESEARCH METHODOLOGY

This section is important for each analysis since the validity of the research largely depends on the research method used and the quality of data gathered. In this section, the researcher applies the use of a qualitative method via zoom & phone interviews and a quantitative method via questionnaires to gather data. Using a mixed-method, the researcher employed these methods to analyze the loopholes in the pharmaceutical supply chain and methods for improving the control of counterfeit drugs in Nigeria.

The research cohort was made up of pharmaceutical distributors, pharmacists, and consumers. The method of data collection for each group varied, a zoom & phone interview was used for pharmaceutical distributors and pharmacists while a google generated questioner was distributed to consumers and pharmacists as well. The purpose of the questioner was to enable the researcher to gather appropriate data and information to facilitate correct statistical analysis. The questioner administered to the consumers was aimed to evaluate the current level of acceptability of current technologies available for minimizing the spread of counterfeit drugs and further assess the factors which influence the purchasing decision of consumers. While the questioner administered to pharmacists aimed to evaluate basic knowledge on supply chain management, assess knowledge of anti-counterfeit technology, and gauge their response to their role in fighting counterfeit drugs.

The interview aimed to gain new ideas and personal perception from both distributors and pharmacist while gaining knowledge on the current state of the pharmaceutical supply chain and also gaining new knowledge on factors which hinder the successful implementation of laws. These recommendations were placed under various themes which gave the researcher an insight into giving a sustainable conclusion. Also, the data gathered from both groups were compared to data from the secondary data (literature finding) to facilitate the researchers' conclusion on the research study.

### 3.3 RESEARCH PHILOSOPHY

Research philosophy is the belief or approach used in gathering, interpreting, and evaluating data. This research explores the pragmatism philosophy because this philosophy explores the plurality of methods. The **pragmatism philosophy** is based on the proposition that researchers should use both philosophical and methodological approach when researching a topic. The pragmatic philosophy is mostly associated with **mixed methods** or multiple method research approach (Kaushik and Walsh, 2019).

This research philosophy was used for this research based on the philosophy which it represents. The pragmatic philosophy was implemented using both the qualitative and quantitative approach to gather information from industry experts to explore their opinions

and gain insight from their knowledge of the topic. It was also used to explain the information gathered from participants which facilitated the researcher in making an applicable conclusion for the research. Also, it was used to collect basic information from pharmacists and understand consumer position on existing technologies. The data collected was used to help the researcher have a more valid conclusion. Using an inductive method development of themes is directed by the content of the data. As stated earlier this is an ***exploratory research*** that aims to explore the opinion of industry experts, hence using the ***inductive method***, themes extracted will be based on data gathered using the ***thematic analysis***.

Using a qualitative approach, the pragmatic philosophy was adopted towards data gathered from the interview done with Pharmaceutical Distributors and Pharmacist. The data gained from these interviews were from their experience thus far in the industry, their perspective on the subject, and their suggestions. There was no bias in this study because this research was independent of the researcher and there was no personal interest or human interference with the study. As a requirement to obtain appropriate results using the pragmatic philosophy the level of validity and level of depth as obtained from these professionals were inclined to be subjective, with a reliable and good representation of knowledge.

Using a quantitative approach, towards gathering data from the consumers and pharmacists using a properly structured questionnaire via google forms, this was used to analyze and interpret data collected objectively. This part of the research had minimal to no interaction with participants which prevented any form of bias in the research.

### 3.4 RESEARCH STRATEGY

To gather valid and authentic data they are seven ways in which it can be achieved, but for this research, the researcher focused on interviews and questioner. To analyze the loopholes which exist in the pharmaceutical supply chain and propose methods for improvement, the researcher evaluated the awareness of consumers of the present technologies, the perspective of the distributors and pharmacist on the current state of the pharmaceutical supply chain and their views as well on the poor implementation of laws within the pharmaceutical supply chain. As seen from the literature review thus far, there is still a gap in research and study of methods to

improve the infiltration of counterfeit drugs into the pharmaceutical supply chain. Also, no study has been identified which includes consumers, pharmacists, and distributors within the country, to ascertain the depth of knowledge of the current technologies available to control the spread of counterfeit drugs. Furthermore, as mentioned above the implementation of policies has been poor, hence during this research, lessons from other countries that have successfully managed the situation will be used as a basis to also support this study.

The major participants of this research were pharmaceutical Distributors, Managers or Owners of Pharmacies and Consumers in general. Distributors and Pharmacists were duly informed of the purpose of the research and the confidentiality of their responses. The purpose of the research was explained properly on the first page of the questionnaire and the permission of participants was requested before proceeding to respond to the questions. 202 consumers responded to the consumer questioner and 55 pharmacists responded to the pharmacist questioner. 6 distributors were interviewed, and 7 pharmacists were interviewed.

All questionnaires were generated online and filled in the absence of the researcher. The consumer questioner consisted of five sections with 20 questions in total while the pharmacist questioner had six sections with 21 questions in total. All questions were asked according to the objective of the research.

### 3.5 COLLECTION OF PRIMARY DATA

The collection of data was done via two methods, primary and secondary data collection. Secondary Data collection was done via Literature reviews and primary data collection was done via the use of qualitative and quantitative methods respectively. The collection of primary data was done via interview and questioner. The primary research via the qualitative research method was done through a semi-structured interview whereby addressing the main objective of the research. These interviews were done with pharmacist-owners and managers who have held the position for a reasonable number of years. The position and years of experience were part of the selection criteria, because the researcher understands that pharmacists with

these positions, will have more access to the ordering and supply of the drugs, and the more the years the more the experience.

All questions administered during the interview were structured in line with the objective of the research, each question fell under one of these groups, assessment of the knowledge of supply chain, knowledge of distribution laws, and knowledge of anti-counterfeit technologies.

The author used both qualitative and quantitative analysis for the pharmacist group because the questionnaire alone, will not give the researcher the liberty to probe deeper or ask further questions, but that can be done during an interview. The combination of the two methods gave the researcher access to more pharmacists to gain the basic data, while the interview gave the researcher more information, and the opportunity to probe deeper into the response of participants. The interview process also gave the researcher new insights, fresh perspectives, and more information.

The interview approach was used for only distributors because access to distributors was limited and the need to ask more questions was necessary because there is a gap with this study involving distributors. The questioner approach was used for consumers to gather statistical data of current responses to existing technologies and also have a knowledge of trends and patterns associated with response to existing technologies.

Each section of the interviews and questioner covered all the objectives of the research, knowledge of current technologies, knowledge of pharmaceutical distribution laws, assessment of the pharmaceutical supply chain, Knowledge of anti-counterfeit technology, and NAFDAC Assessment and for consumers' willingness to try new technologies.

### 3.6 PROCEDURE AND SAMPLE

To test the validity and reliability of data collected a pilot study of six participants was conducted of the questions. This pilot study gave the researcher direction on how to structure the question better. A total of 270 participants participated in this research, this comprised of 202 consumers and 55 pharmacist responses to the questionnaire, and a total of 13 interviews, comprising of 7 pharmacists and 6 distributors.

All interview participants were well-experienced stakeholders in the industry and had over 5 years' experience. The research topic was properly explained to participants, and a proper

introductory paragraph was written in the first section of the questioner. All participants volunteered willingly and were glad to be part of the study. The researcher got participants from LinkedIn, and Referrals from friends and family. Questionnaires were filled at the participant's convenience and Interviews were held at the participant's time and convenience. Before each interview was recorded the researcher asked the participants if they were comfortable with it.

### 3.7 ACCESS AND ETHICAL ISSUES

All participants were given a brief introduction of the topic both verbally and in a written form, to ensure all participants were duly informed of the research and the purpose of the research. All participants were asked for verbal approval before proceeding with the interview and participants who responded no to voluntarily participating in the survey, the form automatically submitted to prevent any form of involuntary response.

All questions were structured with caution and the identity of participants was kept anonymous. The questions allowed participants to respond freely without any form of coercion to prevent any form of bias. The choice of participation was strictly the prerogative of the participant and participants were permitted to withdraw from the study at any time.

### 3.8 INCLUSION AND EXCLUSION CRITERIA

The primary participants of this study were Pharmaceutical Distributors and Pharmacists to understand their view of the current state of the supply chain and gain new perspectives from their experience. While the consumers where secondary participants to access their current knowledge and openness to new technologies. The inclusion criteria for pharmacists where owners and managers of pharmacies who are actively involved in drug order and liaise more with distributors. Distributors were automatically excluded if they were not willing to participate in the study. As mentioned earlier participants who declined to respond to the questionnaire were excluded from the study.

An introductory section was attached to the questionnaire and an introduction was given by the researcher before the beginning of the interview. All participants responded based on their

discretion and were duly informed of their right to withdraw at any time during the cause of the study.

### 3.9 CONCLUSION

The methodology applied in this research was a pragmatic philosophy, the researcher applied a mixed-method approach considering the two types of participants involved in the study. The data collection was a combination of online distributed questionnaires and a semi-structured interview with industry stakeholders (distributors and pharmacists), which amounted to a total of 270 participants in total.

The data collected was analyzed and compared to the results and conclusions gotten from the literature review. The researcher uses both qualitative and quantitative approaches to understand the level of awareness of the consumers on the present technologies and also gain new insights and learn from the experience and perception of industry experts' response and also get new suggestions and recommendations.

All responses and finding obtained via the use of this method were analyzed in the finding and analysis chapter.

## CHAPTER 4: FINDINGS AND ANALYSIS

### 4.1 OVERVIEW

This chapter evaluates the response on the state of the pharmaceutical distribution system in Nigeria, access the challenges faced with effectively implementing supply chain laws and reforms, analyzes the participant's knowledge on supply chain management, and evaluates the consumer's awareness of current technologies. As mentioned earlier no sufficient literature has been identified that included the distributors and consumers in the analysis in the country.

Hence to analyze the interview data the researcher will be engaging the use of ***Thematic Analysis***; this method is referred to as the method in which patterns and topics are defined analyzed and interpreted. The researcher used this method of analysis because it is a flexible method that allows the researcher to find themes where there are no clear ideas of what patterns or themes been sort for in exploratory research. This works well for the researcher because she is using an exploratory method, whereby exploring views of industry experts. The data from the interviews directed how the themes where developed.

The survey for the pharmacies was conducted to get basic information concerning the topic and access their knowledge of the topic. The survey for the consumers was done to evaluate their knowledge of the current anti-counterfeit technologies present and their willingness to embrace new technologies. The survey data were analyzed and interpreted using ***Microsoft Excel***.

***Response Rate:*** A total of 20 people were scheduled to be interviewed, 10 distributors, and 10 pharmacists. A total of 13 participants responded to the interview, 7 pharmacists and 6 distributors with two responding via text, recording a response rate of 65%

The survey was distributed to a total of 370 participants. 70 pharmacists and 300 consumers. A total of 55 pharmacists responded to the survey and a total of 202 consumers responded to the survey giving a total of 257 responses. Hence, recording a response rate of 69.45%.

### 4.2 FINDINGS (QUALITATIVE DATA)

For better understanding, the themes found during the interview will be listed for a better understanding of this section. The response of participants will be represented in quotes which will be evaluated critically along with the content of each subject for the research.



A total of 10 pharmacists were scheduled to be interviewed, but only 7 responded to the interview. A total of 10 distributors were scheduled to be interviewed, 2 preferring to respond via email, but no response was recorded and 1 not responding to either calls or text. A total of 6 participants responded to the interview, with 2 responding via text.

All pharmacists who were interviewed fell into this category, they have been practicing between 3 to 20 years and have either owned or managed a pharmacy between 1 to 15 years. Out of the 7 pharmacists interviewed 4 were managers and 3 were owners.

All distributors who participated in the interview process have been in the business for more than 5 years. 4 participants responded via phone interview while two responded via text.

### 4.3 DISCUSSION OF THEMES

From the response during the interview, the two groups of industry experts were interviewed with different questions and some similar questions, some themes from both groups kept occurring. Recurring themes during the interview where the ***open market, unskilled people, greed & corruption, awareness, poor supply chain management system, and improvement of current anti-counterfeit technologies.***

#### 4.3.1 Open Market

This theme constantly occurred during the interview, though they were no questions directly asked about open markets in both interviews carried out with each group of participants the conversation on the open markets came up.

According to most of the participants for both groups, when asked “*what aids the supply of counterfeit drugs*”, a significant number of them responded with the ***presence of “open markets”***. According to 4 of the participants they likened the people selling in the open markets to “traders”. Repeated amongst 7 participants they highlighted that these people are out to make profit and do not care about the consumer's health or safety. According to a participant he mentioned that; *“In Nigeria, they are people who are not pharmacist who own distribution outlets, they are traders, they have no integrity and are more concerned with buying and selling and will do anything to make money”*

Also, two participants one from the distributor group and one from the pharmacist's group highlighted the part the open market plays during the out of stock period. One participant

highlighted that *“during the out of stock period some counterfeiters quickly take advantage of the period, send a sample of the scarce product to countries like China and quickly dup the packing, the batch number, and other features similar to the product and bring it back into Nigeria and sell”*. The second stated that; *“when there is stock out some dubious people even wholesalers go to China and duplicate the packs of these drugs, make something else, write on the body and supply. And because it is in high demand, people don’t look carefully, they just buy”*. This implies that the presence of the open market indeed poses a challenge to the pharmaceutical supply chain and also aids the infiltration of counterfeit drugs.

