The impacts of Drug Importation Regulation on Local Pharmaceutical manufacturers in Lagos Nigeria.

Research dissertation presented in partial fulfilment of the requirements for

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August 2020

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I certify that the dissertation entitled:

"The impacts of drug importation regulations on the local pharmaceutical manufacturing in Lagos Nigeria" submitted for MSc in Pharmaceutical Business and Technology is the outcome of my own research work result and that where reference is made to work of others, due acknowledgment is given.

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Dedication

This research work is dedicated to the local pharmaceutical manufacturers in Nigeria for their tremendous contributions in the Nigeria health care system irrespective of the harsh business environment.

TABLE OF CONTENT

List of Tables

List of Figures

Figure 21a: Prosecution of corrupt regulatory officials in Nigeria pharmaceutical industry

Figure 21b: Patronizing made in Nigeria Drugs

Figure 21c: Establishment of CROs by the Government

Figure 21d: Investment in R&D by the Government

Figure 21e: Provision of soft loan facilities by the Government.

Figure 21f: Provision of tax incentives and subsidies for locally produced drugs.

Figure 21g: Review of importation tariff for APIs and finished products

Figure 21h: Review of the entire drug regulations.

List of Abbreviations

FMOH: Federal Ministry of Health

LGA: Local Government Area

WHO: World Health Organisation

NGN: Nigerian Naira

Y.O.Y: Year-Over-Year

NAFDAC: National Agency for Food and Drug Administration and Control

PCN: Pharmaceutical Council of Nigeria

PMGMAN: Pharmaceutical Manufacturing Group Manufacturing Association of Nigeria

UNIDO: United Nations Industry Development Organization

ECOWAS: Economic Community of West African States

APIs: Active Pharmaceutical Ingredients

NRAs: National Regulatory Authorities

WHO/PQT: World Health Organization Prequalification Team

CAPA: Corrective and Preventive Actions

ERP: Expert Review Panel

GDP: Gross Domestic Products

SON: Standard Organization of Nigeria

NDLEA: National Drug Law Enforcement Agency

CPC: Consumer Protection Council

RUD: Rational Use of Drug

NCE: New Chemical Entities

MDDC: Mega Drug Distribution Centre

SDDC: State Drug Distribution Centre

WHO: World Health Organization

NMRA: National Medical Regulatory Authority

QAACT: Quality Assured ACT

SSA: Sub Saharan Africa

FGN: Federal Government of Nigeria

CROs: Clinical Research Organization

CMOs: Contract Manufacturing Organizations

R&D: Research and Development

ARVs: Antiretroviral HIV Drugs

ACT: Artemisinin Based Combination Therapy

UN: United Nation

Abstract

The thesis aims at evaluating the impacts of drug Importation regulation on local pharmaceutical manufacturers in Lagos Nigeria by carrying out a questionnaire-based surrey and zoom interviews for quantitative and qualitative analysis respectively. In achieving the objectives of the study, the knowledge, awareness, and drawbacks faced by the local pharmaceutical industry were appropriately considered in order to derive at effective recommendations to improve local drug manufacturing in Lagos Nigeria.

Both groups (local drug manufacturers/importers) in the pharmaceutical industry were compared to derive at their perspective on the impacts of drug importation regulations on their business. A total of 77 out of the 117 participated actively in the survey, of whom they combine pharmaceutical importation and local pharmaceutical manufacturing. Interesting, 83% of the participants admitted that the importation regulations in Nigeria are outdated and ineffective/inconsistent and have impacted negatively to the growth of the industry. However, an overwhelmingly majority of the local drug manufactures/importers also attributed the frequent taxation from state and non-state regulators as a major draw backs to local drug manufacturing that have yielded to the 25% capacity production of the Nigeria local drug manufacturing.

Furthermore, most of the respondent admitted that the lack of basic infrastructures like power, road networks, water etc. from the Nigeria government have drastically discouraged local drug manufacturing and encouraging drug importation chiefly from India. On the contrary, majority of local manufacturers/importers agreed that the foreign CMOs have widen the scope of pharmaceuticals available in Nigeria and encouraged the circulation of fake and substandard drugs and affected the growth of the local manufacturing negatively.

In conclusion, the local manufacturers recommended that the growth of the depends majorly on the contributions of the government in providing soft loans, shutting down the open drug market in Nigeria, implementation of the drug regulations, setting up a vision for the industry, provision of tax breaks, investment in R&D, reviewing of the importation regulations to encourage local drug manufacturers, and lastly government should patronize made in Nigeria drug products.

CHAPTER 1: INTRODUCTION

1.1 Overview

The Nigeria Pharmaceutical Industry

Before the existence of drug manufacturing in the 1960s, the pharmaceutical industry in Nigeria were predominantly based on importation of large scale of pharmaceutical products. The early stage of drug manufacturing in Nigeria began in 1944 with May and Baker Nigeria PLC. Currently, there are more than 115 registered pharmaceutical manufacturers in Nigeria providing high quality medicinal products to Nigerians and West Africa. They have equally contributed positively to the growth of Nigeria economy. The pharmaceutical companies in Nigeria are in the business of manufacturing pharmaceutical dosage forms like analgesics, antimalarial, antibiotics, anti-retroviral, antacids, haematinics, vitamins and minerals, cough and cold remedies, anti-diarrheal, antihistamines anti-ulcer, antihypertensive, anti-diabetics etc. The above products can be found in registered hospitals, pharmacies, and distribution outlets in Nigeria. (Pharmapproach, 2019). Akiny 2013, in his research work on Counterfeit Drugs in Nigeria Reports that despite the numerous numbers of pharmaceutical companies present in Nigeria, only about 60 of them are in active manufacturing of pharmaceutical products in Nigeria.

Ogaji and Alawode 2014, reported that the manufacture of pharmaceutical products in Nigeria are carried out by both indigenous and multinational companies. These companies are predominantly located in Lagos Nigeria, the commercial centre of the country and the contiguous states. Most of the pharmaceutical companies are into the production of liquid pharmaceutical products because it is cheap to set up because of the few unit operations associated with liquid pharmaceutical manufacturing.

According to the pharmaceutical manufacturing group of manufacturers association of Nigeria (PMGMAN) and United Nations Industrial Development Organization (UNIDO), the local pharmaceutical manufacturing industry in Nigeria has the capacity to meet 25% of the local demand while the remaining 75% are derived from importation of drugs from China and India. (Ikon and Chukwu, 2017). Almost all the local drug manufacturers in Nigeria buy API from other manufacturers outside the country and then formulates into drugs and there is no research and development program in Nigeria. (Akande-Sholabi, 2020).

In the same vein, the Nigeria pharmaceutical industry contributes to the overall health of citizens living in Nigeria. It is a sector of the economy that is complex because of the presence of many stakeholders like the manufacturers, national regulators, wholesalers and retailers, Government ministries and other relevant stakeholders.(Obukohwo *et al.*, 2019). The (PMG-MAN) reported that the Nigerian pharmaceutical sector has the capacity to be the number one producer and distributor of pharmaceutical products within the sub-Saharan African countries with the aid of nine Nigerian pharmaceutical companies who exports their products to the ECOWAS countries. The nine Pharmaceutical companies includes Drugfield Pharmaceuticals Ltd, Emzor Pharmaceutical Industries Ltd, Evans Medical Plc, Fidson Healthcare Plc, GlaxoSmithKline Nigeria, May & Baker Nigeria Plc, Mopson Pharmaceutical Industries Ltd, Neimeth International Pharmaceuticals, PZ Cussons Plc. (Obukohwo *et al.*, 2019).

As the global pharmaceutical industry has contributed greatly to the global economy with estimated market share of about $857 Billion, the Nigerian pharmaceutical market worth only about $1.3Billion which is less than 0.25% of the national gross domestic products (GDP). Also, the sale of pharmaceutical product in Nigeria is very low (0.2Billion against the US market of 381B according to Prince Water House). This is as a result of forex exchange that brought down the buying capacity of the pharmaceutical industry in equipment, APIs and excipients. (Adeyeye 2018)

Nigeria is also among the countries that has experienced corruption in their pharmaceutical system and is equally struggling to reduce the production and trafficking of substandard drugs. In 2001 the Nigeria drug regulator NAFDAC experienced organizational restructuring and proper regulation towards the reduction of counterfeit drugs in the industry which still requires further improvement (Garuba *et al.*, 2009). In line with the research work conducted by (Garuba *et al.*, 2009) counterfeit drugs in Nigeria cut across unregistered pharmaceutical products with NAFDAC, drugs without APIs, re-labelled expired drugs and drugs sold with incomplete manufacturers information. In 2001 about 68% of the drugs sold in Nigeria were not registered with NAFDAC and in 2004 about 40-50% of counterfeit drugs were available in Nigeria Pharmaceutical market.

	Products	Installed capacity/year
1	**Analgesics**	
	Tablets	40 billion
	Syrup/suspension	70 million litres
	Ointments/Balms	700 million tubes
2	**Antimalarials**	
	Tablets	8 billion
	Capsules	5 billion
	Syrups	50 million litres
3	**Antibiotics**	
	Tablets	20 billion
	Capsules	20 billion
	Syrups	40 million litres
4	**Antiretrovirals**	
	Tablets	20 billion
	Syrups	30 million litres
5	**Vitamins**	
	Tablets	50 billion
	Capsules	40 billion
	Syrups	80 million litres
6	**Antitussive syrups**	45 million litres
7	**Infusions**	500 million litres
8	**Antacids**	
	Tablets	30 billion
	Syrups	50 million litres
9	**Antiseptics / Disinfectants**	60 million litres
10	**Injectables**	400 million vials

Table 1: The Production Capacity of Local Drug Manufacturers in Nigeria (UNIDO, 2011)

Between 2001 and 2005, thirty (30) Indian and Chinese pharmaceutical companies and one Pakistan drug manufacturing company was noted to be producing counterfeit drugs and were banned from exporting their drug products to Nigeria. Also in 2001, under the leadership of Dr Dora Akunyili as the director general of NAFDAC, she made significant restructuring and reforms that included the orientation and training of NAFDAC staff, establishment of more NAFDAC state offices, optimization of drug analysis laboratories, strict enforcement of drug regulations, public seizure and destruction of fake drugs and public awareness programs. The sole objective was to re-establish NAFDAC mandate to "Safeguard the health of the Nation". The above positive development minimized the circulation of fake and counterfeit drugs by more than 80% from its initial stage in 2001. Also, the number of unregistered drugs by NAFDAC for sales was reduced from 68% to 19% and it enabled the increase in the local production of drugs in Nigeria. Before the reforms in 2001 the effect of counterfeit drugs had led to detrimental impact on the society. In 1990, 109 children died from

taking paracetamol syrup manufactured with toxic ethylene glycol instead of propylene glycol, this was a tragedy that took place more than 50years after its occurrence in the United States. (Garuba *et al.*, 2009)

Foreign CMO on Drug Quality in Nigeria

The CMO from China and India supplies mostly anti-malaria, anti-biotic and vitamins. Among all these categories of drugs produced by the CMO in China and India, anti-malaria has the lowest standard APIs. In the same vein, the activities of fake CMO has brought embarrassment and removed the confidence bestowed on the healthcare system and providers. (Akunyili 2005). Akulayi *et al* stated that Nigeria is among the country with the highest malaria burden in the world. This places the populace at risk of substandard malaria drugs from China and India. Hajjou *et al.,* 2015, reported that 86.4% of drug from Asian countries are counterfeit with the inclusion of India and China according to his research work on the quality of medicines from Africa, Asia and South Africa.