#### 4.3.2 Unskilled People

Unskilled people, untrained and non-professionals, these were themes that also re-occurred during the interview process. The presence of unskilled people was highlighted by participants to be part of the factors which facilitate the loopholes in the supply chain. This is because the regulatory body in charge of approving does so without a thorough check of applicants. These unskilled people according to a participant *“they are part of the driving force behind the spread of counterfeit drugs”*. Some participants also linked these unskilled people to the factors which aid the spread of counterfeit drugs. According to a participant He stated that *“Non-professionals and unskilled people are involved in the business of distributing drugs, but are more concerned with the money than the quality of the product”*. This implies that the presence of unskilled workers facilitates the distribution of counterfeit drugs, hence as recommended by one of the participants it is important for the regulatory body to be strict with who they approve to practice.

#### 4.3.3 Greed & Corruption

One of the research questions for this study is *“why laws are poorly implemented?”* 80 percent of participants responded by saying the presence of corruption and greed has affected the effective implementation of laws and regulations. A participant highlighted that *“laws are poorly implemented because everything has been politicized”* another participant stated that *“Laws have been poorly implemented because of greed and corruption in the system”*. For laws to be properly implemented members of regulatory bodies need to have integrity, that way they will be more strict with the implementation of laws.

#### 4.3.4 Awareness

All participants agreed that as pharmacists they play a vital role in reducing the spread of counterfeit drugs. A significant number of the participants stated they need to educate and enlighten consumers on the dangers of counterfeit drugs and also advise them on the need to purchase drugs from the right pharmacies. Furthermore, some participants also highlighted the need for NAFDAC to enlighten consumers on the MAS technology and the need to be vigilant on where they purchase drugs and also be sensitive to the kind of products they purchase. A participant highlighted that *“More awareness on the current anti-counterfeit technologies should be made and people should be enlightened on how to identify counterfeit drugs”* and another participant mentioned that *“Adequate counseling should be given to consumers on why they should be vigilant on where they purchase drugs from.”* This implies that consumer awareness will help reduce the spread of counterfeit drugs.

#### 4.3.5 Poor Supply Chain Management System

From the Literature review, proper supply chain management is one of the ways the infiltration of counterfeit drugs into the pharmaceutical supply chain can be prevented. A significant number of participants know about supply chain management, but according to one participant the *“awareness of supply chain management is still coming up in Nigeria”*. According to another participant *“supply chain management has the potential to reduce the infiltration of counterfeit drugs into the pharmaceutical supply chain if it is properly monitored, as of now it is not properly monitored and I do not think Nigeria is ready to embrace it yet”*. Furthermore, another participant highlighted the need to implement supply chain management, he stated: *“it will help reduce the spread of counterfeit drugs because the agency in charge of counterfeit drugs in Nigeria has lots of challenges, especially logistics problem which aids the infiltration of counterfeit drugs into the supply chain”*. Though 6 out of the 7 pharmacists interviewed agreed that supply chain management can reduce the spread of counterfeit drugs, one participant stated that *“From my own experience I would say No, it can't. Within the Nigerian market, I don't think supply chain management can quell the bane of counterfeit drugs. The reason is that in the Nigerian market, there are players whose entire business is built on the production and sale of counterfeit drugs and they are people who even seek them out and buy from them to*

*make more money. We have a corrupt system in place here which thrives on such practices, and the lack of strong regulation and implementation of laws are already grounds that allow for these fraudsters to thrive and prosper. These fraudsters know how to work around NDLEA, SON, and NAFDAC*". This answer indicates that if laws are not properly implemented, proper supply chain management will not be sufficient enough. It can be deduced that proper supply chain management will be good, but for the Nigerian pharmaceutical supply chain, it cannot work alone.

#### 4.3.6 Improvement of Current Anti-counterfeit Technologies.

A significant number of participants know about anti-counterfeit technologies. The technology which occurred frequently was the Mobile Authentication Service (MAS) technology. The majority of participants agreed that it has helped a bit in reducing the spread of counterfeit drugs but it needs to be improved. One participant highlighted that *"it has not been effective enough because most drugs don't carry the MAS feature."* Another participant stated that *"MAS technology has not sufficiently helped because the response time is slow, and sometimes it takes up to 3 days to receive a response and sometimes consumers receive false replies, genuine drugs are tagged as fake and vice versa."* While another participant mentioned that *"MAS technology has helped cut down the spread of counterfeit drugs but not enough. More enlightenment needs to be done because many people are not aware of it"*. This implies that the MAS feature has the potential to minimize the spread of counterfeit drugs, but it needs to be improved for it to be effective.

In conclusion, from the data gathered above, it can be deduced that the presence of unskilled workers, and open market, are the drivers that aid the infiltration of counterfeit drugs. It can further be extracted that, the poor implementation of laws is a result of greed and corruption on the part of the regulatory bodies. This factor was also mentioned in a study by Erhun et al as a contributory factor, where the *"effectiveness of some regulatory bodies is negatively affected by the corruption of some officials in the Nigerian health care system"* (Erhun et al., 2013). Some of the challenges the open market pose are during the out of stock period, a lot of counterfeit drugs are produced and supplied to unsuspecting pharmacists and consumers. Hence the need to implement proper anti-counterfeit technologies is necessary. One of the

reforms recommended is the need to facilitate awareness amongst consumers and for distributors to buy from the approved pharmaceutical supply chain. Finally as mentioned by two participants, border controls need to be enforced strictly to monitor the drugs coming into the country.

## 4.4 FINDINGS (QUANTITATIVE DATA)

### 4.4.1 CONSUMER ANALYSIS DATA REPRESENTATION

DEMOGRAPHICS	Frequency	Percentage
1. I agree to voluntarily participate in this research study and give consent to my response been used for research purposes.		
Yes	202	100%
No	1	0%
<b>2. Gender</b>		
Female	107	53%
Male	95	47%
<b>3. Age</b>		
18-30	130	64%
31-40	35	17%
41-50	19	9%
50 and older	18	9%
<b>4. Highest Level of Education</b>		
No formal education	1	0%
Postgraduate	129	64%
Secondary School	5	2%
Undergraduate	67	33%
<b>5. Occupation</b>		
Employed	82	41%
Retired	4	2%
Self-employed	43	21%
Student	64	32%
Unemployed	9	4%
<b>6. Area of Residence</b>		
Rural	22	11%
Small town	1	0%
Urban	179	89%

*Table 2: Demographics*

The purpose of this section is to study the characteristics of the population based on their age, gender, occupation, area of residence, and education. The ratio of females to males was 53% to 47%. The ratio of participants residing in rural areas to those in the urban was 11% to 89%. This section of the interview gave the researcher insight into the characteristics of people who responded to the survey.

KNOWLEDGE OF EXISTING ANTI-COUNTERFEIT TECHNOLOGY	Frequency	Percentage
<b>7. How often do you scratch the code to check the authenticity of the drugs?</b>		
Always	16	8%
Never	65	32%
Often	15	7%
Rarely	51	25%
Sometimes	55	27%
<b>8. Are you aware of the Mobile Authentication Service to verify the authenticity of the drugs you purchase?</b>		
No	41	20%
Yes	161	80%
<b>9. How did you get to know about the Mobile Authentication Service?</b>		
<b>10. Is the Mobile Authentication Service, User Friendly?</b>		
No	9	4%
Not Applicable	75	37%
Yes	118	58%
<b>11. How will you rate the response time of the Mobile Authentication Service?</b>		
1	20	12%
2	7	4%
3	62	38%
4	42	26%
5	32	20%

Table 3: KNOWLEDGE OF EXISTING ANTI-COUNTERFEIT TECHNOLOGY

This section was required for the researcher to propose new methods, to propose new methods she will need to know how well the current methods are been used by consumers. This will help her direct her recommendations for either new technologies or more improvements. From the above response 80% of participants are aware of the MAS technology, but those who used it always or often where 8% and 7%. 58% of respondents admitted that the feature is friendly but 38% rated the response time 3 over 5 which can be interpreted as fair.

This implies that the majority of participants are aware of the MAS feature but as seen in the table below more awareness needs to be done on the need to use it.

ASSESSMENT ON RESPONSE TO COUNTERFEIT DRUGS	Frequency	Percentage
<b>12. Have you ever had an encounter with counterfeit drugs or do you know anyone who has?</b>		
No	114	56%
Yes	88	44%
<b>13. In your opinion, do you think consumers can help reduce the spread of counterfeit drugs?</b>		
No	21	10%
Yes	181	90%
<b>14. If you scratched the code and realized the product is counterfeited, will you?</b>		
<b>15. [How likely will the price of a drug affect your buying decision?]</b>		
Likely	64	32%
Most Likely	57	28%
Most Unlikely	12	6%
Neutral	44	22%
Unlikely	25	12%

*Table 4:Assessment on Response to Counterfeit Drugs*

This section weighs in on the current performance of the current technology available to consumers to verify the authenticity of the product purchased. This gives the researchers an insight into factors that influence the consumer's decision and allows the reader to view how consumers purchase drugs. 44% of respondents have had an encounter with counterfeit drugs and 28% and 32% of respondents agreed that the cost of a drug will most likely and likely affect their buying decision.

This data implies that a good number of participants have not encountered counterfeit drugs and 90% of participants agreed that consumer behavior can minimize the spread of counterfeit drugs.

NAFDAC ASSESSMENT	Frequency	Percentage
<b>16. How will you rate the government's effort in fighting against the spread of counterfeit drugs?</b>		
1	41	20%
2	52	26%
3	83	41%
4	19	9%
5	7	3%
<b>17a. [In your opinion, will you agree that the government is effective at communicating the risk of counterfeit drugs in Nigeria]</b>		
Agree	66	33%
Disagree	48	24%
Neutral	58	29%
Strongly Agree	13	6%
Strongly Disagree	17	8%
<b>17b. [In your opinion, will you agree that NAFDAC has done a good job in publicizing the use of the MAS feature?]</b>		
Agree	65	32%
Disagree	32	16%
Neutral	76	38%
Strongly Agree	17	8%
Strongly Disagree	12	6%
<b>17c. [In your opinion, do you think the MAS feature should be applied to all drugs. ]</b>		
Agree	74	37%
Disagree	3	1%
Neutral	35	17%
Strongly Agree	87	43%
Strongly Disagree	3	1%
<b>18. If NAFDAC published a list of Licensed pharmacies within your area will you adhere strictly to it?</b>		
Yes	194	96%
No	8	4%
<b>19. Would you be open to using new technologies to help minimize the spread of counterfeit drugs?</b>		
Yes	198	98%
No	4	2%
<b>20. Do you think the whistleblower policy will be useful in reducing the distribution of counterfeit drugs in Nigeria?</b>		
Yes	183	91%
No	19	9%

Table 5: NAFDAC Assessment



This section was used to evaluate the efforts of the regulatory body from the consumer's perspective.

This section was needed to help the researcher evaluate the performance of the regulatory bodies and access consumers' willingness to help reduce the spread of counterfeit drugs.

This data implies that NAFDAC has made sufficient effort so far, but needs to work on consumer awareness, application of anti-counterfeit features to more drugs and consider the use of some new methods to reduce the spread of counterfeit drugs.

#### 4.4.2 PHARMACISTS DATA REPRESENTATION

DEMOGRAPHICS	Frequency	Percentage
<b>1. I have read and understood the information and I voluntarily agree to participate in this research study.</b>		
No	0	0%
Yes	55	100%
<b>2. Gender</b>		
Female	26	47%
Male	29	53%
<b>3. Age</b>		
18-30	12	22%
31-40	21	38%
41-50	17	31%
50 and older	5	9%
<b>4. Highest Level of Education</b>		
Bachelor's Degree	33	60%
Masters Degree	20	36%
PhD	2	4%
<b>5. Which of these roles do you hold?</b>		
Pharmacy Manager	38	69%
Pharmacy Owner	17	31%
<b>6a. How long have you been practicing in this field?</b>		
1-5 years	19	35%
6-10 years	18	33%
Less than 1 year	3	5%
Over 10 years	15	27%
<b>6b. How long have you managed or owned your pharmacy?</b>		
1-5 years	23	42%
6-10 years	13	24%
Less than 1 year	10	18%
Over 10 years	9	16%

Table 6:Demographics

This section was needed to help the researcher access the background of the health professionals filling this questionnaire. The two roles were pharmacy owner or pharmacy manager because these are the two roles directly involved with the order and receiving of drugs. This questionnaire had more responses from the pharmacy managers which was 69% while the pharmacy owners were 31%.

ASSESSMENT OF SUPPLY CHAIN MANAGEMENT	Frequency	Percentage
<b>7. Do you know what pharmaceutical supply chain management is?</b>		
No	1	2%
Yes	54	98%
<b>8. How did you learn about it?</b>		
Learned in school (Relevant textbooks and Journals)	47	85%
Pharmaceutical Newsletter	2	4%
Self-Taught (Internet/ Social media)	3	5%
Took a PGD course in logistics and supply chain management. Also did various certification courses.	1	2%
Word of Mouth (Interaction with colleagues and experts)	2	4%
<b>9. Aside from checking the supply of drugs to confirm if the products delivered corresponds with your order, do you check to confirm if they are genuine?</b>		0%
No	2	4%
Yes	53	96%

*Table 7: Assessment of Supply Chain Management*

This section was to evaluate if participants have a knowledge of supply chain management. 98% of respondents showed they know about supply chain management, where 85% showed they learned in school.

From the data gathered above, it can be extracted that the majority of pharmacists know about the supply chain and also check the authenticity of products before placing it on the shelf.