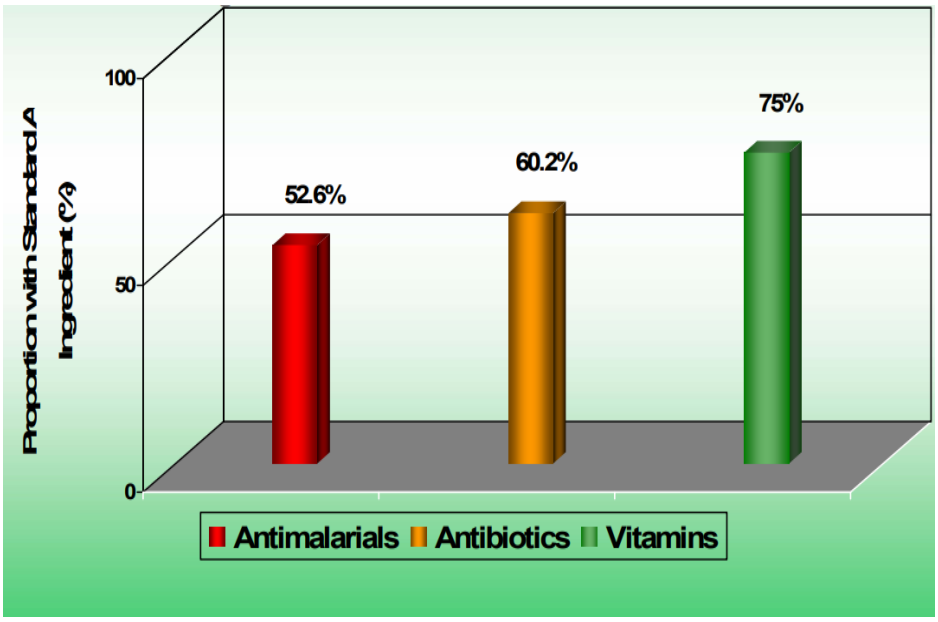

Figure 1: Percentage of drugs with standard active ingredients. (Akunyili 2005)

Furthermore, China and India supply affordable medicines to developing countries like Nigeria. The imports of antibiotics and unspecified medicaments from India and China is cheap when compared with high-income trading countries. This is because Indian and Chinese companies lower the price of their medicines in order to compete with the high-income trading countries. (Hafner and Popp, 2011)

Pharmaceutical Regulations

Effective regulation of medicinal products requires a comprehensive legal backup accompanied with adequate governance system, strong technical knowledge, scientific manpower, reliable funding, pioneering of regulatory activities and its performance monitoring to checkmate its implementation. (Ndomondo-Sigonda *et al.*, 2017).

The regulation of the pharmaceutical industry in Nigeria is handled by two agencies that are both under the control of the Federal Ministry of Health (FMoH). (UNIDO 2011). The two agencies are equivalent to the National Medicines Regulatory Authority (NMRA) by its goal of protecting and promoting the health of its citizens. (Ekeigwe, 2019). The National Agency for Food and Drug Administration and Control (NAFDAC) came into limelight by Decree 15 of 1993 which replaced the Department of Food and Drug Administration and Control (NAFDAC) in the Federal Ministry of Health.

NAFDAC regulates and controls the Pharmaceutical industry in Nigeria. In the same vein NAFDAC regulates all drug products and substances, chemicals, bottled water and packaged food with the inspection of manufacturing premises for the compliance of GMP. NAFDAC role is to protect public health via the promotion of wholesomeness, quality, safety and efficacy of processed food, medicines, medical devices, chemicals, and packaged water with the inclusion of public enlightenment, enforcement activities. NAFDAC role also cut across the creation of regulations and standard specifications for the stake holders involved in regulated products. (UNIDO 2011)

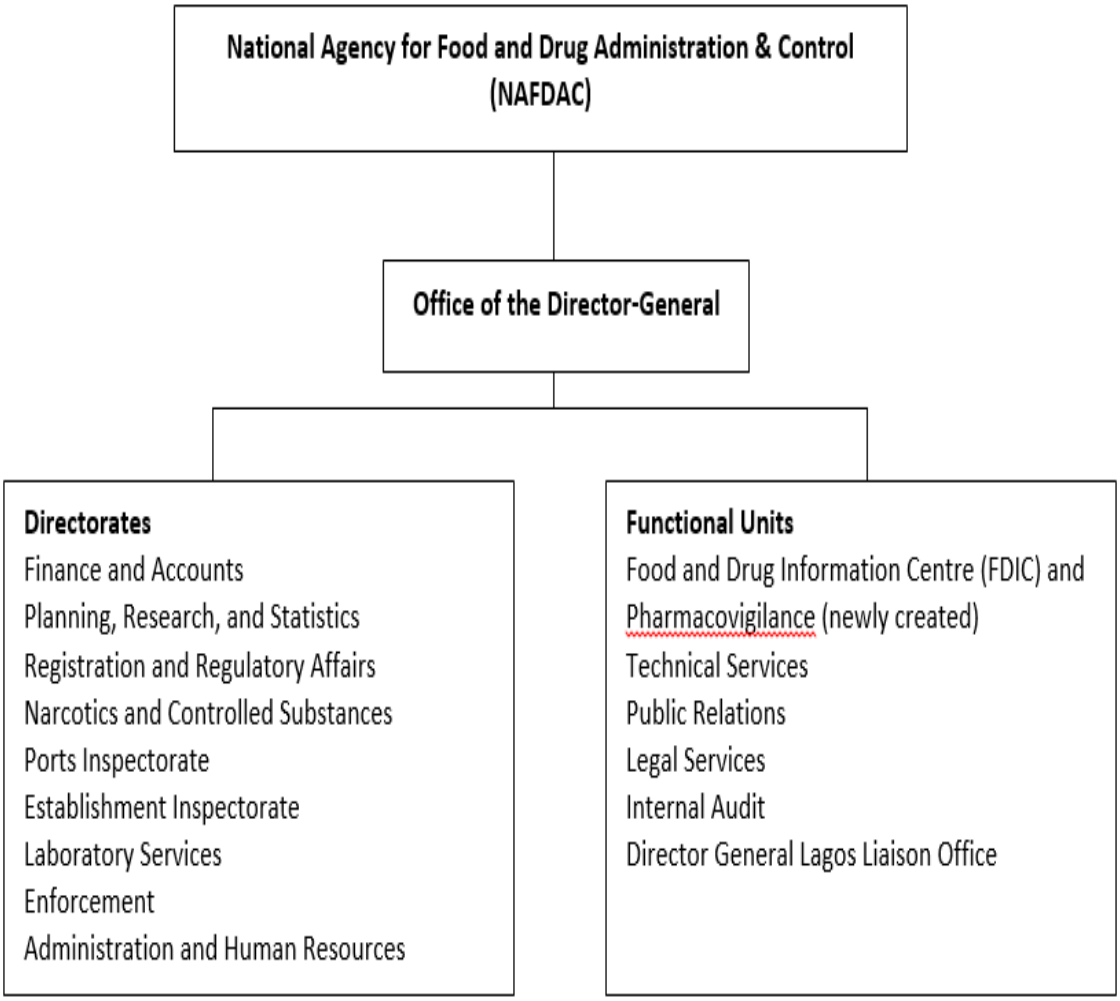

Figure 2: Organogram of NAFDAC (Garuba *et al.*, 2009)

The regulation of the practice of pharmacy and training of pharmacist with the inclusion of the development of basic pharmacy curricula for degree programmes and compulsory continuing education programmes are handled by the Pharmacist Council of Nigeria (PCN). The mandate of the PCN also include, the regulation of all pharmaceutical premises like manufacturing facilities, retail outlets and pharmaceutical warehouses. The PCN regulates the premises to ensure the adherence of GMP and equally approves premises for pharmaceutical production. (UNIDO 2011)

Regulatory Body	**Mandate**
Corporate Affairs Commission (CAC)	Company registration
Federal Ministry of Commerce	Brand name registration and trademark approval
Nigerian Export Promotion Council (NEPC)	Export of regulated products
National Health Insurance Scheme (NHIS)	Registration and regulation of Health Maintenance Organizations (HMOs)
Pharmacists' Council of Nigeria (PCN)	Inspection and registration of pharmaceutical retail, wholesale and manufacturing premises Registration of pharmacists Regulation of the practice of pharmacy Inspection of manufacturing premises
National Agency for Food and Drug Administration and Control (NAFDAC)	Evaluation and registration of pharmaceutical products Post-market surveillance and risk analysis of registered products Control of product import and export Regulation of product promotion and public education
National Office for Technology Acquisition and Protection (NOTAP)	Regulation of technology acquisition and protection, including Intellectual Property Rights (IPR) issues, patents, benefit sharing, etc.

Table 2: List of Nigeria regulatory agencies important to the pharmaceutical industry with their mandates

Importance and Needs for Adequate Importation Regulations of Drugs in Nigeria.