EVALUATION OF STAFF ASSESSMENT	Frequency	Percentage
<b>10. Which do you consider more when hiring?</b>		
Experience	48	87%
Qualification	7	13%
<b>11. Do all staff receive training before starting?</b>		
No	2	4%
Yes	53	96%
<b>12. If yes, please tick any of these that apply?</b>		

*Table 8:Evaluation of Staff Assessment*

This section gives the researcher insight into how well staffs are trained to ensure they are aware of the necessary measures in place to prevent sales of counterfeit drugs and can also identify the counterfeit product.

COUNTERFEIT PRODUCTS	Frequency	Percentage
<b>13. Have you ever been supplied counterfeit drugs?</b>		
No	42	76%
Yes	13	24%
<b>14. If yes, which of these did you do</b>		
Contact distributor & report to authorities	7	15%
Contact the distributor	6	13%
Discard products and inform colleagues	1	2%
Report to authorities	33	70%
<b>15. Who is responsible for reporting counterfeit drugs? (Choose all that apply)</b>		
Consumers	6	11%
Healthcare Professionals (Doctors/Nurses/Pharmacist)	44	80%
Pharmaceutical Distributors	3	5%
Pharmaceutical Manufacturers	2	4%

*Table 9:Counterfeit Products*

This section is to access how much experience professionals have with counterfeit products and who is responsible for reporting any case of counterfeiting.

This data implies that the responsibility of reporting counterfeit drugs is mostly the responsibility of Health Care Professionals and most pharmacists are ready to report to the appropriate in an event they are supplied counterfeit products.

KNOWLEDGE OF ANTI-COUNTERFEIT TECHNOLOGY	Frequency	Percentage
<b>16. Are you familiar with anti-counterfeit technologies?</b>		0%
No	2	4%
Yes	53	96%
<b>17. If yes, kindly choose all anti-counterfeit technologies you are familiar with?</b>		
Colorimetry	1	2%
Color Shifting Codes	1	2%
Embed-Codes	2	4%
Hologram	8	15%
Mobile Authentication Service (MAS)	39	74%
Radio Frequency Identification (RFID) Tags	2	4%
<b>18. Do you think any of these technologies will be useful and viable in fighting the threat of counterfeit drugs in Nigeria?</b>		
No	0	0%
Yes	54	100%

*Table 10: Knowledge of Anti-Counterfeit Technology*

This section is to evaluate how well the respondents knew about anti-counterfeit technology and how visible it is in working in Nigeria.

This data implies that pharmacists are conversant with anti-counterfeit technologies, but the majority are more familiar with the MAS feature. According to Justine and Ilomuanya, they mentioned the introduction of new anti-counterfeit technology by NAFDAC such as Raman Spectroscopy, Black Eye, and RFID, but from the above data, only 4% are aware of the RFID technology and neither Black Eye nor Raman Spectroscopy were mentioned in the space for others. This indicates that NAFDAC needs to carry out more awareness on the new technologies, to minimize the spread of counterfeit drugs. As agreed by all participants this will be viable to fight against counterfeit drugs.

KNOWLEDGE OF PHARMACEUTICAL DISTRIBUTION LAWS	Frequency	Percentage
<b>19. Are you familiar with Pharmaceutical Distribution laws in Nigeria</b>		
No	4	7%
Yes	51	93%
<b>20. How did you learn about it?</b>		
Learned in school (Relevant textbooks and Journals)	39	75%
Not Applicable	1	2%
Pharmaceutical Newsletter	5	10%
Self-Taught (Internet/ Social media)	3	6%
Word of Mouth (Interaction with colleagues and experts)	4	8%
<b>21. Will you consider upgrading your knowledge of present laws?</b>		
No	0	0%
Yes	55	100%

*Table 11: Knowledge of Pharmaceutical Distribution Laws*

This section is to access how well pharmacists are aware of current pharmaceutical distribution laws.

This section will enable the researcher to know if the professionals need to upgrade their knowledge for policies to be effective. 93% of respondents admitted to being familiar with distribution laws and 75% of respondents admitted to being taught in school.

This implies that most participants are aware of pharmaceutical distribution laws in Nigeria and are ready to upgrade their knowledge on it. Hence what needs to be done is for the regulatory bodies to ensure the proper implementation of laws.

## 4.5 GRAPHICAL REPRESENTATION OF DATA

### 4.5.1 Graphical Representation of Consumer Response

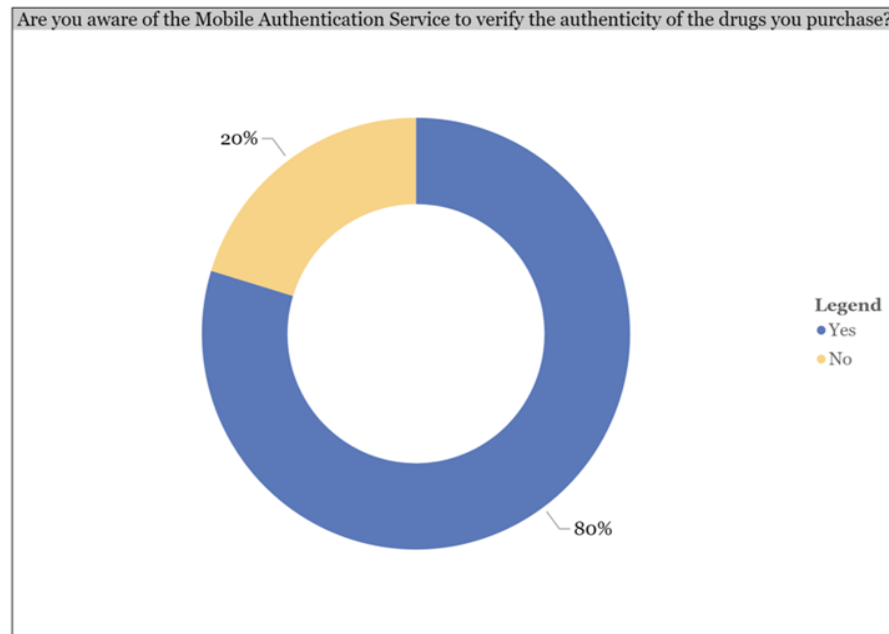


Figure 7: Awareness of MAS

This chart represents how well consumers are aware of MAS technology, out of the total number of respondents 80% are aware of the technology.

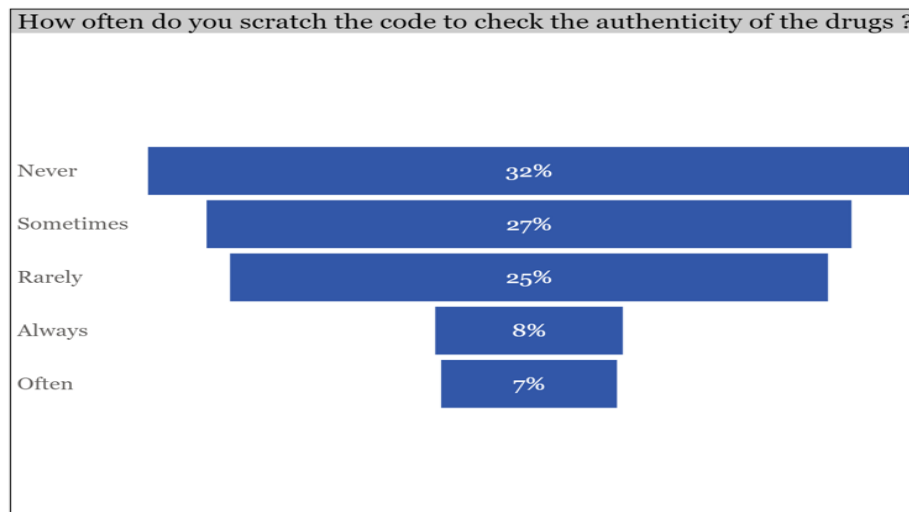


Figure 8: Use of MAS

This chart represents how well respondents use the MAS feature, showing the highest to the lowest with 32% never using it and 7% using it often.

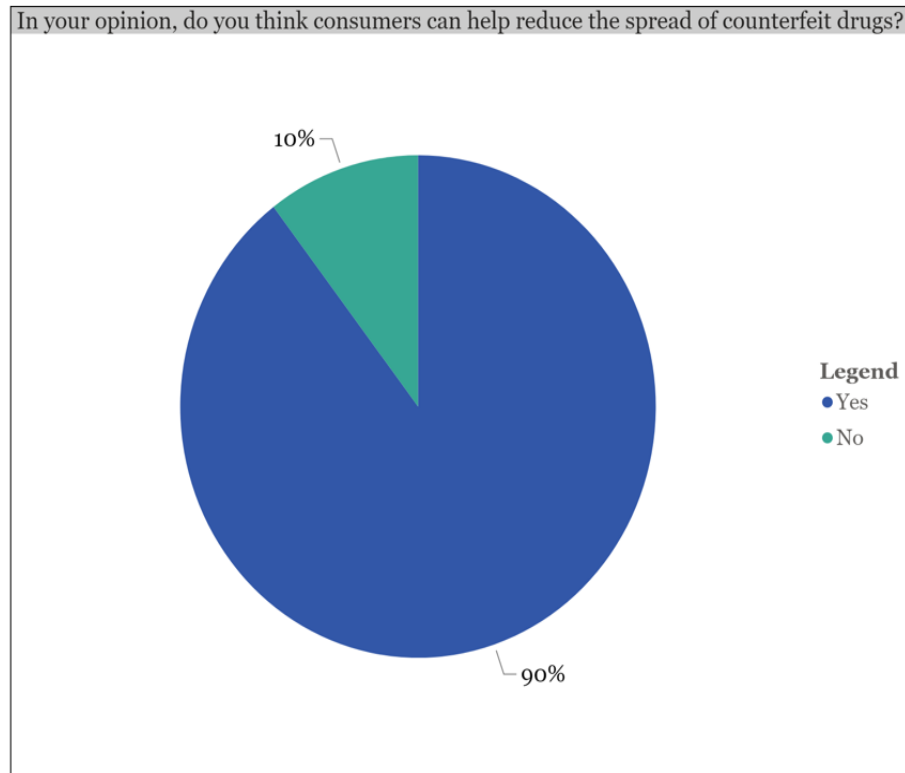


Figure 9: Can Consumers reduce the spread of counterfeit drugs?

This chart shows how well consumers agree to play a part in reducing the spread of counterfeit drugs in Nigeria.

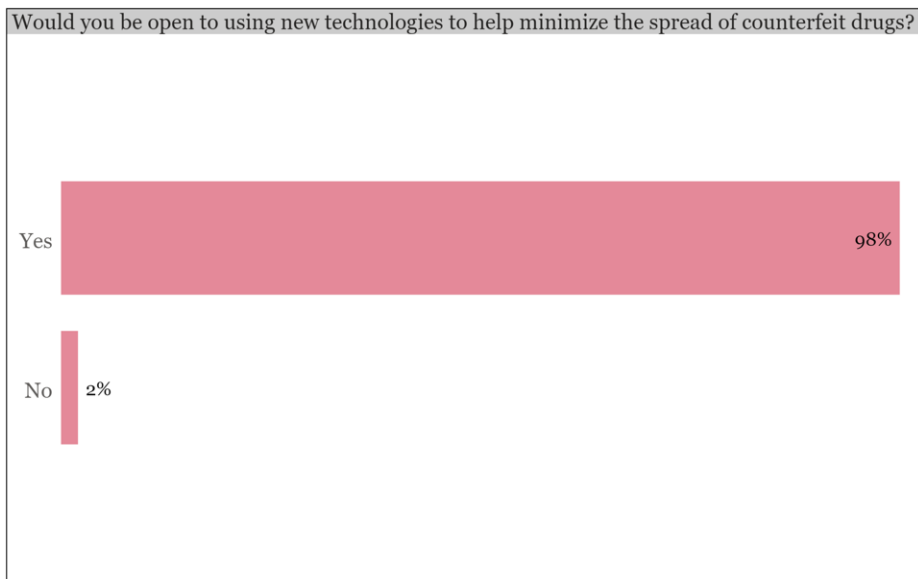


Figure 10: New Technology

This chart further shows the respondents' willingness to try new technologies to stop the spread of counterfeit drugs.

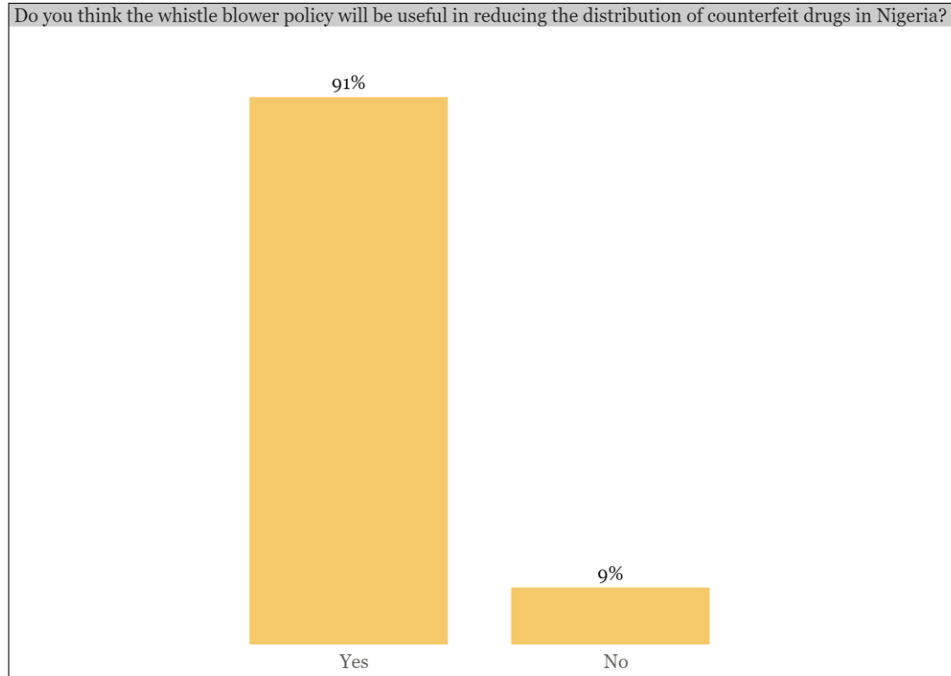


Figure 11: Whistle Blower Policy

Research from other countries shows that the whistleblower policy has helped reduce the spread of counterfeit drugs. To reduce the spread of counterfeit drugs the researcher intends to evaluate how well consumers will accept this method using this chart.

#### 4.5.2 Graphical Representation of Pharmacists Response

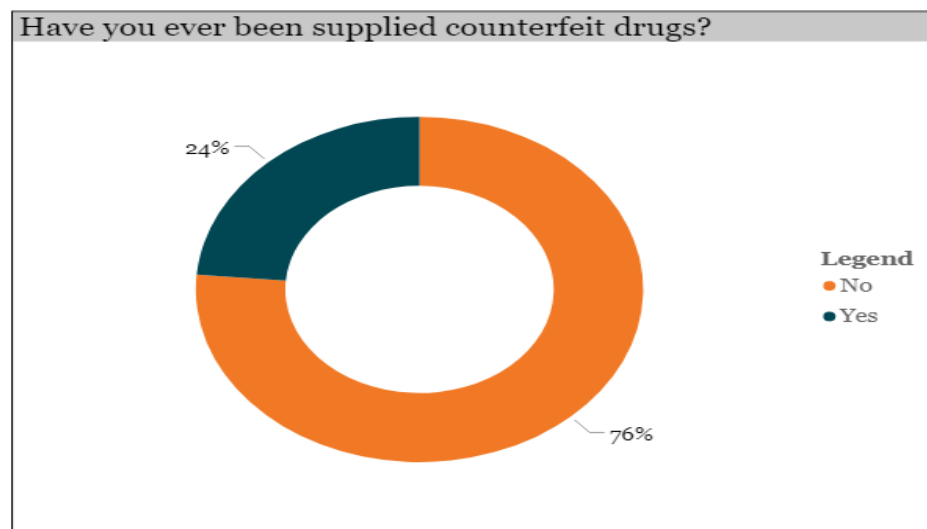


Figure 12: Counterfeit Drugs Supply



This chart evaluates how frequent pharmacist experience the supply of counterfeit. 24% agreed to have been supplied counterfeit drugs, while 76% agreed otherwise.

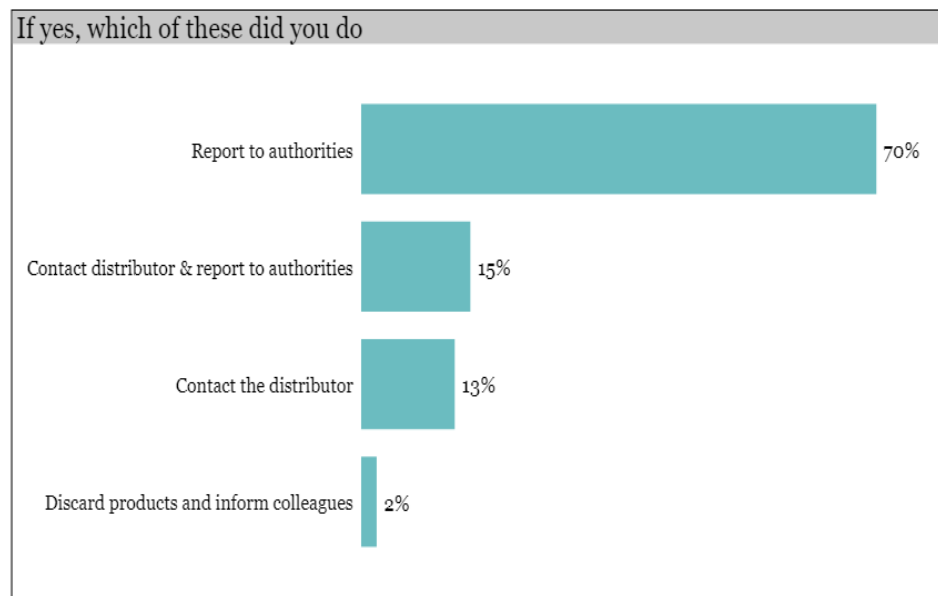


Figure 13: Response to counterfeit drugs supply

This chart evaluates how pharmacists report the supply of counterfeit drugs. 70% responded to reporting to the authorities.

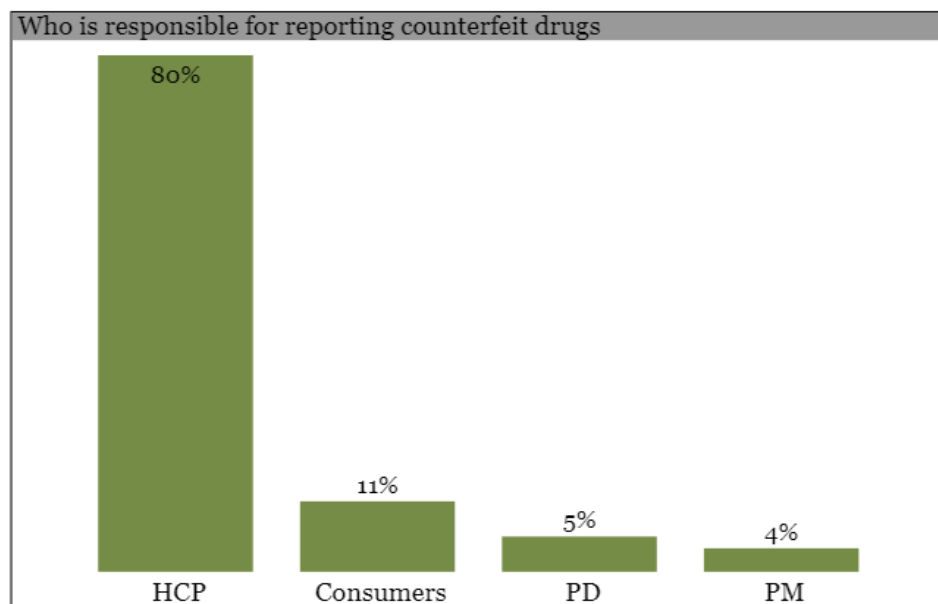
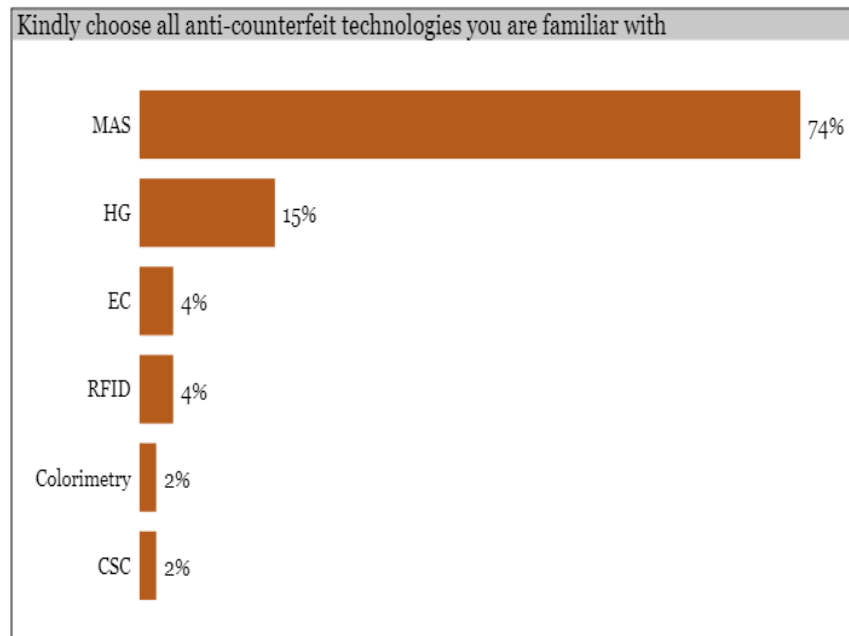


Figure 14: Responsibility of reporting Counterfeit Drugs

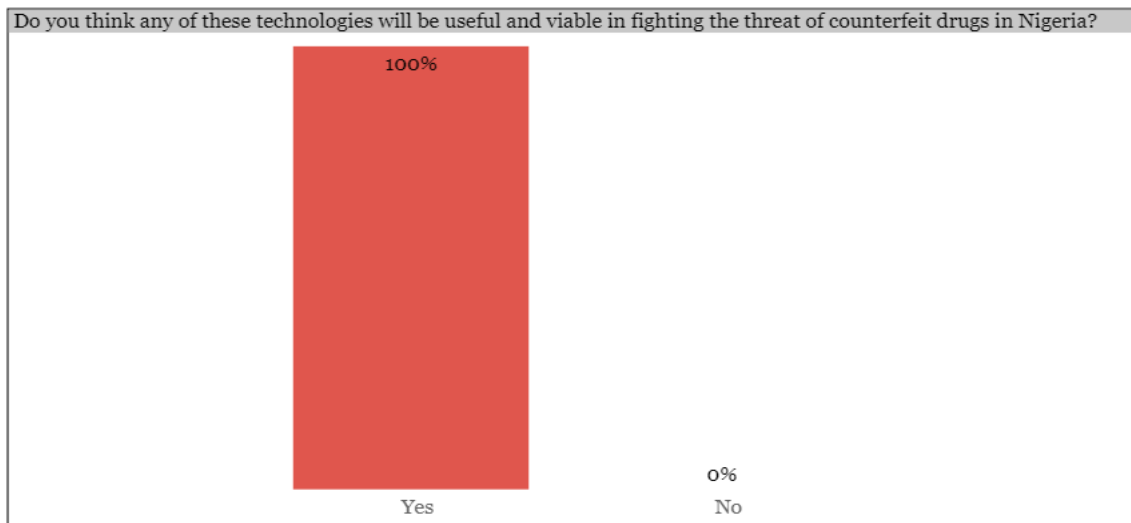
This chart evaluates pharmacists' responses to who is responsible for reporting counterfeit drugs. Where HCP is Health care professionals, PD is pharmaceutical distributors and PM is Pharmaceutical Manufacturers.



*Figure 15: Anti-counterfeit technology*

This chart evaluates the different anti-counterfeit technologies pharmacist are familiar with.

74% of pharmacists are familiar with the Mobile Authentication Service. The other technologies stated here are Hologram (HG), Embed-Codes (EC), Radio Frequency Identification (RFID) Tags, and Color Shifting Codes (CSC).



*Figure 16: Usefulness of anti-counterfeit technology in reducing counterfeit drugs*

All pharmacists agreed with these technologies been viable to fighting the threat of counterfeit drugs in Nigeria

## CHAPTER 5: CONCLUSION

### 5.1 OVERVIEW

This chapter highlights answers to the research questions based on data gathered via the primary data and further compares the results gathered via secondary data and primary data. Recommendations for practice and further studies are outlined and limitations faced during the research are stated.

### 5.2 ANSWERS TO THE RESEARCH QUESTIONS

**1. *What are the factors that challenge the effective implementation of Distribution Laws and Regulations in Nigeria, who is responsible for ensuring these laws are implemented?***

From the response gathered from the interview with pharmacists and distributors, it can be extracted that the factors affecting the proper implementation of distribution laws are corruption & greed, and insufficient efforts on the part of the regulatory bodies to implement these laws. From the survey, it can be seen that industry experts are conversant with these laws, but the problem is the implementation which is majorly the responsibility of the regulatory bodies who act as custodians of these laws.

The responsibility of ensuring laws are implemented lies in the hands of three people **the government** who sign the bills into power and entrust it in the hands of the **regulatory bodies** to ensure the laws are properly implemented and the **industry experts** who are supposed to follow the laws properly. As mentioned in one of the interviews the government needs to look for a way to motivate and support the regulatory bodies better. Also, the regulatory bodies in charge need to ensure that people who break these laws face the full consequence of the law. Industry experts should also be ready to report any suspicious activities they notice to the right authorities.

**2. *What reforms from other countries can be recommended to improve the pharmaceutical supply chain system in Nigeria and can consumer behavior help to minimize the spread of counterfeit drugs?***

From the data gathered from the consumer analysis survey, the majority of the respondents agreed that consumer behavior can help reduce the spread of counterfeit drugs. This question was mentioned as a result of the part consumers play in reporting illegal activities through the whistleblower policy in the United States. To evaluate if the whistleblower policy was viable in the Nigerian pharmaceutical industry, 91% of respondents agreed that yes, it will help minimize the spread of counterfeit drugs.

From interviews with distributors, some of the procedure to become a distributor is similar to what is being practiced in the US. For example, the purchase of drugs from the *established customary supply chain*. In Nigeria, they are two major national distributors (WWCV & Assene-Laborex) that supply to other distributors. These are the major intermediaries between the manufacturing companies and the distributors. The difference between the two countries is that in the US, distributors are bound by law to purchase from approved distributors also known as the *customary distribution chain*, while Nigeria has no such law, which allows unregulated buyers to access and affect the drug supply chain. Furthermore, in the US if a distributor does not buy from the customary supply chain, they are expected to provide a pedigree to the retailer which shows the movement of drugs through the normal supply chain. The pedigree document requires that every person involved in the distribution of a drug, which is not an authorized distributor or the manufacturer, is required to present a pedigree to the next person on the supply chain, till it reaches the final consumer. This is a reform that can be implemented in the Nigerian pharmaceutical supply chain to reduce the spread of counterfeit drugs.