Adequate and effective importation regulations of drugs in Nigeria prevents the misuse and abuse of drugs and prevent the influx of counterfeits and substandard drugs in Nigeria. The achievement of adequate and effective importation regulation in Nigeria requires the strengthening of the laws and development of the enforcement capacity of the two major regulatory bodies (NAFDAC & PCN). Secondly optimum cooperation from other law enforcement agencies like the Nigerian customs and police are essential for effective and adequate implementation of the importation regulation. (Muanya, 2019)

According to the World Health Organization, effective regulation promotes and protects public health by ensuring that:

1. Medicinal products have the standard quality, safety, and efficacy
2. Medicinal products are manufactured with the cGMP, stored, distributed, dispensed according to the stipulated standard.
3. Unauthorized manufacturing and sale of medicinal products are detected and penalized
4. Health workers and consumers have the adequate information for rational use of medicines.
5. Medicinal Promotion and advertisement are fair, balanced for the purpose of rational use of drugs.
6. Access to medicinal products are not limited by unjustified regulatory work.
   (WHO: Medicines Regulatory Support)

1.2 Research Purpose

The author will study the positive and negative impact of the existing drug importation regulation on local pharmaceutical manufacturers in Lagos Nigeria and the key challenges facing the industry. The study will equally evaluate whether the drug regulation have contributed to the growth of the importation of drugs in Nigeria and thereby affecting the growth of the local manufacturers negatively. To round up the research, the author will study the negative and positive influence of the foreign contract manufacturing organization on local drug manufacturing and quality of drugs in Nigeria.

Recommendation will equally be given for the growth of the local pharmaceutical industry in Nigeria.

1.3 Significance of Study

Nigeria dependency on China and India for drugs is indeed a problem for the Nation. This research work will fill the major gaps in current literature towards the negative impact of drug importation regulation on the local pharmaceutical manufacturing, to be able to eliminate the 75% dependency of imported drugs by Nigerians. In the same vein, the research work will identify whether the

existing drug regulations has contributed negatively to the growth of the local pharmaceutical manufacturing in Nigeria and thereby promoting the growth of the importation of drugs in Nigeria.

Furthermore, the research work will be able to find out the impacts of foreign CMO from China and India on drug quality. To be able to save the county from the effects of fake and substandard medicinal products that have brought embarrassment and removed the confidence bestowed on the healthcare system and providers in Nigeria. Finally, recommendations based on the current challenges of the local pharmaceutical manufacturing will be available at the end of this research work.

1.4 Research Objectives

The study objectives are follows:

- To identify the key regulations on drug importation and its impact on Local Manufacturing in Nigeria
- Identify the impact (positive and/or negative) of foreign contract manufacturing on local drug manufacturing *quality
- Identify the key challenges faced by local drug manufacturers in Nigeria
- Provide recommendations to improve the local drug manufacturing in Nigeria.

1.5 Research Questions

1. Are drug importers aware of the key regulations on drug importation in Nigeria and understand the need for its implementation?
2. Are the current regulations on drug importation in Nigeria responsible for the 25% production capacity of the local manufacturers which have made the remaining 75% of the drugs used Nigeria to come from China and India?
3. Are the foreign contract manufacturing activities in India and China producing quality, efficacious and safety drugs for Nigerians?
4. Do the locally manufactured drugs in Nigeria meet the WHO/global standards for quality, efficacy, and safety?

1.6 Conclusion

In summary, it is significant to point out that in the past years, the number of pharmaceutical companies in Nigeria has increased and it has not reflected in the increase in local production of quantity and quality drugs. This is an indication that Nigeria needs a conscious and effective pathway to change or totally minimize Nigeria status as a huge consumer of imported drugs to a producer and exporter of medicines within the sub-Saharan Africa and beyond. Government organization like NAFDAC and PCN are working towards restructuring and providing the enabling environment with regulations and policies required for the growth of the local manufacturing companies to be able to minimize the 75% dependency on china and India for drugs. In the same vein proper understanding of the key challenges facing the local pharmaceutical industry and restructuring of drug importation regulations in Nigeria will help to solve the over dependency on foreign drugs.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

"In a lower-middle-income country such as Nigeria, the lack of quality medicines remains a big issue. "While the prevalence of falsified medicines has dropped, it still remains high. This is because most falsified medicines are imported,"

-Mazi Sam Ohuabunwa, president, Pharmaceutical Society of Nigeria (PCN)

Nigeria is a country in West Africa referred to as the giant of Africa due to its massive population that ranks seventh in the world. (Muhammad, 2017). According to the United Nations Population Fund (UNFPA), Nigeria population is 201 million with an average annual rate of population change of 2.6%.The country life expectancy in 2019 was 55years, Infant mortality rate of 86 per 1000 live birth while maternal mortality ratio is 814 per 100,000 live births (UNFPA). Irrespective of Nigeria large human capital and numerous natural resources, Nigeria is still been held down with poverty, disease, and malnutrition. According to WHO, Nigeria health sector ranks 187th out of 191 countries that was categorized together. The poor rating is due to the lack of standard equipment's for the production and storage of pharmaceutical products. (Obukohwo *et al.*, 2019).

Structural Features

According to the Pharmacists Council of Nigeria (PCN), Nigeria has 128 registered drug manufacturers with 1,534 retail pharmacies, 724 drug distributors and 292 importers in Nigeria in 2010. Nigeria also has 14,607 public and 9,034 private healthcare facilities. Nigeria equally has more than 10,000 unregistered patent and proprietary medicines stores that sell over the counter (OTC) products alone and majority of the medical stores are situated in the rural communities where qualified pharmacist are scarce. (UNIDO, 2011)

2.2 The Current State of Drug Importation in Nigeria

Drug Importation according to the U.S. Food and Drug Administration, is the importation of drug products (ready to use dosage form) and drugs in Bulk quantities (e.g. active pharmaceutical ingredients or API) (Commissioner, 2020). The 75% of the drugs used in Nigeria are predominantly imported from China and India with less coming from Pakistan, Egypt and Indonesia etc. (Ikon and Chukwu, 2017) and (Raufu, 2003). According to the report from the Pharmaceutical Society of Nigeria (PSN), minimum of 70% of the pharmaceutical products sold in Nigeria are fake and are been imported mostly from India, China, Pakistan, Egypt and Indonesia. (Raufu, 2003). To curb the exports of substandard finished products in Nigeria, India and China placed life imprisonment and death penalty respectively for any company that export substandard and fake drug products to Nigeria. The law was extended to APIs imported in Nigeria during the international conference in Morocco on pharmacovigilance. (UNIDO 2011)

Furthermore, Nigeria imports all active pharmaceutical ingredients (APIs) mostly from India and China. The imported APIs stays for three months or more at the seaport for its clearance from customs and NAFDAC to make sure it fulfils the stipulated standards. In the same vein, pharmaceutical grade starch is also imported mostly from China in addition with the locally produced pharmaceutical starch in Nigeria. (UNIDO 2011)

The massive dependency on importation of pharmaceutical products is as a result of lack of basic R&D for the understanding of APIs and drug excipients, limited capacity in pharmaceutical and bio-analytical techniques, poor training in cGMP and lack of API/excipients production facilities in Nigeria. The dependency on imported pharmaceuticals remain an opportunity for Nigerians to profit from the pharmaceutical business landscape. This opportunity can be maximised by

encouraging early phase clinical trial collaborations between local manufacturers and foreign CROs. The local production of API and excipients should equally be adopted for partnership between foreign and local investors. Partnerships through local pharmaceutical collaborations to develop novel drugs will improve quality of manufactured drugs. Governmental interventions such as financial aid and subsidised policies are necessary to minimize the importation of drugs in Nigeria. (Adeyeye 2018)

2.3 Nigeria Drug Distribution Pathways

A research paper published in 2015 on National drug distribution in Nigeria and its implications for the goals of national drug policy, the author stated that the manufacturers and importers play an essential role in the distribution of drugs in Nigeria. They make sure that drugs are available only to the mega distribution centres (MDDC), State Drug Distribution Centres (SDDC) and National Health Programs. The distribution channel is propelled by the MDDC which is a private sector based while the SDDC serves the public sector at the state level. The SDDC supplies to all the public health facilities in the state and is only permitted to sell to National Health programs and to wholesalers. The MDDC is also permitted to sell to wholesalers alone. The wholesalers go ahead to sell to community pharmacies, public and primary healthcare facilities, and private health institutions. The specialization provides boundaries for all the stakeholders in the value chain. The wholesalers are not allowed to retail drugs vice versa for the MDDC and SDDC. At the end of the distribution ladder is the activities of community pharmacies, public and private health institutions that sell drugs to the final users (consumers). In the same vein the community pharmacies are permitted to supply or sell to private health facilities. (Onyebuchi 2015)

Figure 3 below shows the planned model for medicines supplies in Nigeria designed by the Federal Ministry of Health FMoH, Pharmacist Council of Nigeria (PCN), NAFDAC, Pharmaceutical Manufacturing Group, Manufacturing Association of Nigeria (PMG-MAN) and WHO country office in Nigeria in alignment with National Drug Policy (NDP).

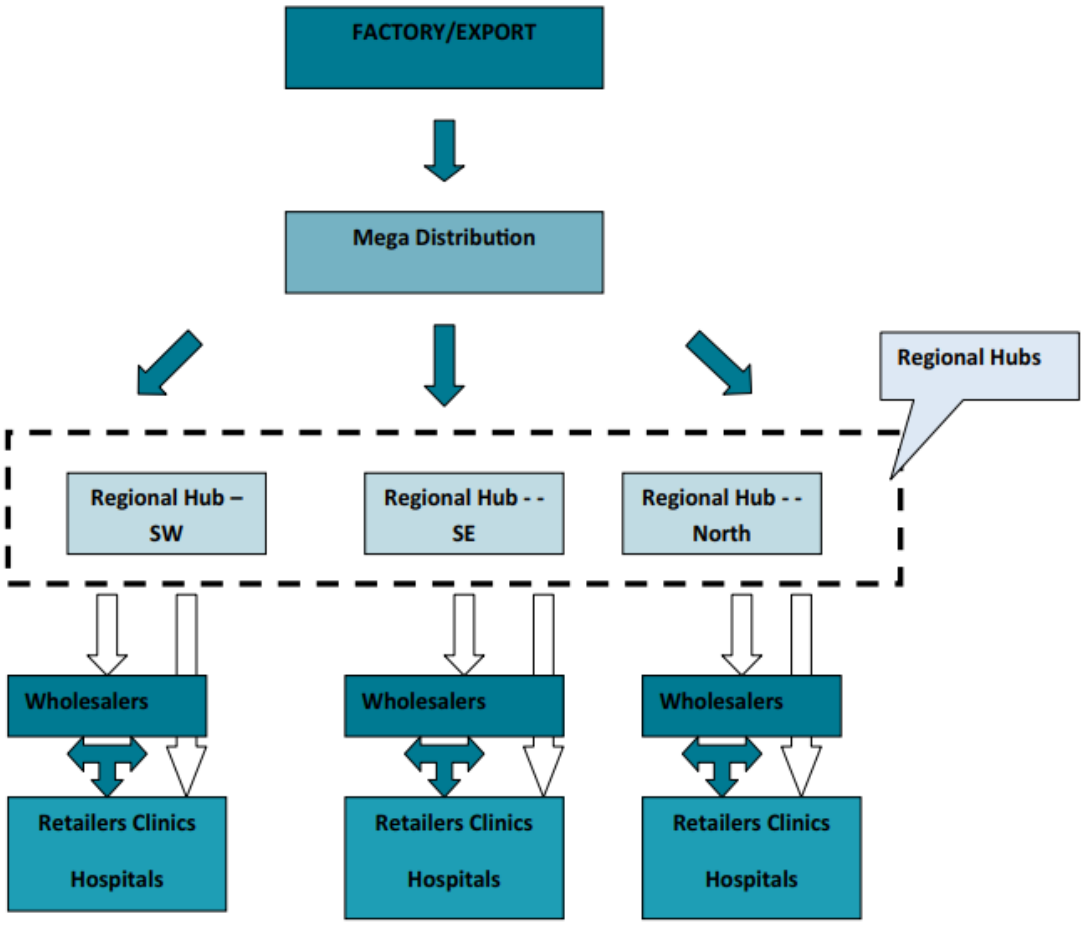

Figure 3: The planned model for medicines and medical supplies in Nigeria (UNIDO 2011)

2.4 *Nigeria Expenditures in the Importation of Drugs*

According to the United COMTRADE database on international trade, Drug importation in Nigeria reached USD 606.31 million in 2018 against the initial forecast of USD 789 million reported by business monitor international while the importation of drugs from India and China (key players) was USD 242.26 million and USD 111.61 million respectively (Trading Economics, 2020 forecast).

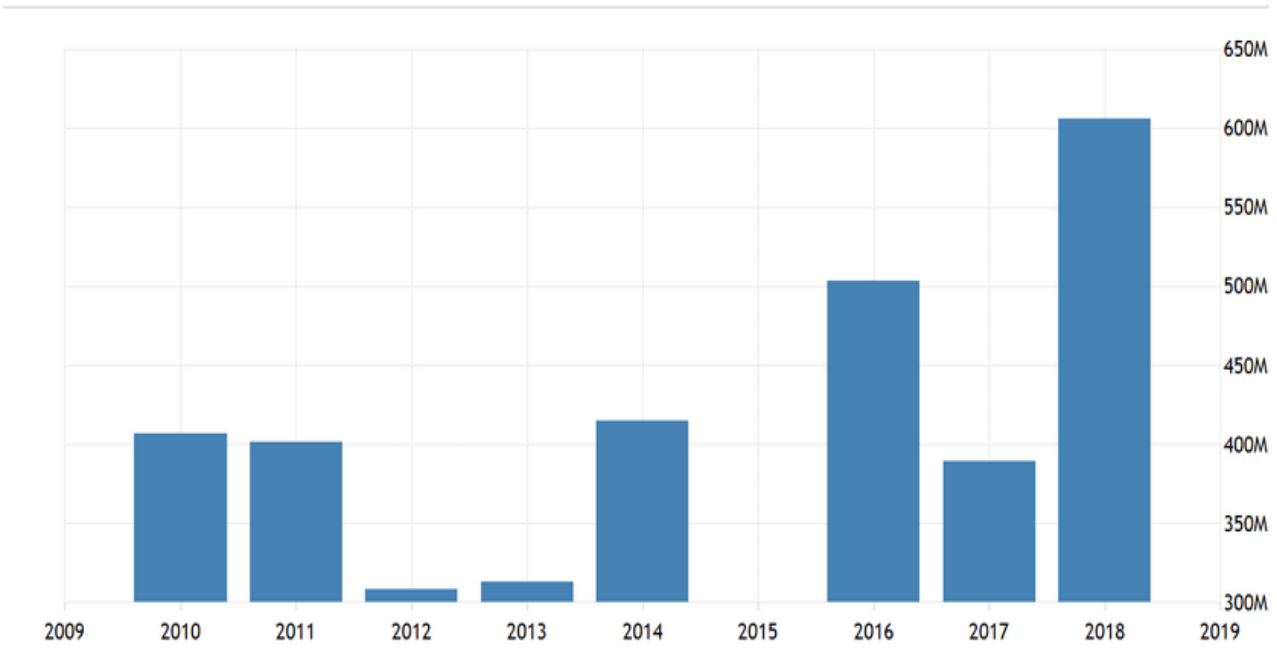

Figure 4: Drug Importation in Nigeria from 2009 to 2018. (Trading Economics, 2020 forecast)

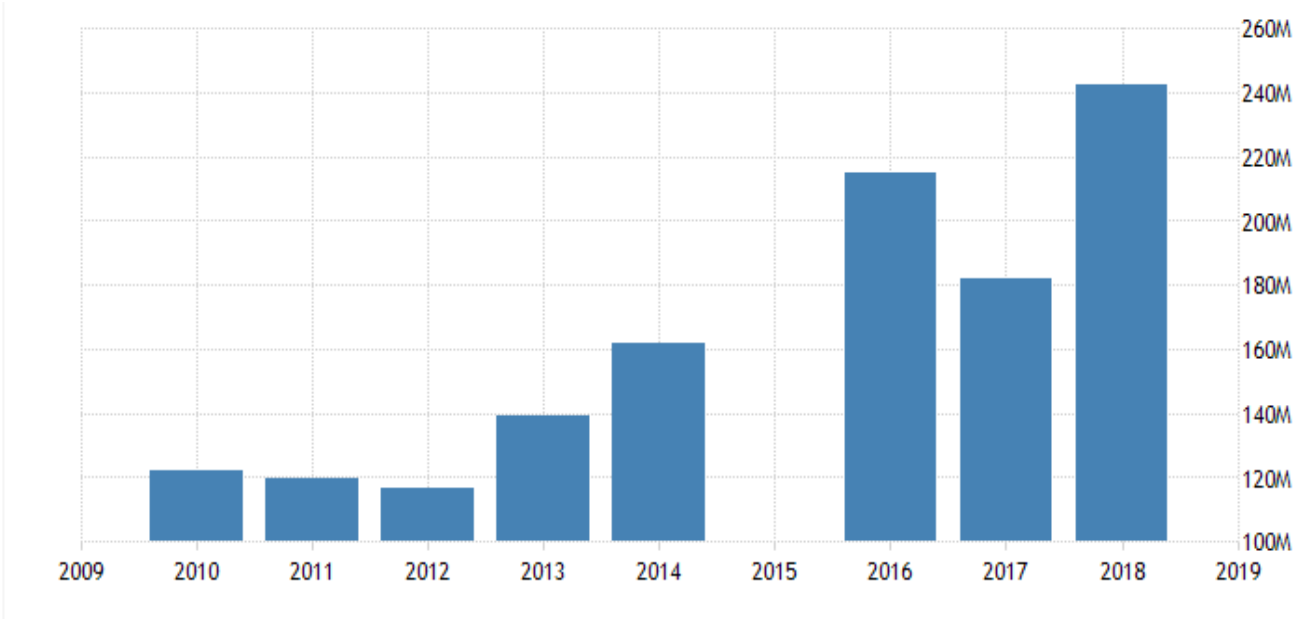

Figure 5: Nigeria Pharmaceutical Products Imports from India from 2009-2018 (Trading Economics, 2020 forecast)

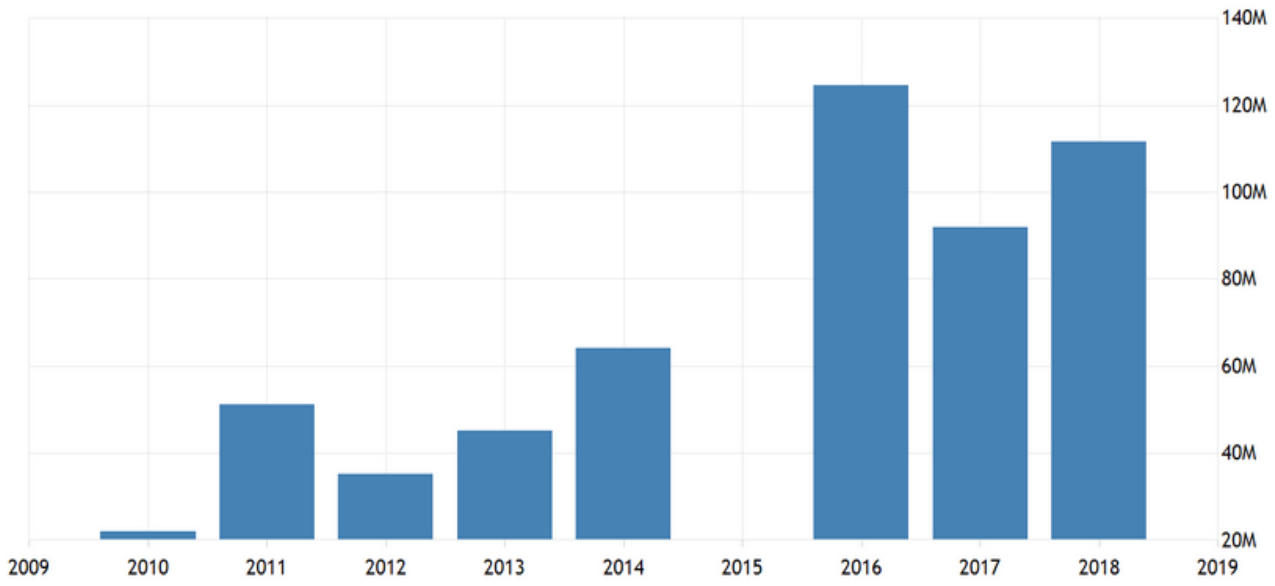

Figure 6: Nigeria Pharmaceutical Products Imports from India, 2009-2018 (Trading Economics, 2020 forecast

2.5 Importation of Prescription Medicine (POM)

According to the key note address on imperatives for National Drug Security, Prof. M.C Adeyeye, the current Director General of NAFDAC stated that Nigeria imports between 70-80% of their prescription medicines (POMS) while the remaining 20-30% are produced by the local manufacturers ranging from about 150 registered manufacturers. (Adeyeye 2018)

Year	Imported (%)	Local (%)	Total
2005	870 (78%)	247 (22%)	1117
2012	1321 (85%)	231 (15%)	1552
2017	551	89	640

Table 3: Number of Registered Imported Prescription Medicines (POMS) in Nigeria (Adeyeye 2018)

2.6 *Drug Importation Policies in Nigeria*

The importation of drugs in Nigeria can only be carried out via the approved seaports and airports by the federal government of Nigeria.