From the survey response majority of participants are open to trying new technologies. The implementation of pedigree will allow consumers to verify the origin of drug products they purchase and also validate the authenticity. As recommended by industry experts more awareness should be done to educate consumers.

**3. *What are the loopholes in the pharmaceutical distribution system in Nigeria that facilitate the infiltration of counterfeit drugs and what are the challenges faced with closing the open markets in Nigeria?***

According to responses from the interview with industry experts, they highlighted that as long as you buy from the right source, the chances of being supplied counterfeit drugs are very minimal. Though two participants from the interview mentioned they purchase from open markets sometimes, they quickly added they ensure they check what was purchased, but this does not change the risk associated with purchasing from the open market. This might also imply that occasionally distributors might purchase products from open markets whereby increasing the risk of purchasing counterfeit drugs.

The data gathered from the interview highlighted that the loopholes in the pharmaceutical distribution channel which facilitate the infiltration of counterfeit drugs are the open market which is a result of greed and poverty, other factors which facilitate these loopholes are corruption, poor implementation of laws, and the presence of unskilled individuals in the channel.

The challenges faced with closing down the open market is the regulatory body in charge is not strict with who they register to practice, this is where the problem of unskilled individuals comes in as well. Furthermore, the problem of the weak regulatory structure has allowed these open markets to keep running.

As obtained from secondary data, Chukwu et al stated that the distribution system in Nigeria is highly affected by poor management, insufficient and an inadequate number of qualified workers. An inadequate number of qualified workers was also mentioned by some participants during the interview as one of the challenges currently faced by the pharmaceutical distribution system in Nigeria. The insufficient number of qualified workers is one loophole that has facilitated the infiltration of counterfeit drugs and has also made it difficult for the government to shut down these open markets. As recommended by one of the participants, the regulatory body in charge of registering pharmacists and giving license should be more thorough and strict to who they approve for practice.

### 5.3 COMPARING RESULTS FROM PRIMARY DATA AND SECONDARY DATA

According to a study carried out by Mark Willis he recommended educating consumers on the risk of counterfeit drugs can help minimize the spread of counterfeit drugs (Willis, 2018). Furthermore, according to previous research, China also launched a public awareness program to create awareness on the legitimate channels to acquire medical treatment. This awareness enabled consumers to identify counterfeit products. This recommendation can also be seen in the response from industry experts who were interviewed were a significant number of them recommended that consumers should be educated and counseled on the risk of counterfeit drugs and the need to purchase drugs from the right pharmacies

From the results gathered from the interview, it aligns with data gathered from Erhun et al study on *Drug regulation and Control in Nigeria: the challenge of counterfeit drugs*. Participants in the interview mentioned that weak distribution law, corruption, poor implementation of laws and shortage of drugs are all ways in which counterfeit drugs penetrate the system. Where 57% of Erhun et al respondents stated corruption was part of why laws were not implemented, 80% of interview participants for this study mentioned corruption is part of the problem. Also, where 60% of respondents from previous research agreed to counterfeiters penalties been reviewed 100% of interview participants of this study agreed for counterfeiters penalties to be reviewed.

Justine and Ilomuanya mentioned the introduction of new anti-counterfeit technologies by NAFDAC such as Raman Spectroscopy, Black Eye, MAS, and RFID (Justine and Ilomuanya, 2016). According to the primary data majority of respondents are familiar with the MAS feature, for the consumers more awareness needs to be done. Though 80% agree to know it, only 8% percent of the respondents ***always*** use it to confirm the authenticity of drugs purchased. Data also gathered via pharmacist survey showed that 74% are aware of the MAS feature but only 4% are aware of the RFID technology and no participant mentioned any of the anti-counterfeit technology mentioned by Justine and Ilomuanya.

According to Chukwu et al, they mentioned the factors affecting the supply chain are poor management and an inadequate number of qualified workers (Chukwu *et al.*, 2017). These factors were also identified by participants during the interview sessions.

The loopholes facilitating the infiltration of counterfeit drugs are the number of unqualified workers are more than the qualified workers, the presence of the open markets, and poor implementation of laws. To control the supply of counterfeit drugs more consumer awareness needs to be done and industry experts need to familiarize themselves with more anti-counterfeit technologies.

#### 5.4 CONTRIBUTION & LIMITATIONS OF THE RESEARCH

Previous studies showed gaps in studies involving pharmaceutical distributors, most studies where done mostly with consumers. Furthermore, previous studies only analyzed the use of MAS technology by consumers, but none evaluated the consumer's openness to new technologies and willingness to be part of a policy that reports suspicious activities. The pharmacist population evaluated in previous studies were not evaluated on the techniques they use to check products and were not accessed on their knowledge of anti-counterfeit technology, supply chain management, and distribution laws.

Based on the data obtained from this research from the 257-survey response and 13 interview response. The findings from this research will contribute to consumer awareness on current anti-counterfeit technologies available for their safety and make them conscious of where they purchase drugs from based on the section of the survey which analyzed consumer purchasing decision. Furthermore, based on the interview response and survey response, pharmacists and distributors will become more aware of checking products supplied and will also upgrade their knowledge of current anti-counterfeit technologies.

This research will also prompt stakeholders in the Nigerian pharmaceutical supply chain to improve the pharmaceutical supply chain management system to minimize the logistics problems currently been faced as mentioned by one of the participants.



The limitations faced during this interview where slow response from participants, access to pharmacists who had 5 years' experience, and more was not 100%, hence the researcher had to engage pharmacists with less than 5 years of experience. Access to strictly pharmacist-owners was not easy hence out of the 7 participants interviewed 3 were pharmacist-owners and 4 were pharmacist managers. Also, from the survey, a total of 55 pharmacists responded were 38 responses where from pharmacy managers and 17 responses were from pharmacy owners. During the period of the interview, the network was poor hence the ability to hold video calls as proposed earlier was not possible. Due to this, the researcher was unable to evaluate their response via body language, she was only able to use the tone of their voice to validate their interest in the study. Unfortunately, due to time, the researcher could not interview more people, a total of 7 people from the two sample groups did not respond to the interview.

## 5.5 RECOMMENDATIONS FOR PRACTICE

Consumers need to be educated on the need to use the current anti-counterfeit measures available to help reduce the spread of counterfeit drugs and for their safety. At the moment only a few drug products carry the MAS feature, manufacturing companies and the regulatory body in charge should try and enforce the presence of the MAS feature on all drugs in Nigeria. Though some drugs are more counterfeited than others, all drugs are still counterfeited in the end. The MAS feature proved to be user- friendly but it is important that the issue of wrong confirmation and delayed response needs to be resolved and consumers should be encouraged to use the feature more. Aside from the MAS feature more visual anti-counterfeit features should be introduced such as Holograms for the verification of drugs because this is more straight forward and easy to use because sometimes a consumer's phone might not be accessible and those in the rural areas will benefit from the visual features as well.

For industry experts, they should be educated on more anti-counterfeit technologies and they should also adopt the culture of checking products received despite the trust they have for the source, because as mentioned by some participants sometimes products are swapped and diverted. The introduction of pedigree or e-pedigree as used in the US in the Nigerian pharmaceutical system will help in monitoring the supply of counterfeit drugs and this will also

make everyone involved in the supply chain take responsibility. Also, the use of blockchain will be a viable technology in tracking the end to end distribution of drugs. The regulatory bodies should be strict in implementing laws on registering qualified people. They should also position competent officials at the borders to monitor the kind of drugs imported into the country.

## 5.6 RECOMMENDATION FOR FURTHER STUDIES

Further studies can be done on a larger group of participants to gain more depth and a wider perspective for analysis. Due to time constraints, the researcher could not interview more people for the interview. Also, further research can be done on the available anti-counterfeit technologies introduced by NAFDAC and the awareness of stakeholders. This research only scratched the surface of this area of the study, but it showed they are gaps in the knowledge of recent anti-counterfeit technologies by industry experts. Further research can look into this topic and propose methods to how industry experts can upgrade their knowledge. Also, further research can be done on the Nigerian pharmaceutical sector (registration, procurement, inspection, and distribution), the research can pick one sector and analyze it and propose areas of improvement or look at the four levels, analyze it, and propose areas of improvement. More research needs to be done in rural areas in Nigeria to ascertain the challenges faced with transporting genuine drugs to the area and how It can be improved.

Future research can also look at the impact of poor border activities on the pharmaceutical supply chain in Nigeria.

## 5.7 FINAL CONCLUSION/REFLECTION

The research process was rigorous but was exciting, educative, and insightful. Findings from the research developed the researcher's knowledge on the subject and also gave her a better understanding of the challenges faced by the pharmaceutical supply chain. This study also gave answers to questions the researcher had based secondary data and educated her better on the roles of stakeholders in the pharmaceutical supply chain.

The loopholes in the pharmaceutical supply chain are the presence of the open market as highlighted by participants in the interview and also stated in previous studies. Furthermore,

these open markets which are as a result of greed and poverty are the catalyst that facilitates the distribution of counterfeit drugs. Corruption, poor implementation of laws, and the presence of unskilled individuals in the channel are factors that also facilitate the loophole in the pharmaceutical supply chain. As extracted from primary data the regulatory bodies need to be more strict on who they approve to operate a pharmacy, this will reduce the operation of the open markets and also the spread of counterfeit drugs.

From primary data and literature review findings one of the methods that can improve the control of counterfeit drugs is consumer awareness. The need for consumers to be aware of the drugs they purchase and where they purchase it from is important. Also, introducing more visual anti-counterfeit features will help and consumers should be encouraged to use the current MAS feature on products.

Pharmacists and distributors are advised to procure drugs from verified sources because the chance of buying counterfeit drugs is minimized. The government and the regulatory bodies should invest in more security features for the pharmaceutical supply chain and drugs.

Pharmacists and distributors should also upgrade their knowledge of current anti-counterfeit technologies. Pharmacists should take time to check products supplied to ensure they are authentic.

Findings from primary data recommended that border controls should be strict to minimize the smuggling of counterfeit drugs into the system. Though the majority of respondents agreed that the implementation of proper supply chain management will help reduce the supply of counterfeit drugs and control the issue of stock out, laws need to be effective for the successful implementation of supply chain management.

## REFERENCE

- Akunyili, D. (2010) 'THE CHALLENGES FACED BY NAFDAC IN THE NATIONAL REGULATORY PROCESS AS IT RELATES TO ESSENTIAL DRUGS FOR PREVENTION OF MATERNAL AND NEWBORN DEATHS IN NIGERIA'. *Tropical Journal of Obstetrics and Gynaecology*, 27(1), pp. 81–87. Available at: <https://www.ajol.info/index.php/tjog/article/view/85148>.
- Bagozzi, D. and Lindmeier, C. (2017) *1 in 10 Medical Products in Developing Countries Is Substandard or Falsified*. World Health Organization. Available at: <https://www.who.int/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified> (Accessed: 24 March 2020).
- Boumil, S.J. *et al.* (2010) 'Whistleblowing in the Pharmaceutical Industry in the United States, England, Canada, and Australia'. *Journal of Public Health Policy*, 31(1), pp. 17–29. Available at: <https://www.jstor.org/stable/40542247> (Accessed: 19 August 2020).
- Chambliss, W.G. *et al.* (2012) 'Role of the Pharmacist in Preventing Distribution of Counterfeit Medications'. *Journal of the American Pharmacists Association: JAPhA*, 52(2), pp. 195–199. DOI: 10.1331/JAPhA.2012.11085.
- Chukwu, O.A., Ezeanochikwa, V.N. and Eya, B.E. (2017) 'Supply Chain Management of Health Commodities for Reducing Global Disease Burden'. *Research in Social and Administrative Pharmacy*, 13(4), pp. 871–874. DOI: 10.1016/j.sapharm.2016.08.008.
- Enyinda, C.I. and Tolliver, D. (2009) 'Taking Counterfeits out of the Pharmaceutical Supply Chain in Nigeria: Leveraging Multilayer Mitigation Approach'. *Journal of African Business*, 10(2), pp. 218–234. DOI: 10.1080/15228910903187957.
- Erhun, W.O., Babalola, O.O. and Erhun, M.O. (2013) 'Drug Regulation and Control in Nigeria: The Challenge of Counterfeit Drugs'. *World Health & Population*, 4(2). DOI: 10.12927/whp..17597.
- Eronmhonsele, J.I. (2015) 'Detecting Counterfeit Drugs through Mobile Authentication Service (MAS): Users' Challenges in Edo South Senatorial District'. *International Journal of Pharmaceutical Science Invention*, 4(9), pp. 13–18. Available at: [http://www.ijpsi.org/Papers/Vol4\(9\)/C0409013018.pdf](http://www.ijpsi.org/Papers/Vol4(9)/C0409013018.pdf) (Accessed: 26 July 2020).

Fatokun, O. (2016) 'Curbing the Circulation of Counterfeit Medicines in Nigeria'. *The Lancet*, 388(10060), p. 2603. DOI: 10.1016/S0140-6736(16)32121-3.

Federal Ministry of Health. (2020) *Mission and Vision. Federal Ministry of Health*. Available at: [https://www.health.gov.ng/index.php?option=com\\_content&view=article&id=82&Itemid=474#](https://www.health.gov.ng/index.php?option=com_content&view=article&id=82&Itemid=474#) (Accessed: 30 May 2020).

GAN Business Anti-corruption. (2017) *Nigeria Corruption Report. GAN Integrity*. Available at: <https://www.ganintegrity.com/portal/country-profiles/nigeria/> (Accessed: 18 July 2020).