Also, the importation of drugs via all land borders is prohibited in order to end the importation of substandard and counterfeit pharmaceutical products. (UNIDO 2011)

The Federal Ministry of Health (FMoH) in agreement with PMG-MAN on April 2005 banned the importation of 18 essential medicines for the sole purpose of encouraging local production after the assessment of the capacity of the local manufacturers. Similarly, importation duties for active pharmaceutical ingredients (APIs) for antiretroviral HIV drugs and artemisinin-based combination therapy (ARVs/ACTs) was placed at 0%, other raw materials were placed at 5% and finished products were placed at 20%. The packaging materials of pharmaceutical products is available in the Nigeria local market apart from aluminium. (UNIDO 2011)

SEA PORTS	AIRPORTS
• Apapa Area 1 Sea Port, Lagos	• Murtala Mohammed International Airport, Lagos
• Calabar Sea Port, Calabar	• Mallam Aminu Kano International Airport, Kano
• Port Harcourt 1 Sea Port, Port Harcourt	• Port Harcourt International Airport, Port Harcourt
	• Nnamdi Azikiwe International Airport, Abuja

Table 4: Government Approved ports for the importation of medicines in Nigeria (UNIDO 2011)

2.7 *The Regulation of Imported Drugs in Nigeria*

By a combination of a law, regulatory agency, and technology, we can begin to have a handle on falsified medicines."

-Mazi Sam Ohuabunwa, President, Pharmaceutical Society of Nigeria (PSN)

Drugs are not classified as consumer products and the consumers do not have the power to take decisions on the type of drugs to use, when to use the drugs, how to use them and analyse the benefits and risks since no medicine is completely safe. The manufacturing of drugs, its distribution and dispensing requires specialised knowledge and professional expertise. The modern medicines

regulations began after the successful breakthroughs experienced in the 19th century in the areas of chemistry, physiology, and pharmacology. These advancements provided the enabling environment for current drug research and development and regulations applicable today. (Rägo and Santoso, 2003)

A recent article published in 2019 on "Drug manufacturing and access to medicines: The west African Story, a literature review of challenges and proposed remediation" The author stated that in fulfilling regulatory mandate and services in the pharmaceutical sector in Nigeria, "*it requires clear legal mandate, governance structure, quality management systems, human and financial resources, regulatory infrastructure and fair, vigorous enforcement activities without compromise".* (Ekeigwe, 2019)

In a publication titled the challenges faced by NAFDAC in the national regulatory process as it relates to essential drugs for prevention of maternal and new-born deaths in Nigeria, the author established that drug regulation requires public policies which has the capability to control the industry for the good of the public. Effective regulations promote the sale of safe, efficacious and high-quality products in Nigeria. It equally requires aggressive strengthening of every facet of the regulatory activities for a growing economy like Nigeria. (Akunyili 2010)

Another paper published in 2013 titled "Counterfeit drugs in Nigeria: A threat to public health", the author stated that the major roles of NAFDAC includes the regulation and control of imported pharmaceutical products. NAFDAC body achieves this by inspecting imported drugs at the different airports and seaports in Nigeria. The Registration of pharmaceutical products remains a prerequisite before any drug is permitted to be sold in the Nigeria market. Drug products must be analysed and tested to make sure that its efficacy, safety and quality is not compromised.

But currently the NAFDAC forensic laboratory that performs quality control analysis is below the capacity required to handle the volume of test required to be conducted for the analysis of imported drugs. These constraints have encouraged the importation and distribution of fake and adulterated drug products. To solve this problem Government intervention is required and also the current use of handheld spectrometers that permits the inspection and authentication of products at its point of sale has contributed massively in detecting counterfeits drug products in Nigeria. (Akiny 2013).

A study conducted from May 2007 to August 2007 on transparency of Nigeria's public pharmaceutical sector and perception from policy makers was based on the WHO assessment tool of medicines regulatory system 2007. This utilised the qualitative and quantitative details on the extent of transparency and susceptibility to corruption in four pharmaceutical sectors (registration, procurement, inspection (ports and establishment) that requires regulations. The author used standardize questionnaires that has open and closed ended indicator questions derived from the WHO assessment instrument. Also, fourteen (14) semi-structured interviews were carried out with all the stakeholders including NAFDAC and government officials.

The conclusion of the study showed that the registration, procurement, inspection (ports and establishment), inspection of establishments and distribution points of Nigeria pharmaceutical system got 5.8, 8.9, 6.4, 7.0 and 8.9 respectively out of the set standard of 10points. In view of the WHO assessment instrument used, the above scores indicated a moderate vulnerability to corruption in the inspection (ports and establishment) and minimal vulnerability to corruption in the procurement and distribution of drugs. The general rating proved that the Nigeria's pharmaceutical system is 7.4 out of 10, which depicted a marginal vulnerability to corruption. The overall rating was made weak by poor scores from the area of drug registration and inspection of drugs at the ports of entry in Nigeria. (Garuba *et al.*, 2009)

In conclusion to this research findings, the author rated the limitations predominant in the regulatory framework of the pharmaceutical sector accordingly. It is obvious that the regulatory deficiencies resulted in the high rate of corruption in the inspection (ports and establishment), which is an avenue for the importations of drugs not in the essential drug list etc. The outcome of this negligence directly affects the growth and progress of the local manufacturing in Nigeria. The research work would have contributed more to the pharmaceutical industry in Nigeria if the author delved further in exploring the impacts of the regulatory weakness predominant in drug registration, procurement, inspection (ports and establishment) and distribution towards the local pharmaceutical manufacturing industry in Nigeria. Also, the author was not able to provide recommendations on how to curb the stated limitations.

A research published in 2013, titled "Drug regulation and control in Nigeria: The challenges of counterfeit drugs". Data was collected from questionnaires and interviews to get the required information for the research work. Questionnaires and interviews were collected from the

regulatory and non-regulatory agencies. The regulatory bodies include: (a) Federal Task Forces on counterfeit and fake drugs (b) NAFDAC (c) PCN, the non-regulatory bodies also include Nigeria Association of Industrial Pharmacist and the (PMG/MAN).

At the end of the research work it was discovered that the regulation guiding the importation, manufacturing, sale, distribution and exportation of drugs in Nigeria are not adequate to monitor and control the sale of drugs in Nigeria, the Implementation and enforcement of the stipulated drug regulations are deficient, the task force set up by the government to implement the regulation of drugs are not effective in discharging their duties due to poor staff strength, financial constraints and lack of essential equipment's. (Erhun *et al.*, 2013).

The above limitations in the regulation of drugs in Nigeria can facilitate the importation of substandard drugs. In the same context, encouraging the importation of drugs that are not in the essential drug lists. This led to the compromise of the essential drugs list that was designed to encourage the growth of the local pharmaceutical industries in Nigeria. The author noted the deficiencies in the regulation of Drugs in Nigeria and provided recommendations. But the impacts of the poor implementation of the pharmaceutical regulation towards the local drug manufacturing in Nigeria was not further researched.

The research work conducted by Erhun *et al* (2013) is in accordance with a recent research work in 2019 titled "Nigeria: Weak Regulation Fuels Rise in Medical Errors, Drug Problems in Nigeria". They discovered that drug regulations and its enforcement are weak, and it is responsible for the prevalence of fake drugs, abuse, and misuse of medicinal products in Nigeria. In similar fashion, to strengthen the drug regulations it requires the improvement of the enforcement capacity of the regulators (PCN and NAFDAC) and the collaboration of the law enforcement agencies like Nigerian police and customs. (Muanya, 2019b).

The above literatures reviewed on the importation regulations in Nigeria shows that the regulations are weak, outdated and promote the prevalence of fake and substandard drugs. In the same vein, the regulatory bodies lack the capacity and structure to enforce regulations. These limitations have negatively affected the growth of the local pharmaceutical industries in Nigeria.

2.7:1The Key Regulations on Drug Importation

1. **An Act to prescribe a National Drug Formulary and Essential Drugs List and to prohibit importation into and manufacture in Nigeria of any drug not in the List. [1989 No. 43]**

a. Prohibition on importation of drugs not in the List:

The formulary gives the drug information for the already selected drugs in the essential drug list. No Importer will be allowed to import into, advertise, display for sale, sell or manufacture in Nigeria any drug that is not available in the list

b. Importation of Drugs not in the List

Notwithstanding the provision stated in section 1 of this Act, the minister can permit the importation or manufacturing of drugs that are not in the list on the basis of the following conditions.

- The drug is a cure for any uncommon disease
- A disease that needs highly specialized skill for its diagnosis and treatment
- A drug with more activity that is more than the one in the list but was omitted because of little experience with it under local conditions. After proper research and recommendation by the regulated body the importer or manufacture may be allowed to import such drug and the drug will be added to the list.

c. Offences and Penalties

- Defaulters in the Importation or manufacturing of drugs not in the essential drug list will pay a fine of ₦100,000 or imprisonment for a term that does not exceed five years.
- In a situation where the offence under this Act is committed by a body corporate, all the director or person in authority in that corporate shall be held accountable.

d. Removal of Drug from the List

Notwithstanding the provisions of section 5 of this Act, the minister has the capacity to remove any drug from the list in a situation where there is adequate conviction that the safety of the drug in view is a risk to humanity. (LawCareNigeria 2019)

The above act was reviewed last in 1989 and requires further review to avoid its negative impacts on the local pharmaceutical industry in Nigeria and the dependency on imported drugs. This act will not encourage the reduction of the 75% of drugs imported predominantly from China and India if not reviewed. The worse part of the act is the weak penalty for any importer who imports drugs that are not in the essential drug list. It is stated in the act that defaulters who are guilty of the offence and liable, on conviction, will pay a fine of ₦100,000 (One Hundred Thousand Naira) (equal to $278 by the exchange rate of one dollar to ₦360) or imprisonment for a term that does not exceed five years. The truth of the matter is that, there is no importer of drugs in Nigeria who cannot afford ₦100,000 fine with ease and also the alternative of imprisonment for a term that does not exceed five years will never be a viable option for the defaulters.

In conclusion, the essence of the essential drug list of the federal Republic of Nigeria that was approved in 1988. Got its legal backup in 1989 with few of its benefits of encouraging local pharmaceutical industrial and eradicating fake drugs in Nigeria has been defeated with weak penalties that will end up encouraging drug importers to continue to import drugs that are not in the list and also defeat the rational use of drugs.

2. **Guidelines for Registration of Imported Drug Products in Nigeria (human and veterinary drugs)**

The above guidelines reviewed on 1st of May 2018 provides the registration requirements for the manufacturing, importation, exportation, advertising, and distribution of drugs in Nigeria. It states that no drug shall be manufactured, imported, exported, advertised, distributed in Nigeria without fulfilling the provisions of NAFDAC Act CAP NI (LFN) 2004, with the inclusion of other related Legislations and attached Guidelines. (NAFDAC 2018)

The registration Guidelines if adhered will reduce the influx of substandard and fake drugs in Nigeria, because it is of international standard. The registration requirements cut across documentation requirements, with Importation permit and label vetting, submission of samples for laboratory analysis, tariff, and labelling guidelines. On successful completion of the application, the applicant gets a Certificate of Registration that remains valid for a period of five years. It is crystal clear that the registration requirements do not impact the local manufacturers of drugs negatively unless there are compromise and corruption pioneered by the officials of Registration and

Regulatory Affairs Directorate, National Agency for Food and Drug Administration and Control (NAFDAC).

Furthermore, the guideline permit drug importers in Nigeria to import drugs for a period of 10years after which they can start producing locally should be revisited and if feasible be reduced to 5years to encourage the local production of drugs in Nigeria. Also, its effective implementation should equally be monitored to ensure that the importers adhere to this stipulated guideline.

3. **An Act to provide for the prohibition of sale and distribution of counterfeit, adulterated, banned or fake, substandard or expired drug or unwholesome processed food, and of sale, etc., of drugs or poisons in certain premises or places. [1999 No. 25.]**

The section one of this act state that "any person who (a) produces, imports, manufactures, sells, distributes or is in possession of; or (b) sells or displays for the purpose of sale; or (c) aids or abets any person to produce, import, manufacture, sell, distribute or display for the purpose of sale, any counterfeit, adulterated, banned or fake, substandard or expired drug or unwholesome processed food, in any form whatsoever, commits an offence under this Act and shall, accordingly, be punished as specified in this Act". The penalty stipulated for the defaulters of section one of this act is a "fine not exceeding ₦500, 000 (equal to $1,390 by the exchange rate of one dollar to ₦360) or imprisonment for a term of not less than five years or more than fifteen years or to both such fine and imprisonment". (NAFDAC 2018)

According to an article published in 2010 titled the challenges faced by NAFDAC in the national regulatory process as it relates to essential drugs for prevention of maternal and new-born deaths in Nigeria. The author stated that NAFDAC has reviewed this act and sent it to the National Assembly in 2001 at various times as a legislating request and no feedback have been received. (Akunyili 2010).

The inability of the National Assembly to approve the reviewed act is also among the factor that is encouraging the importation of counterfeit products in Nigeria. It has negatively affected the growth of the local pharmaceutical manufacturing in Nigeria. Some Drug importers will be ready to face the weak penalties on the quest to import fake and substandard drugs in Nigeria.

2.7.2 Laws Governing the Manufacturing, Sale and Distribution of Drugs in Nigeria

The following laws regulate and control the manufacturing, sale and distribution of drugs in Nigeria.

a. Poisons and Pharmacy Act, Cap 366 of 1990

The law regulates the compounding, sales, distribution, supply and dispensing of drugs and it controls every type of drugs and poisons.

b. Food and Drug Act Cap 150 of 1990

The act prohibits the selling of some food, drugs, cosmetics and devices as treatment for some diseases. The Act prohibits the importation, exportation, distribution and sale of specified drugs. It equally prohibits practices that includes fake packaging, labelling, and advertising as well as producing food and drugs in unhealthy environment. It conveys the power to appoint inspecting officers and food and drug analysts.

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

This Act prohibits the production, importation, manufacture, sale, and distribution of any counterfeit, adulterated banned or fake drugs. It also prohibits pharmaceutical traders to sell any drug in an open market without permission from the proper authority.

d. Pharmacists Council of Nigeria, Decree 91 of 1992

This is the repetition of the Pharmacists Act of 1964. This decree established the PCN which is charged with the following responsibilities: (a) Establish the average knowledge and skill expected of persons requesting to be a registered members of the pharmacy profession, (b) Creation and maintaining of register of persons qualified to practice as members of the Pharmacy profession, (c) Prepare and review the code of conduct, and (d) Regulate and control the practice of the Pharmacy profession. The Council has an investigating panel and disciplinary committee to penalize defaulting pharmacists accordingly.

e. **NAFDAC Decrees No. 15 of 1993**

This decree establishes the National Agency for Food and Drugs Administration and Control. The agency oversees the following functions

- Regulation and controlling of importation, exportation, manufacturer, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water, and chemicals.
- Carry out appropriate tests and ensure compliance with specification established and approved by the council for the adequate control of the quality of food, drugs etc., with the inclusion of their raw materials and production with production activities in factors and other establishments.
- Carry out appropriate investigation towards the production environments and raw materials for foods, drugs etc. and equally established appropriate quality assurance systems that cut across certification of the production sites and regulated products.
- Carryout the inspection of food, drugs etc.
- Compilation of standard specifications and regulations and guidelines required for production, importation, exportation, sales and distribution of food, drugs etc.
- Handling of registration of foods, drugs etc
- Establishment and maintenance of relevant laboratory or other institutions strategic areas of Nigeria as may be required for the performance of the activities.

f. Drugs and Related Products (Registration) Decree

This decree makes the provisions for the prohibition of the manufacturing, exportation, advertisement, sale or distribution of drugs, drugs productions, cosmetics, or medical devices unless it has been registered in accordance with the provisions of the decree. It also provides the procedures for applying for registration of a drug product, conditions under which information supplied by an applicant is disclosed, and provision for the termination or suspension of certificates of registration and clinical trials. The above laws indicates that the Nigerian government has positively responded by legislation to prevent chaotic drug distribution situation in Nigeria. (Erhun *et al.*, 2013).

The above laws governing the manufacturing, sale and distribution of drugs in Nigeria requires immediate review to be able to address the emerging changes in the industry. Muanya, (2019) also stated that the existing pharmacy regulations are predominantly made of antiquity because the first pharmacy regulation was approved in 1887 and has been improved to be able to achieve regulations like the PCN Cap 17 LFN 2004 and the PPA Cap 535 LFN 1990. The above acts of negligence to review

and update the regulations has minimized the efficiency of the PCN in performing their statutory obligations. In the same vein, the author suggested that outright death sentence as prevalent in other countries for people caught with falsified drugs and illicit substance in Nigeria. This will reduce the influx of counterfeit and substandard drugs in Nigeria.

2.8 NAFDAC Administrative Guidelines to end the Importation of Counterfeit Drugs in Nigeria

1. Inspection of factories anywhere around the world prior to the registration or renewal of drugs. This is to ensure the adherence of Good Manufacturing Practice (GMP).
2. NAFDAC employments of analyst in India, China, and Egypt for the re-certification of drugs prior to its exportation to Nigeria.
3. NAFDAC request for pre-shipment information from importers prior to the shipment of their drugs to Nigeria.
4. The request for NAFDAC clearance from Nigerian banks prior to processing the required financial documents for importers of drugs. (NAFDAC 2018)

The above administrative guideline encourages the local production of drugs in Nigeria. Only few importers that has the capacity to fulfil all the requirements will be granted access to imports drugs in Nigeria.

2.9 The Challenges of Drug Regulation in Nigeria

An article published in 2010 titled the challenges faced by NAFDAC in the national regulatory process as it relates to essential drugs for prevention of maternal and new-born deaths in Nigeria. The author, a former director (NAFDAC) from 2001-2008, stated the factors that limit effective drug regulation in Nigeria includes corruption involving drug counterfeiters offering bribes to the regulatory officials to allow them compromise the stipulated regulatory benchmarks, weak or little regulation for drugs meant for export to the extent that NAFDAC banned about 30 Indian and Chinese company with 1 Pakistan company from 2001 to 2010 to stop exporting fake drugs to Nigeria. Advancement in Copying Technology such that brand owners find it difficult to recognize their brands and counterfeits, false declaration by importers on the content of goods in their containers, inadequate and weak regulation predominant in the Nigerian pharmaceutical industry such as 3 months to 5 years or fine of ₦10,000 imprisonment for importing fake drugs in Nigeria, lack of awareness on the issue concerning fake drugs, chaotic medicinal distribution system, lack of

team coordination among government regulatory bodies, ineffective record keeping of health related activities and lastly the Irrational use of drugs in Nigeria. (Akunyili 2010)

2.9.1 The *Impacts of Drug Regulations on Local Pharmaceutical Manufacturing.*

According to a research article on Capacity Utilization in Pharmaceutical Industry in Nigeria, there are series of available literature towards the impacts of the different Government regulation and policies towards the manufacturing sector but there is none specifically referring to the pharmaceutical manufacturing sector is available at the moment. The research reveals that few of the local pharmaceutical industry believes in the capabilities of the intervention fund coming from the Federal government in form of NAFDAC Central Bank of Nigeria (NAFDAC-CBN) fund to change the situation for better. It was generally accepted that the importation prohibition towards few of the essential drug impact positively on the pharmaceutical industry. In the same vein the President's Emergency Plans for AIDS Relief (PEPFAR) funds and the current World Health Certification drive championed by few of the local pharmaceutical companies in Nigeria remains an interesting areas that can significantly change the capacity utilization of the local pharmaceutical industry in Nigeria. (Ikoni Ogaji and Alawode, 2014)

2.10 The Impact of CMOs from China and India on Pharmaceutical Quality in Nigeria.

> *"Where domestic capacity is lacking, local production will inevitably increase the supply of substandard drugs in the market"*. *--Bate*