Garuba, H.A., Kohler, J.C. and Huisman, A.M. (2009) 'Transparency in Nigeria's Public Pharmaceutical Sector: Perceptions from Policy Makers'. *Globalization and Health*, 5(1), p. 14. DOI: 10.1186/1744-8603-5-14.

Gillette, F. (2013) 'Inside Big Pharma's Fight against the \$75 Billion Counterfeit Drug Business'. *Bloomberg Businessweek*, (4313), pp. 58–61. Available at: <http://search.ebscohost.com/login.aspx?direct=true&db=buh&AN=85006944&site=ehost-live> (Accessed: 24 April 2020).

Goyit, K., Amagon, K.I. and Dangiwa, D.A. (2016) 'An Assessment of Drug Supply Chain System in Selected Facilities in Abuja and Plateau State, Nigeria'. *West African Journal of Pharmacy*, 27(1), pp. 64–77. Available at: [https://www.researchgate.net/publication/320383623\\_An\\_assessment\\_of\\_drug\\_supply\\_chain\\_system\\_in\\_selected\\_facilities\\_in\\_Abuja\\_and\\_Plateau\\_State\\_Nigeria\\_1\\_2\\_3](https://www.researchgate.net/publication/320383623_An_assessment_of_drug_supply_chain_system_in_selected_facilities_in_Abuja_and_Plateau_State_Nigeria_1_2_3).

Justine, A. and Ilomuanya, M.O. (2016) 'Securing the Pharmaceutical Supply Chain: A Study of the Use of Mobile Authentication Service (MAS) among the Nigerian Populace Utilizing Antimalarials'. *African Journal of Pharmacy and Pharmacology*, 10(39), pp. 839–848. DOI: 10.5897/AJPP2016.4667.

Kapoor, D., Vyas, R. and Dadarwal, D. (2018) *An Overview on Pharmaceutical Supply Chain: A Next Step towards Good Manufacturing Practice. Drug Designing & Intellectual Properties International Journal*. Available at: <https://lupinepublishers.com/index.php> (Accessed: 28 May 2020).

Kaushik, V. and Walsh, C.A. (2019) (9) 'Pragmatism as a Research Paradigm and Its Implications for Social Work Research'. *Social Sciences*, 8(9), p. 255. DOI: 10.3390/socsci8090255.

Khan, M.H. *et al.* (2011) 'Perceptions and Practices of Pharmaceutical Wholesalers Surrounding Counterfeit Medicines in a Developing Country: A Baseline Survey'. *BMC Health Services Research*, 11(1), p. 306. DOI: 10.1186/1472-6963-11-306.

Kollmorgen, S. (2015) 'The World's Medical Supply Chain Is Riddled With Counterfeit Drugs'. *The New Republic*, 20 April. Available at: <https://newrepublic.com/article/121589/counterfeit-medicine-global-problem> (Accessed: 20 July 2020).

Lon, C.T. *et al.* (2006) 'Counterfeit and Substandard Antimalarial Drugs in Cambodia'. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 100(11), pp. 1019–1024. DOI: 10.1016/j.trstmh.2006.01.003.

Mackey, T.K. *et al.* (2015) 'Counterfeit Drug Penetration into Global Legitimate Medicine Supply Chains: A Global Assessment'. *The American Journal of Tropical Medicine and Hygiene*, 92(Suppl 6), pp. 59–67. DOI: 10.4269/ajtmh.14-0389.

Mackey, T.K. and Liang, B.A. (2011) 'The Global Counterfeit Drug Trade: Patient Safety and Public Health Risks'. *Journal of Pharmaceutical Sciences*, 100(11), pp. 4571–4579. DOI: 10.1002/jps.22679.

Mhugos. (2014) *Four Participants in Every Supply Chain*. *SCM Globe*. Available at: <https://www.scmglobe.com/four-participants-in-every-supply-chain/> (Accessed: 10 August 2020).

Millar, A. (2020) *The Rise of Counterfeit Medicines in Africa*. *Pharmaceutical Technology*. Available at: <https://www.pharmaceutical-technology.com/features/counterfeit-drugs-africa/> (Accessed: 25 April 2020).

Mohanta, D.C. (2014) *Role And Importance of Distributors in SCM*. *authorSTREAM*. Available at: <http://www.authorstream.com/Presentation/gcmohanta29-3788217-role-importance-distributors-scm-gcm/> (Accessed: 10 August 2020).

Morris, J. and Stevens, P. (2006) 'Counterfeit Medicines in Less Developed Countries Problems and Solutions'. *International Policy Network*. Available at: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.470.2406&rep=rep1&type=pdf>.

NAFDAC. (2017) *About NAFDAC – NAFDAC. National Agency for Food and Drug Administration and Control: NAFDAC*. Available at: <https://www.nafdac.gov.ng/about-nafdac/> (Accessed: 30 May 2020).

NAFDAC. and Sproxil. (2015) *NAFDAC Mobile Authentication Service (MAS). Sproxil®*. Available at: <https://sproxil.com/nafdac-mobile-authentication-service-mas/> (Accessed: 21 July 2020).

NDLEA. (2018) *NDLEA | » Vision/Mission. National Drug Law Enforcement Agency (NDLEA)*. Available at: <https://ndlea.gov.ng/about-ndlea/vision-mission/> (Accessed: 30 May 2020).

Ogbonna, B.O., Ilika, A. and Nwabueze, S. (2015) 'NATIONAL DRUG POLICY IN NIGERIA, 1985-2015'. *World Journal of Pharmaceutical Research*, Vol 4(6), pp. 248–264. Available at: [https://www.academia.edu/28072831/NATIONAL\\_DRUG\\_POLICY\\_IN\\_NIGERIA\\_1985-2015](https://www.academia.edu/28072831/NATIONAL_DRUG_POLICY_IN_NIGERIA_1985-2015) (Accessed: 30 May 2020).

Ojeme, V. (2010) 'Food Safety: NAFDAC Begins Awareness Campaign - Vanguard News'. *Vanguard Newspaper*, 12 August. Available at: <https://www.vanguardngr.com/2010/12/food-safety-nafdac-begins-awareness-campaign/> (Accessed: 18 July 2020).

Ojo, L. (2017) *National Drug Distribution Guidelines and Its Benefits. Pharmanewsonline*. Available at: <https://www.pharmanewsonline.com/national-drug-distribution-guidelines-and-its-benefits/> (Accessed: 27 April 2020).

Olson, L. (2020) *How Does the Pharmaceutical Supply Chain Work?. Datex Corporation*. Available at: <https://www.datexcorp.com/how-does-the-pharmaceutical-supply-chain-work/> (Accessed: 29 May 2020).

Oyetunde, O.O. *et al.* (2019) 'Mobile Authentication Service in Nigeria: An Assessment of Community Pharmacists' Acceptance and Providers' Views of Successes and Challenges of Deployment'. *Pharmacy Practice*, 17(2). DOI: 10.18549/PharmPract.2019.2.1449.

Peterson, K. (2014) 'Chemical Multitudes Fake Drugs and Pharmaceutical Regulation in Nigeria'. In *Speculative Markets: Drug Circuits and Derivative Life in Nigeria*. Duke University Press. Available at: <https://watermark.silverchair.com/9780822376477-001.pdf> (Accessed: 23 March 2020).

Pharmaceutical Council of Nigeria. (2020) *Pharmaceutical Council of Nigeria: About Us. Pharmacists Council of Nigeria*. Available at: <https://www.pcn.gov.ng/about-us/> (Accessed: 30 May 2020).

Pharmaceutical Security Institute. (2019) *Incident Trends. PSI Website*. Available at: <https://www.psi-inc.org/incident-trends> (Accessed: 11 July 2020).

Raufu, A. (2006) *WHO | Nigeria Leads Fight against 'Killer' Counterfeit Drugs. WHO*. Available at: <https://www.who.int/bulletin/volumes/84/9/06-020906/en/> (Accessed: 25 May 2020).

Robles R., Y., Casauay, J.F.C. and Bulatao, B.P. (2015) 'Addressing the Barriers to Effective Monitoring, Reporting and Containment of Spurious/Substandard/Falsely-Labelled/Falsified/Counterfeit Medical Products through Sustainable Multi-Stakeholder Collaboration and Community/Consumer-Based Interventions A Report Prepared for the Medicines Transparency Alliance, Philippines'. Available at: [https://www.who.int/medicines/areas/coordination/SSFFC\\_Report.pdf](https://www.who.int/medicines/areas/coordination/SSFFC_Report.pdf) (Accessed: 24 March 2020).

Sun, L. (2012) 'Anti-Counterfeiting Situation in China'. p. 26. Available at: [https://www.who.int/medicines/areas/quality\\_safety/regulation\\_legislation/icdra/WM-1\\_2Dec.pdf?ua=1](https://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/WM-1_2Dec.pdf?ua=1).

Tetteh, E. (2009) 'Creating Reliable Pharmaceutical Distribution Networks and Supply Chains in African Countries: Implications for Access to Medicines'. *Research in Social and Administrative Pharmacy*, 5(3), pp. 286–297. DOI: 10.1016/j.sapharm.2008.08.001.

UNIDO. (2011) Available at: [https://www.unido.org/sites/default/files/2011-04/Nigeria\\_Pharma%20Sector%20Profile\\_032011\\_Ebook\\_0.pdf](https://www.unido.org/sites/default/files/2011-04/Nigeria_Pharma%20Sector%20Profile_032011_Ebook_0.pdf) (Accessed: 28 May 2020).

Uzochukwu, C.E. and Chinedu- Okeke, C.F. (2017) 'AUDIENCE AWARENESS AND USE OF MOBILE AUTHENTICATION SERVICE (MAS) IN IDENTIFYING FAKE AND SUBSTANDARD DRUGS IN NIGERIA'. *Mgbakoigba, Journal of African Studies.*, 7(1).

WHO. (2010) *WHO | Growing Threat from Counterfeit Medicines. WHO*. DOI: [/entity/bulletin/volumes/88/4/10-020410/en/index.html](https://www.who.int/bulletin/volumes/88/4/10-020410/en/index.html).

Willis, R.M. (2018) *Counterfeit Pharmaceuticals : Are the U.S. Consumers Aware of the Potential Risks?* Northeastern University. DOI: 10.17760/D20293356.



## APPENDIXES

### Interview Questions for pharmacist

1. How long have you been practicing as a pharmacist?
2. How long have you owned or managed your pharmacy?
3. Do you know about supply chain management?
4. In your opinion, will supply chain management reduce the penetration of counterfeit drugs into Nigeria's pharmaceutical supply chain?
5. How do you select your distributors? Are there specific requirements that influence your choice of selecting a distributor?
6. How is the warehouse or storeroom secured? Is personnel access properly defined?
7. Have you ever experienced a stock out? What is the cause? How did you handle the situation?
8. Do you have a defined structure to guarantee the authenticity of products supplied?( explanations: Aside from checking the supply of drugs to confirm if the products delivered corresponds with your order, do you check to confirm if they are genuine?)
9. Do you agree that as a pharmacist you play a vital role in reducing the spread of counterfeit drugs in Nigeria?
10. Are you aware of any pharmaceutical distribution laws?
11. What do you think is the reason why the implementation of regulations and laws suffer poor implementation?
12. Have you ever been supplied counterfeit drugs?
  - a. What aids the distribution of counterfeit drugs?
13. Are you aware of any anti-counterfeiting technologies, if yes do you think they will help in the spread of counterfeit drugs in Nigeria?
14. In your opinion should the penalties for counterfeiters be Reviewed.
15. Do you have any recommendations or suggestions on how the distribution of counterfeit drugs can be minimized?

## Interview Questions for Distributors

1. How long have you been a pharmaceutical Distributor?
2. What is the procedure for becoming a distributor? Do you need a license to become a distributor?
3. How will you describe the pharmaceutical supply chain, what are the drivers that aid the supply of counterfeit drugs?
4. How do procure your drugs? Do you distribute for a home-based pharmaceutical or an international pharmaceutical company? or a combination both?
5. In your opinion, do you think the procedure for drug procurement should be broken down?
6. Roughly how many pharmaceutical companies do you distribute for?
7. Roughly how many pharmacies do you distribute to?
8. How do you manage multiple distributions?
9. Do you validate how genuine the products are before distribution?
10. Are you aware of any laws or regulations concerning pharmaceutical distributions in Nigeria?
  - a. What do you think is the reason why the implementation of regulations or laws in Nigeria is poor?
11. From research, it has shown that in Nigeria shortage of supply is an avenue which counterfeiters take advantage of? What is the cause of a shortage of supply? And How often do you experience out of stock?
12. Research has shown that the multiple intermediaries (people) in the pharmaceutical supply chain facilitates the supply of counterfeit drugs to pharmacies in Nigeria? Do you agree?
13. Do you think the penalty for counterfeiters should be reviewed?
14. Are you aware of any anti-counterfeit technology that will be useful in reducing the threat of counterfeit drugs in Nigeria?

15. From your years of experience do you have any suggestions or recommendations on how the supply chain can be improved to reduce the loopholes which facilitate the supply of counterfeit drugs?

#### Survey Questions for Consumers

## An Analysis of Loopholes in the Pharmaceutical Supply Chain, and Methods for Improving Control of Counterfeit Drugs in Nigeria: Consumer Survey

Dear Participant,

I am a student of Griffith College Dublin, As part of the requirements to earn an M.Sc in Pharmaceutical Business and Technology, I am working on a dissertation research on possible loopholes present in the pharmaceutical supply chain that aids the distribution of counterfeit drugs in Nigeria, and potential methods for how the supply of counterfeit drugs can be controlled.