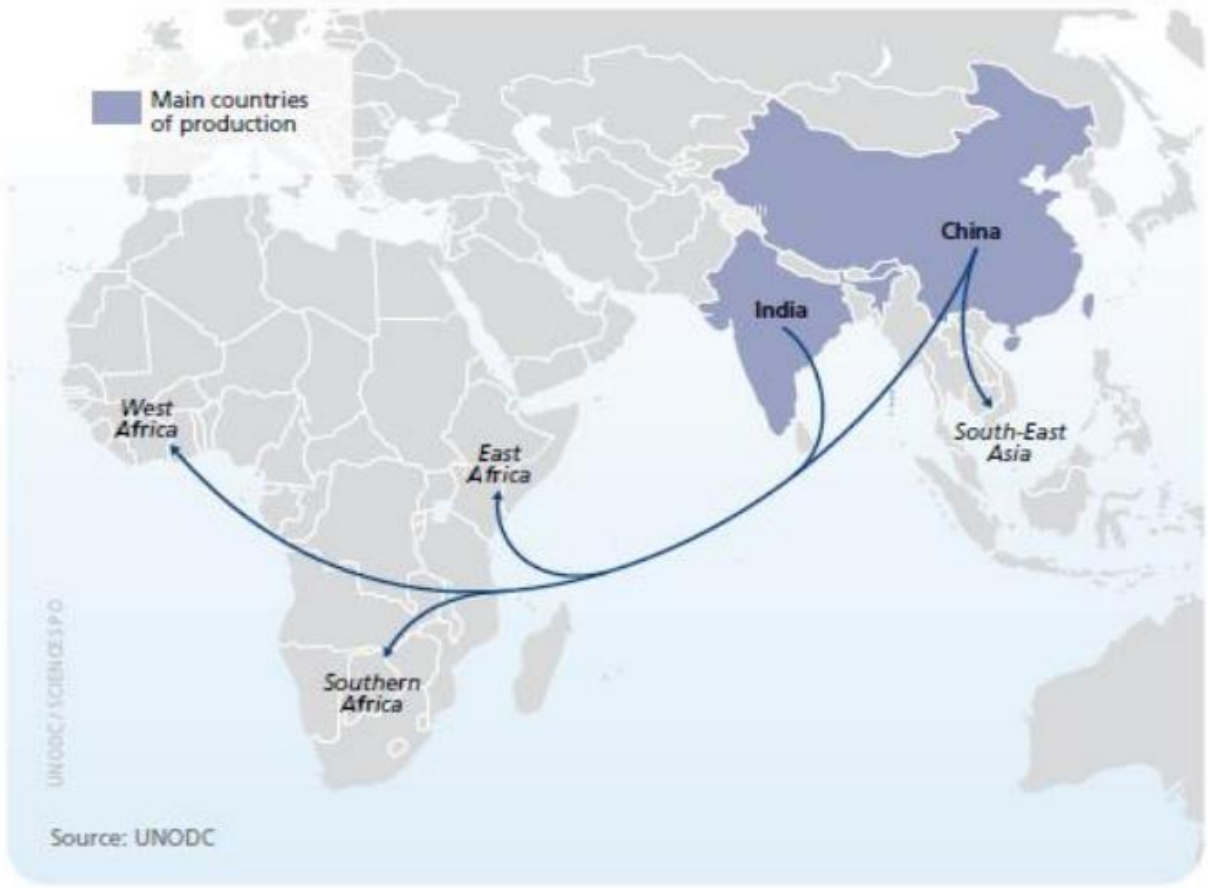

Figure 7: The distribution route for counterfeit medicines from Asia to Africa (Niaufre 2014)

Poor quality medicines are categorized as substandard and counterfeit medicines. The word counterfeit means fake or items that are not genuine or original in nature. Counterfeits medicines are referred to as pharmaceutical products manufactured and sold with the intention of deceptively representing its origin, authenticity, or effectiveness. Counterfeits drugs are likely to have inappropriate quantities of active ingredients or none, may be improperly metabolized in the human body, possess ingredients that are not stated in the label or packaged with inaccurate or fake packaging and labelling. (Oluwatuyi and Omotoba, 2014).

Substandard drugs are referred to as genuine or original medicinal products that does not meet the quality standard stipulated for them. (Newton *et al.*, 2010). Substandard medicines is a product of lack of expertise, poor manufacturing practices or limited infrastructure. (Oluwatuyi and Omotoba, 2014). W.H.O reported that 42% of global cases of substandard and fake medical products are sold in Africa. The UN office on drugs and crime also stated that the vulnerability of Africa to counterfeit

medicinal products is higher with 30% while the developed countries is at 1%. Also, a recent research estimated that one in ten medical products sold in low and middle income countries like Nigeria are fake and substandard. (Atabong, 2019)

A Contract Manufacturing Organization (CMO) is an organization that works for the pharmaceutical industry with the intention of providing clients with overall services ranging from drug development to its manufacturing. The services provided by CMOs includes primary and secondary manufacturing. The former involves the production of bulk active ingredients while the latter is for the production of bulk drug substances to finish medicinal products like pills, injectables etc.(Pandya and Shah, 2013)

The presence of counterfeit and substandard drugs in Nigeria is a clear indication that some of the CMOs that supplies medicines from China and India supplies counterfeits and substandard medicines. According to the research paper titled fake medicines trafficking in West Africa and its supply chains and distribution networks. Nigeria, Benin, Togo, and Ghana were categorized as the four countries in West Africa that consumes counterfeit medicines most. This is because the coastal region of the four countries permit the entry and distribution of counterfeit drugs. For instance, 150,000 counterfeit doses of *postinor 2* which is an emergency contraceptive was seized at the airport in Nigeria. Also, about 14 million euros worth counterfeit medicines was destroyed in Kano (North West of Nigeria) in 2012. (Niaufre 2014).

Bate, (2008) on a paper titled the Local Pharmaceutical Production in Developing Countries, he stated that "*where domestic capacity is lacking, local production will inevitably increase the supply of substandard drugs in the market"*. He further stated that substandard drugs when used for diseases like malaria can kill the patient within few days and also it is capable of causing disease resistant which can only be cured by new and expensive medications. In the same perspective, most of the developing countries like Nigeria, do not have the technical capacity and regulatory structures to manufacture quality medicinal products. The international supplies of drug from mostly India and China are easy to import and at the same cheap. This factor has remained the propelling factor to the high rate of the importation drugs from India and China.

In a recent paper published in 2020 on the risk of fake medicines in Africa. The author stated that "counterfeit drugs are deadly and growing problem". The world health organization reported that

as many as one in ten medicinal products sold in Africa are substandard or falsified. It is a factor that is responsible to the loss of money through the healthcare system and causes deaths of thousands of people in Africa. WHO also reported that between 2013 and 2017 a total of 42% of fake drugs was reported in Africa (Millar, 2020)

A paper titled counterfeit drugs and pharmacovigilance; the author stated that Nigeria is one of the most Nations affected with fake/counterfeit medicines. This is because of the weak or non-existent drug regulatory authorities in Nigeria. The author equally stated that there is no reliable statistics that reports the extent of fake drugs in Nigeria. It is estimated that counterfeits medicines in Nigeria ranges from 25% to 80% derived from research work conducted before 2001. In 1990 a study conducted in Nigeria by Poole found out that 25% to 80% drug samples were fake, 25% was genuine and 50% was classified inconclusive. Adeoye Lambo a former WHO deputy director in 1990 reported that 54% of drugs sold in all major pharmacy shops in Lagos Nigeria were fake and in subsequent years risen to 80% in subsequent year. In similar fashion, Taylor *et al* reported that the test conducted on drugs in Nigeria shows that 48% were fake and substandard. The author also found out that Anti-malaria's, antibiotics, and vitamins are categorized as widely used drugs in Nigeria. Among the drug products anti-malaria was categorized to have the smallest proportion of standard active ingredients. (Akunyili 2005)

In conclusion to above literatures reviewed, it is was proved that there are series of CMOs in China supplying more of substandard and counterfeits drugs in Nigeria. This is reflected in the series of fake and substandard drugs available in Nigeria.

2.10.1 The Negative Impacts of CMOs from China and India on Pharmaceutical Quality in Nigeria.

Bate (2008) reported that the unregulated activities that have increased pharmaceutical manufacturing of drugs in India and China have produced counterfeit and substandard drugs. The fake and substandard drugs have flooded the domestic markets most especially the low-income countries like Nigeria that imports about 75% of their dugs form India and China. Its effects have contributed to the death of 192,000 people in China in 2001 because of substandard medicinal products. Because of the Nigeria high importation of drugs from India, *The Lancet* estimated that almost 40% of drugs labelled to contain artesunate (anti malaria drug) does not have any active

ingredients. W.H.O also estimated that Nigeria has about 70% of adulterated and fake drugs in circulation.

A paper titled counterfeit drugs and pharmacovigilance, the author established that the activities of fake CMO has brought embarrassment and removed the confidence bestowed on the healthcare system and providers. Secondly the local pharmaceutical manufacturers are negatively affected by unfair competition with counterfeiters who only spend money on drug packaging and freight while spending nothing on APIs and excipients. (Akunyili 2005)

A Research paper titled "Monitoring the quality of medicines: Results from Africa, Asia and South America. The research was carried out in a publicly available medicine quality database (MQDB) by the U.S pharmacopeia convention (USP) with 17 countries of Africa, Asia and South America for a period of 2003-2013. The 71% of the samples reported was gotten from Asia, 23% (Africa), and 6% (South America). The samples collected and tested were antibiotic, antimalarial, and anti-tuberculosis medicines. The samples collected was tested using Minilab screening methods and pharmacopeia methods. At the end of the research, eighty-one (81) counterfeit medicines were reported, 86.45 was found in Asia and 13.6% in Africa. (Hajjou *et al.*, 2015).

The above research work indicates the presence of counterfeit drugs in Asian countries with the high percentage rate of 86.4% derived from 17 Asian countries with the inclusion of China and India who are the key suppliers of medicine to Nigeria. The outcome of this research work placed Africa, most especially Nigeria with the highest population in Africa at risk. This is because Nigeria import about 75% of their drugs from China and India and it includes majorly anti-malaria, anti-biotic, and anti-tuberculosis. In conclusion, this research work proved that the quality of drugs from Asian countries are of low quality with 86.4% of counterfeit drugs.

Another research work on the impact of poor-quality medicines in the "developing" world. The author reported that anti-malarial drugs has been the target in the counterfeit drug business. He further reported that during a recent epidemic that occurred in mainland South-East Asian on fake artesunate, 38%-53% of the anti-malaria drugs was gotten from pharmacies and shops. The counterfeit drugs show the wide ranges of different types of fake packaging. (Newton *et al.*, 2010)

Ekwigwe in 2019 reported the survey conducted by WHO on the quality of medicines identified by the United Nations Commission on life-saving commodities for woman and Children (UNCoLSC).

W.H.O selected medicinal products derived from 13 lifesaving commodities that was tested for quality. They selected 10 countries including Nigeria and Burkina Faso. At the end of the study, drug failure rate of 35% and 31% was discovered in Nigeria and Burkina Faso respectively and oxytocin has the highest failure rate. The study by WHO shows that one third of the selected life-saving commodities that are sold and used in Nigeria are substandard and fake. This is to proof that Nigeria is a major contributor to the global statistics of maternal death via postpartum haemorrhage.

The above research work agrees with the other authors on the high prevalence of counterfeit drugs in Asian countries. It is an indication that most of the drugs especial anti-malaria drugs imported from China and India in Nigeria are fake and counterfeit.