Identifying the loopholes in the supply system will help to improve the distribution of drugs and cut down ways by which counterfeit drugs penetrate the supply system. The goal of every health supply chain is to ensure the drugs arrives the final consumer in its best quality.

This survey aims to evaluate consumer awareness of current anti-counterfeiting technologies as established by NAFDAC and further evaluate how well consumers utilize present measures in place. Findings from this study will give the researcher insights into recommending methods that could further help with reducing the spread of counterfeit drugs.

Participation in this research is completely voluntary, and the privacy of every participant is highly assured as all responses will be fully anonymous and strictly confidential. All data generated from this survey will be exclusively used for my research purpose only and they will be stored in line with the General Data Protection Regulation (GDPR).

This survey aims to evaluate consumer awareness of current anti-counterfeiting technologies as established by NAFDAC and further evaluate how well consumers utilize present measures in place. Findings from this study will give the researcher insights into recommending methods that could further help with reducing the spread of counterfeit drugs.

Participation in this research is completely voluntary, and the privacy of every participant is highly assured as all responses will be fully anonymous and strictly confidential. All data generated from this survey will be exclusively used for my research purpose only and they will be stored in line with the General Data Protection Regulation (GDPR).

Thank you for your participation.

\* Required

1. I agree to voluntarily participate in this research study and give consent to my response been used for research purposes. \*

☐ Yes

☐ No

Next

#### Demographics

2. Gender \*

☐ Female

☐ Male

3. Age \*

☐ 18-30

☐ 31-40

☐ 41-50

☐ 50 and Older

4. Highest Level of Education \*

☐ Secondary School

☐ Undergraduate

☐ Postgraduate

☐ No formal Education

5. Occupation \*

- ☐ Employed
- ☐ Self-Employed
- ☐ Unemployed
- ☐ Student
- ☐ Retired

6. Area of Residence \*

- ☐ Rural
- ☐ Urban
- ☐ Other: \_\_\_\_\_

Back

Next

Knowledge of Existing Anti-counterfeit Technology

Presently in Nigeria, we have the Mobile Authentication Service (MAS) feature by NAFDAC, which requires patients to scratch codes and Short Messaging Service (SMS) to verify the authenticity of medicines at the point of purchase.

7. How often do you scratch the code to check the authenticity of the drugs ? \*

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

8. Are you aware of the Mobile Authentication Service to verify the authenticity of the drugs you purchase? \*

- ☐ Yes
- ☐ No

9.How did you get to know about the Mobile Authentication Service?

- ☐ NAFDAC Website
- ☐ NAFDAC Awareness Campaign
- ☐ Pharmacy/ Hospital
- ☐ Word of mouth (Friends, relatives, etc.)
- ☐ Television/Radio/Newspaper
- ☐ Social Media
- ☐ Other: \_\_\_\_\_

10.Is the Mobile Authentication Service, User Friendly? \*

- ☐ Yes
- ☐ No
- ☐ Not applicable

11. How will you rate the response time of the Mobile Authentication Service?

- |           |                       |                       |                       |                       |                       |           |
|-----------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------|
|           | 1                     | 2                     | 3                     | 4                     | 5                     |           |
| Very Slow | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | Very Fast |

#### Assessment on Response to Counterfeit Drugs

12. Have you ever had an encounter with counterfeit drugs or do you know anyone who has? \*

- ☐ Yes
- ☐ No

13. In your opinion, do you think consumers can help reduce the spread of counterfeit drugs? \*

- ☐ Yes
- ☐ No

14. If you scratched the code and realized the product is counterfeited, will you?

- ☐ Return it to the pharmacy you purchased it from.
- ☐ Call the regulatory number as replied on the text.
- ☐ Just dispose of the drug and buy it from another pharmacy.
- ☐ Just dispose and warn others about the particular pharmacy.
- ☐ Other: \_\_\_\_\_

### Purchasing Decision

15. \*

	Most Likely	Likely	Neutral	Unlikely	Most Unlikely
How likely will the price of a drug affect your buying decision?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Does the appearance of a pharmacy influence your buying decision	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How likely are you to check the tamper seal on drug product purchased	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### NAFDAC Assessment

16. How will you rate the government's effort in fighting against the spread of counterfeit drugs? \*

	1	2	3	4	5	
Poor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Excellent

17. \*

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
In your opinion, will you agree that the government is effective at communicating the risk of counterfeit drugs in Nigeria	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In your opinion, will you agree that NAFDAC has done a good job in publicizing the use of the MAS feature?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In your opinion, do you think the MAS feature should be applied to all drugs.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

18. If NAFDAC published a list of Licensed pharmacists within your area will you adhere strictly to it? \*

☐ Yes

☐ No

19. Would you be open to using new technologies to help minimize the spread of counterfeit drugs? \*

☐ Yes

☐ No

**Whistle Blower policy is a policy which permits citizens to voluntarily expose illegal or dishonest dealings to appropriate authorities while remaining anonymous.**

20. Do you think the whistle blower policy will be useful in reducing the distribution of counterfeit drugs in Nigeria? \*

☐ Yes

☐ No



## INTERVIEW FINDINGS FROM PHARMACIST

### Knowledge of supply chain management

All participants knew supply chain management except one participant who has very little knowledge of it. The majority of participants learned from school and one participant learned from journals and newsletters.

### In response to supply chain management as a solution to reducing the infiltration of counterfeit drugs into the Nigerian Pharmaceutical Supply Chain

Participant 1: *"From my own experience I would say No, it can't. Within the Nigerian market, I don't think supply chain management can quell the bane of counterfeit drugs. The reason is that in the Nigerian market, there are players whose entire business is built on the production and sale of counterfeit drugs and they are people who even seek them out and buy from them to make more money. We have a corrupt system in place here which thrives on such practices, and the lack of strong regulation and implementation of laws are already grounds that allow for these fraudsters to thrive and prosper. These fraudsters know how to work around NDLEA, SON, and NAFDAC".*

Participant 2: *"Yes, it will help reduce the spread of counterfeit drugs, because currently the agency in charge of counterfeit drugs in Nigeria is facing a lot of challenges, majorly logistics problem which makes it difficult to get rid of counterfeit drugs."*

Participant 3: *"Yes, it can by ensuring that batches are tracked and traced from the point of the manufacturer to the end-user. So that in a situation where there is a problem along the way the products can be easily traced. If NAFDAC effectively applies supply chain management, it will go a long way in reducing the spread of counterfeit drugs".*

Participant 4: *"Yes, if managed properly it will be effective in reducing the spread of counterfeit drugs".*

Participant 5: *"Yes, if pharmacies purchase drugs from regulated and licensed stores, instead of open markets".*

Participant 6: *"Yes, it can if properly monitored, but if not properly monitored it will be difficult to be used in Nigeria. Many parties involved in the supply chain are not sincere in doing the right things which makes it easy for the infiltration of counterfeit drugs".*

Participant 7: *“Yes it will reduce the spread of counterfeit drugs, though the awareness is still coming up in Nigeria it will help with proper monitoring of the supply chain”.*

#### **Response to characteristics which influence the selection of distributors**

Participants 1 & 5 *select distributors based on integrity, recommendations, and referrals and their track record in the industry.*

Participants 3&4 *Use pharmaceutical representatives, distributors who have direct links with the companies.*

Participants 2 & 7 *Consider the price of the distributor, the quality of products, and the distributors who distribute known brands.* Participant 7 *also added that the location of the distributor is also for the company.*

Participant 6: *The distributor must be a licensed professional and have a NAFDAC registration number and be permitted to distribute.*

#### **Response to the security of storerooms and how stock out is handled**

All participants responded to personnel access been strict and properly secured. Most participants mentioned that only one person has access to the storeroom. Participant 3 mentioned only the manager and the storekeeper have access to the storeroom.

In response to how an out of stock situation is handled, most participants stated that they wait for the distributor to supply the product the because if one licensed distributor does not have the possibility of another licensed distributor have is slim. Furthermore, two participants attributed stock out to High demand and low supply or transport delays from distributors. 4 participants out of the 7 stated they recommend other brands to consumers that have the same effect.

Participant 5 also added that *“when there is stock out some dubious people even wholesalers go to China and duplicate the packs of these drugs, make something else, write on the body and supply. And because it is in high demand, people don’t look at careful, they just buy”*

**Response to how they guarantee the authenticity of products supplied.**

Participant 1: *“For multinational companies, I check if the security features like holograms, MAS are present, but for companies that don’t have these features, I just trust the distributor”.*

Participant 2: *“Uses the MAS feature to check and sometimes confirms with NAFDAC”*

Participant 3: *“Uses the MAS feature and checks for NAFDAC registration number”*

Participant 4: *“Uses the Batch Number, Stock ID and confirms with the company”*

Participant 5: *“Relies on the credibility of the Distributor”*

Participant 6: *“Checks for NAFDAC registration number, confirms with the company, and trust the distributor”.*

Participant 7: *“Checks the packaging of the product and checks the seal of the product”.*

**Response to the role of pharmacists in reducing the spread of counterfeit drugs in Nigeria**

All participants agreed that they play a vital role in minimizing the spread of counterfeit drugs.

Participant 1: *Highlighted that it’s an issue of integrity and as pharmacists, it’s important to take any complaint from a customer very seriously. Also, as a pharmacist, it is important I buy products from the right source no matter the markup and report any form of counterfeit drugs as either reported by a customer or noticed as a pharmacist.*

Participant 2: *stated that amongst all the medical professions, pharmacists hold the highest responsibility in minimizing the spread of counterfeit drugs.*

Participant 3: *“Educate clients on how to buy drugs from registered pharmacies and not drug markets”.*

Participant 4: *“check the products to confirm the authenticity of the product before dispensing it to patients and follow up on patient feedback”.*

Participant 5: *“Advice and counsel patients on the right point of purchase. But the open markets must be shut down, because as long as there are open there is very little we as pharmacists can do because people will still purchase drugs from there which is detrimental to their health, hence the urgent need for the government to do something as soon as possible ”.*

Participant 6: *“By selecting the right distributors and cross-checking products before dispensing them to patients”*

Participant 7: *“By checking products to confirm their NAFDAC numbers, quarantine suspicious batches and start a follow-up investigation on the batch and communicate suspicious batch number to colleagues”*

### **Knowledge of pharmaceutical distribution laws and response to why laws are poorly implemented**

5 participants admitted to knowing distribution laws, while 2 participants were not familiar with any laws, but they all responded to why laws are poorly implemented.

Participant 1: *the poor implementation of laws is because of the relaxed culture in Nigeria, no one takes anything seriously, hence culprits get away with such a great offense as drug counterfeiting.*

Participant 2: *“laws are poorly implemented because everything has been politicized”*

Participant 3: *“corruption has eaten deep, hence the regulatory body in charge is more concerned with allowing anyone to practice whether they are qualified or not, as long as they can sort them out. Unfortunately, they are more non-pharmacist in the business than licensed pharmacists”.*

Participant 4: *“poor implementation is because the chain is wide, a lot of sectors are involved in the process and government is not making enough effort to ensure these laws effectively implemented”.*

Participant 5: *“Laws have been poorly implemented because of greed and corruption in the system”*

Participant 6: *“laws are poorly implemented because they are no strict regulations in the system and greed and corruption have taken over the day”.*

Participant 7: *“laws are not properly implemented because the regulatory bodies in charge are not making enough effort for these laws to be implemented and the consequences are the efficient enough”.*

**Response to experience with been supplied counterfeit drugs and what aids the distribution of counterfeit drugs.**

All participants have not been supplied with counterfeit drugs. They all had similar views on what aids the distribution of counterfeit drugs, but they all stated that as long as you buy from the right source the possibility of been supplied counterfeit drugs is minimal, “it is impossible” as one of the participants said.

All participants mentioned that the major cause of counterfeit drugs in Nigeria is the open markets. If pharmacists or distributors don’t buy from the open markets, the spread of counterfeit drugs will reduce, although some people are specifically in this business for the profit, hence some pharmacists buy only from the open markets without caring about the consequences on the consumers”. Some participants also added greed, corruption, and poverty to the factors which aid the distribution of counterfeit drugs and participant 2,3,6 &7 also added the poor implementation of laws and relaxed behavior from regulatory bodies.

**Knowledge of anti-counterfeit technology, and response to how it will help reduce the spread of counterfeit drugs**

5 participants were familiar with anti-counterfeit technologies, all 5 were familiar with MAS while participant 1 is also familiar with Holograms and tamper seals, while participant 5 is also familiar with RFID. 2 participants were not familiar with anti-counterfeit technologies.

*According to participant 1, “these anti-counterfeit technologies have been useful in fighting the spread of counterfeit drugs but not in a widespread manner. This is because these technologies are expensive and companies are trying to cut down cost, but companies which use these technologies use them to protect their products from counterfeiting”. Participant 2 highlighted that the “MAS technology has not sufficiently helped because the response time is slow, and sometimes it takes up to 3 days to receive a response and sometimes consumers receive false replies, genuine drugs are tagged as fake and vice versa. MAS has not been efficient enough. He also stated the more anti-counterfeit technologies should be deployed because the MAS technology has been*

*dubbed by counterfeiters too". Participant 3 stated that "MAS technology has helped cut down the spread of counterfeit drugs but not enough. More enlightening needs to be done because many people are not aware of it. He also advised new technologies should be introduced". Participant 5 mentioned that "the MAS technology has not been effective enough because not all drugs have the feature and consumers need to be educated more on the anti-counterfeit technology. Participant 7 stated, "that the effective use of anti-counterfeit technologies will help reduce the spread of counterfeit drugs".*

#### **Response to reviewing the penalties for counterfeiters**

All participants agreed that the penalty for counterfeiters should be reviewed, not just reviewed but strongly implemented when reviewed. Two participants likened it to murder and recommended all culprits should be given a death sentence and one participant recommended life in imprisonment. Other participants strongly recommended a review is overdue.

#### **Recommendations and suggestions**

Participant 1: *"As a country, we should strengthen our supply chain system to reduce the event of stock-outs which gives room for these fraudsters. But what we need is for more companies in Nigeria to invest in security features for their original drugs with subsidies from the government. These companies should properly advertise and educate the populace on the presence of these security features so that they are more armed with information that can help them identify the fakes when they make their purchases. When I worked for GSK as a Medical Representative marketing Augmentin, we were trained on how to let our customers know about the security features on the drug. At Onitsha head bridge, they had 4 different grades of the same Augmentin we were marketing, all fake. We had to do a lot of work to expose their shady practices and make sure that our customers could tell the difference. It's a lot of work but someone has to do it and it falls on the Nigerian government through its regulatory bodies and the companies who own the products to fight this nuisance".*

Participant 2: *“There should be a central distribution point for all drugs and all open markets should be shut down. The central distribution should be monitored and controlled by professionals, by pharmacists who understand the pharmaceutical distribution network, this is one-way the distribution of counterfeit drugs can be reduced in the system”.*

Participant 3: *“The Pharmaceutical Council of Nigeria should ensure only registered pharmacists are allowed to sell drugs and handle all drug-related matters because unfortunately, corruption has affected the system whereby lame-men, men who are out to make money are allowed to be part of the system”.*

Participant 4: *“All necessary regulatory bodies should do more, and all health professionals should be involved in the fight against counterfeit drugs. Furthermore, the government should ensure the movement of drugs are followed properly and consumers should be careful where they purchase drugs from and also confirm the authenticity of the product before using it”.*

Participant 5: *“More drugs should carry the MAS features, the government should strengthen our regulatory bodies, pharmacists should support pharmacists, consumers should be properly educated on the importance of purchasing drugs from proper pharmacies and if possible corruption should be removed from the system”*

Participant 6: *“Laws guiding the border should be implemented effectively and the Importation and exportation of drugs should be properly monitored. All companies exporting drugs into Nigeria should be thoroughly cross-checked and all duly registered with NAFDAC”.*

Participant 7: *“Drugs should not be purchased from open markets, because drugs bought from the right source reduces the spread of counterfeit drugs”.*

## INTERVIEW FINDINGS FROM DISTRIBUTORS

All distributors who participated in the interview process have been in the business for more than 5 years. 4 participants responded via phone interview while two responded via text.

### **The procedure of becoming a pharmaceutical distributor**

According to all participants, you have to get a license and be registered with the pharmaceutical council Of Nigeria (PCN) before you can start anything, after getting your license then you procure your pharmaceutical premise and ensure the required distance between each premises is adhered to as per FMOH standard. There must be a pharmacist on ground just in case anything goes wrong. Then the ministry of health officials will come and inspect to ensure everything is done according to the stated requirement. This inspection is carried out three times before you are finally approved to distribute drugs. Participant 1 also added that the procedure of becoming a distributor has been evolving since she became a distributor in 2000, and every year your premise council license is taken for revalidation. Participant 3 added you will need to secure another license if you intend to be importing drugs into the country.

#### **Response to describing the pharmaceutical supply chain**

Participant 1: *“the pharmaceutical supply chain is evolving, it keeps evolving”*

Participant 2: *“at this point, I will say the pharmaceutical supply chain is perfect because everyone in the system is advancing, but sometimes we face logistics problems which cause a delay in supply of goods”*

Participant 3: *“it’s relatively fair, with the coming of marketing companies (also known as national distributors) such as Worldwide Commercial Ventures (WWCV) and “ Assene-Laborex”, these companies have introduced a different distribution pattern by act as an intermediary between the manufacturing companies and the distributors”.*

Participant 4: *“there is not much control over the pharmaceutical supply chain because a lot of unskilled and untrained people have been allowed into the system which has tampered with the integrity of the system. Ones you have the money the regulatory body in charge gives you license to start, and most of these people do not care about the health of the patients, they are more concerned about the profit they will make”.*

Participant 5: *“It is more specialized than consumer goods or commodity chains, thus requires regulation and skilled handlers in health logistics and regulatory and quality management. From the distribution angle, up till recently lots of the major players in the sector, have either been pulled from a different skill class in pharma, totally*



*inexperienced, or unrelated skills. A problem aided by a weak regulatory structure that has left the regulatory controls to the ethical discretion of the pharmacists in production, distribution, or retail. For example, the National Drug Distribution Policy 2012 is still unimplemented to date”.*

Participant 6: *“The chain is disorganized, and the presence of the open-drug market drives the counterfeiting industry”*

**Response to the procedure of drug procurement and If the procedure should be broken down.**

In response to drug procurement, all the participants mentioned they procure their drugs from these national distributors (WWCV and Assene-Laborex ) because these companies have the right to majority of the international drugs been sold in Nigeria.

Participant 1 highlighted that for other manufactures within the country such as Emzor, Farmatech, etc. you will have to go and meet them with your license to show interest and if they do their background check, if you have clean records then you become a distributor. Participant 3 & 6 mentioned they purchase some products from open markets as well from specific distributors, Participant 4 said he imports some of his drugs, and Participant 5 mentioned he procures some of his drugs from the public health distribution system. They all responded that more people need to be part of the procurement system but at the same time it needs to be improved.

**Response to distribution log and how they manage multiple distributions**

All participants highlighted that they distribute to a lot of companies ranging from 20 and above which includes both hospitals and pharmacies. All participants highlighted that pharmacies they distribute to have a logbook with them, and most time the pharmacies are the ones who come to pick-up the product. For every delivery or pickup, each pharmacy sign in the distributor log and the staff on ground from the distributors' side signs to prove they were the ones who handled the transaction process. As for Hospitals, they go with logbooks, the storekeeper signs, and delivery officers' signs as well.

**Response to product validation before distribution.**

Participant 2 mentioned they check the expiration dates before distribution and confirm the batch numbers as well. Participant 3 mentioned they check if the seal is in order before signing the letter that comes with the delivery. Participant 1 & 4 highlighted they trust the source where they purchase drugs from, so they don't check. Participant 5 & 6 responded yes to checking the products before distribution.

### **Knowledge of pharmaceutical distribution laws and response to why laws are poorly implemented**

Participant 1: *"I told you that there's a law, say that if you want to be a national distributor you've got to have warehouses in the six geo-political zones of Nigeria. So there is a law, there is a pharmaceutical distribution bill. So, there is a law. I wouldn't say that implementation is poor, I would say that the law was made it has made it difficult for people to enter easily, because of all the infrastructure you have to put in place, if they are not implementing it we would have more than two distributors. Do you get what I'm saying, if they are not implementing it everybody would be doing it, they are implementing, they are searching, they are checking, that's why we only have two that have the financial strength, doing it. And, indeed, the open market is still operating, it indeed is an ill in our society, for how many now, I've been a pharmacist for how many years' now, since 1992 that's 28 years that has been the story, you know, complain about the open market and nobody has an answer, to how the open market would stop. I don't know maybe somebody would come and they would be wisdom for the person to stop the operation of these open markets, but right now there isn't any like that, hence the open market is still operating. We as professionals should look inward and stop blaming people for our woes, you know let us all decide if we do not want open market do not register them when they apply for registration, as simple as ABC. That's all, but the market is still on, so we can't blame anybody for that except pharmacist council".*

Participant 2: *“Well the challenge there is that it has been implemented but people tend to break them, that is why there is a lot of drug trafficking in the world, but people tend to break these rules for their selfish interest”.*

Participant 3: *“corruption and those in government are not doing their job”*

Participant 4: *“the laws are static, the regulatory body in charge has the stipulation of what should be done but the implementation is poor. This can be further attributed to the fact that 50-70 percent of people distributing drugs are not pharmacist”*

Participant 5: *Yes, “poor implementation is as a result of Low level of workforce and motivation/support for the regulators from the government. Knowledge and awareness of consumers (MAS – mobile authentication system used for example) Institutional and systemic corruption could also play a big role as the drive to make money at the expense of ethics could be overwhelming on the system. Deregulated distribution channels, e.g. Nigeria host the largest open drug markets in West Africa, or probably Africa, these have over the years rivaled the relatively organized distribution channels. They also enjoy support (indirect) from multinational pharmaceuticals who compete for profit”.*

Participant 6: *“Corruption & lack of political will on the part of the government”.*

**Response to how often out stock is experienced and the cause of our stock and how it is handled.**

All participants responded to experiencing out of stock regularly.

Participant 1: *“you always have, you will be out of stock and you’ll restock again, and you will be out of stock, as I said these national distributors they keep on changing laws. For example, you’ve placed in your order and normally they say they will collect postdated cheque from you that will clear in a month and then before the end of the month your stock finishes, you say I need stock they tell you to pay up for the last one, the check is in their hand though, but no goods till the previous cheque has been cleared”.*

Participant 2: *“when there is a high demand for a product but low supply, sometimes its due to scarcity of the product in the market which makes the price go up and because of that we tend to go for other brands that have lower prices, that are available at that*

*moment to give our customers and sometimes if it's a foreign drug that is not produced in Nigeria it could be because it has not been cleared by the customs".*

Participant 3: *"scarcity could be caused by raw material scarcity or government policy on a particular product and greed. During scarcity, we opt for alternative brands or a verified alternative supplier from another company. "During the out of stock period some counterfeiters quickly take advantage of the period, send a sample of the scarce product to countries like China and quickly dup the packing, the batch number, and other features similar to the product and bring it back into Nigeria and sell".*

Participant 4: *"we experience out of stock regularly because of delay in transportation and upsurge in a particular disease. Sometimes we look for an alternative brand, but when it's a rare drug we wait till its available, this is where counterfeiters take advantage of".*

Participant 5: *"Inaccurate demand forecast, limited production capacity, logistics factors, or related reasons. Rather the counterfeiters benefit from the lower production costs (of producing counterfeits) and have eroded the original manufacturers of the profits and incentives to expand their markets."*

Participant 6: *"it is caused by the low production capacity of pharmaceutical companies."*

**Response to the number of people involved in the pharmaceutical distribution chain.**

Participant 1: *"I don't think we are even enough. if the national distributors are many, it will allow distributors to order drugs even before the next cheque is due, but because they are only two in Nigeria, we have to follow their rules"*

Participant 2: *"Yes they are a lot of people involved in the supply chain, and it's helping the supply chain."*

Participant 3: *" the Nigerian market is large and due to corrupt government people who don't have any business been distributors are given the license to supply drugs"*

Participant 4: *"the people involved in the supply chain are not enough because the rural areas are yet to be covered, most distribution outlets are in the city".*

Participant 5 fairly agreed while participant 6 responded yes, they did not give any further explanation after this considering they responded via text.

#### **Knowledge of anti-counterfeit technology, and response to how it will help reduce the spread of counterfeit drugs**

Participant 1: *"Yes, the MAS technology and hologram. For the hologram I think anybody can create the hologram, for the mobile authentication, I think it needs a little bit more work, there was one incident about a drug that I bought from WWCV, a GSK product and then somebody scratched it and the numbers were supposed to be ten but on that paper, they were nine, so the person sent and of course they would say it is fake because the numbers are incomplete. When the customer called the number, the official responded rudely, but when I called the official responded properly and confirm the drug was genuine".*

Participant 2: *"the MAS technology and checking the batch number of products produced. These technologies have been useful in reducing the threat of counterfeit drugs and the use of sale representative has also helped reduce the infiltration of counterfeit drugs into the system"*

Participant 3: *"NAFDAC registration number. It has been effective in differentiating authentic products from fake products"*

Participant 4: *"No"*

Participant 5&6 responded yes to the knowledge of anti-counterfeit technology.

#### **Response to reviewing the penalties for counterfeiters**

All participants stated that the penalties for counterfeiters should be reviewed and not just reviewed implemented effectively.

#### **Recommendation and suggestions**

Participant 1: *"right now as it is, I would say they should leave it as it is now, although as I said we are evolving when people get tired, more people will find a way to raise money and there would have many more national distributors, and then I think it should be easier I guess at least there won't be monopoly".*

Participant 2: *"I believe the pharmaceutical supply chain can be improved through the use of maybe internet services, you can order online, rather than writing paper snapping and sending, or there should be an app or software whereby you just click and it makes it easier for you to order".*

Participant 3: *"the presence of national distributors have improved the drug distribution system in Nigeria. I will encourage that more national distributors should come in because they act as a mediator between the manufacturing companies and the distributors. Patent stores should only sell what they are approved to sell. Furthermore, the routes in which drugs come into Nigeria should be checked. NAFDAC officials should be placed at all borders to inspect pharmaceutical products coming into the country".*

Participant 4: *"the distribution of drugs should be left strictly to professionals, those who are interested in the wellbeing of patients and not those who out to make profit. Constant monitoring should be done within the industry and a regulatory body to specifically monitor drug crimes should be inaugurated under NAFDAC".*

Participant 5: *"If the distribution is better strengthened and structured, the open market systems can be easily phased out. Employ new technologies, e.g. blockchain has a promising prospect in helping to track end to end distribution of medicines. IOTs (internet of things) such as real-time tracking systems as well can improve chain visibility".*

Participant 6: *"Registered Pharmacists & pharmacies, should be fully & wholly involved & made to manage all drug distribution channels to aid tracking of drugs from the production level to consumption and all open drug markets must be closed down forthwith".*