2.10.2 The Positive Impacts CMOs from China and India on Pharmaceutical Quality in Nigeria

A study conducted in 2011 on China and India as suppliers of affordable medicines to developing countries, the research work discovered that the imports of antibiotics and unspecified medicaments from India and China are cheap when compared with high-income trading countries. This was because India and Chines companies lowered the price of their medicines to compete with the high-income trading countries. And currently India is the leading supplier of medicines within the sub-Saharan part of Africa. In like manner, Nigeria run a trade deficit on pharmaceutical due to the lack of manufacturing and innovative capability. The above is one of the reason behind the importation drugs from India and Chinese companies. (Hafner and Popp, 2011)

In another research work titled raising the Technological Level, the Scope for API, Excipients, and Biologicals Manufacture in Africa. The author discovered that generics producers in India and China supply almost all the APIs that is used in the production of medicines in African countries like Nigeria etc. According to the author, Investment and research and development activities that are required in the production of APIs remain the major limitation responsible for the high dependency of APIs from India. (Fortunak *et al.*, 2016).

In conclusion, there is no literature addressing the positive impacts of Indian and Chinese CMOs on drug quality apart from the fact that they supply cheap drugs to Nigeria. The Indian and Chinese pharmaceutical suppliers have done more harm than good in supplying cheap drugs to a developing country like Nigeria. This is because of the poor investment and research and development prevalent in the health care system of Nigeria. This calls for more regulatory actions to eliminate

the bad eggs in the system. This research work will also find out the positive impacts of Indian and Chinese companies apart from the supply of cheap drugs to Nigeria.

2.10:3 The Problem of Local Drug Manufacturing in Nigeria

Muanya (2019) stated the contribution of PCN in the reduction of local production of drugs in Nigeria. The PCN attributed it to "policy reversals and inconsistency in government policies" as one of the limiting factors. Secondly the issue of corruption and import duties that encourages and favours drug importers while suffering the local manufacturers. The government inability to patronize made in Nigeria drugs is also another limiting factor. Apart from inconsistency in government policy, the local producers are facing problems of poor infrastructure, lack of patronage and uncontrolled market space. (Muanya, 2019a)

Ezeigwe (2019) stated that the challenges in medicinal manufacturing in Africa especially Nigeria to includes lack of infrastructures like transportation system, communication networks and constant power supply, the over dependent of the health care system of medicinal products from India and China, the importation of medicinal raw materials and equipment's, inability to attain the WHO pre-qualification as a result of functional and technical constraints, limitation of skilled personnel required for drug development, lack of clinical research organizations (CROs) and bioequivalence centres that prevents the discovery of quality generics and branded medications, poor government investment to promote R&D for drugs and provisions of incentives to local manufacturers. Furthermore, the funding of R&D in Nigeria and West Africa is minimal. R&D are supported with 1% in the health budget. The prevalent of porous border that encourages smuggling of substandard and fake drugs, poor medicinal regulations that encourages the proliferation of fake and substandard drugs while the original products from the local manufacturers are abandoned.

Conclusion

At the end of a holistic study and reviewing of literatures on research papers and articles published in Nigeria and other part of the world, it was discovered that Nigeria drug regulations are outdated, weak and promotes the prevalence of fake and substandard drugs. The weak regulations have negatively affected the growth and progress of the local pharmaceutical manufacturing industry in Lagos Nigeria. In like manner, the literature review discovered that the regulations guiding the importation, manufacturing, sale, distribution, and exportation of drugs in Nigeria are not adequate to monitor and control the sales of drugs in Nigeria. Its implementation and enforcement are deficient, the task force set up by the government to implement the regulations are not effective in discharging their duties due to poor staff strengths, financial constraints, and lack of essential equipment.

The above weakness in the drug importation regulations in Nigeria have promoted the importation of fake and substandard drugs in Nigeria from China and India where there are unregulated activities in their pharmaceutical industry. This have made the local pharmaceutical manufacturers to be competing with cheap substandard and fake drugs with less or no APIs. It has also led to the importation of drugs that are not in the essential drug list that is designed to encourage the growth of the local pharmaceutical industries in Nigeria. Furthermore, the journals and papers reviewed shows that Nigeria imports 75% of their drugs from India and Chinese CMOs, and the unregulated activities of the Indian and Chinese pharmaceutical industry have contributed to the high prevalence of fake and substandard drugs in Nigeria.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Overview

Section. No	Primary Data	Part A	Part B
1	Approach	Quantitative analysis	Qualitative analysis
2	Philosophy	Positivism	Interpretivism
3	Source	Questionnaire: Microsoft forms app sent out via online (WhatsApp and Emails)	Zoom Interviews
4	Structure	6 sections made up of 16 questions	10 – 30 minutes of zoom interviews
5	Subjects	Local Drug Manufacturers (77)	▪ Local Drug Manufacturer's (4) ▪ Drug Importers (4) ▪ PSN President ▪ PGMAN Secretary

Table 5: Research Methodology and Primary Data collection

3.2 Research Approach

To determine the impacts of drug importation regulations on local pharmaceutical manufacturing in Lagos Nigeria, the author adopted a quantitative and qualitative research method by using questionnaire surveys and zoom meeting interviews.

The survey was distributed electronically to the local pharmaceutical manufacturing industries in Lagos Nigeria, who are also key importers of drugs in Nigeria. They are the main research group and were asked to fill the survey through the cooperation and assistance of the union (PMGMAN) that made their contacts available to the author. The cooperation between the local pharmaceutical unions in Nigeria assisted the author in gathering the required information and data used for the statistical analysis. The questions asked was specifically meant to get the general perception of the key players in the Nigeria pharmaceutical industry. Most importantly, to determine the impacts of

drug importation regulations on local pharmaceutical industry in Lagos Nigeria. Along the same lines to get the challenges and recommendation for the growth of the industry that have depended so much on CMOs from India and China for 70% of their drugs.

The qualitative approach of this research was via zoom meeting interviews to understand personal experience of the local drug manufacture's and importers who have been in the business for more than one decade. In similar fashion, the pharmaceutical union bodies (PSN & PMGMAN) pioneered by seasoned drug manufacturers and importers with 15-33years experience in the industry were interviewed to further get a clear perceptions and recommendations for the growth of the local pharmaceutical industry.

Comparisons was made from the data generated after the analysis from the two groups with the literatures findings to arrive at the authors concluding view on the research work.

a. Research Philosophy

Positivism and interpretivism was adopted as the main philosophy guiding this research work. Its adoption for the study is to actualize excellent explanation of all the information derived from all the respondent. It also assisted in arriving to an appropriate conclusion to the study carried out by the author.

The author designed a well-articulated questionnaire suitable for adequate data collection, analysis, and interpretation from the local drug manufacturers. To achieve excellent research work, human bias or opinion was avoided and only the data generated was used for the study.

Furthermore, in achieving excellent research work, the author made use of electronic survey to eliminate any connection between the participants during the period this research work was conducted.

The use of interpretivism for all the data generated from qualitative analysis via zoom meeting interviews yielded in primary data from personal opinions and values of the regulators, local drug manufacture's and importers. Although the information received from them are personal views, but it was a clear expression of their experience/knowledge they have acquired for a long period of time as major players in the pharmaceutical industry.

3.3 Research Strategy

The strategy of the research was aimed at evaluating the impacts of drug importation regulation on local pharmaceutical manufacturing in Nigeria and understanding the challenges faced by the local pharmaceutical industry with recommendations to improve the industry.

As confirmed from several literatures reviewed, it was confirmed that there are series of available literature towards the impacts of the different Government regulation and policies towards the manufacturing sector in Nigeria but there is none specifically referring to the pharmaceutical manufacturing sector in Nigeria is available at the moment.

The local drug manufacturers and importers that participated actively in this research paper were pre-informed of the purpose of the research work that is been carried out by the author in accordance with the academic requirements for the award of M. Sc in Pharmaceutical Business and Technology. The author articulated the questionnaire in a very concise format to address the pertinent issues of the local pharmaceutical industry. It was administered to 117 participants who are members of PMG MAN Union and currently involved in local manufacturing and importation concurrently.

a. Collection of Primary Data

As properly explained in the research strategy, the primary data was generated only from questionnaire's, designed for the local drug manufacturers/importers as the cohort from the pharmaceutical industry required for this study. All the 16 questions were designed to receive the perception, recommendations and experience of local drug manufacturers/importers for the actualization of the research objectives.

Section 1: Demographics

This part is on demographics with three questions that requires specified options from the respondent to select from. The aim of the questions is to determine the category of their business. E.g. local drug manufacturing, drug importation and both.

Section 2: Nigeria Essential Drug List (EDL)

This part of the research questionnaire have four questions that will enable the generation of the participant knowledge of drug importation regulation especially the EDL. It also helped in generating data on the participant's opinions and recommendation for the EDL.

Section 3: Drug Importation Policies and Regulations

The drug importation policies and regulations section are made up of six questions aimed at getting further information on the participant's knowledge of drug importation regulations and its associated penalties. In similar fashion to know the participants view on drug importation reviews.

Section 4: Contract Manufacturing Organizations

This section consists of two question aimed at knowing the impacts of CMOs on local drug manufacturing and the main location for CMOs for Nigeria Pharmaceutical companies.

Section 5: Recommendations

This last section is made up of questions channelled in receiving the respondent's views on the mapped-out recommendations for the growth of the local drug manufacturing industry in Nigeria.

b. Sources

The survey questionnaire generated was sent to the local manufacturers/importers through the union secretariat (PMG-MAN) for effective reach out using Microsoft forms application. Data was gathered from 77 participants made up of local manufactures who also drug importers. For efficient data generations and comparison, the author used Microsoft excel sheet for the representation of the findings via pie charts.

Furthermore, zoom interviews were performed with the PSN president, PMGMAN secretary and with 4 local drug manufacturers and 4 drug importers with a minimum of 15years in the industry.

c. Access and Ethical Issues

The author gave a brief introduction of the research topic to all the local manufacturers/importers involved in the survey questionnaire and interviews and they understood that the research project is a part of an academic requirements for the fulfilment of the authors MSc program.

In designing the survey questions, the author avoided any question that will demand the personal data of the respondents and all the questions asked are in accordance with the author's objectives. The participation by the respondents is optional and they are permitted to withdraw at any time.

d. Inclusion and Exclusion Criteria

The local drug manufacturers/importers include senior directors in the pharmaceutical Industry in Lagos Nigeria who were categorized by the author as the key decisions makers in their respective pharmaceutical companies. The participants who refused to be involved in the survey were by default considered as excluded from the research work. This was the only inclusion or exclusion criteria used for the enrolment of the participants.

The survey was designed with an introductory letter which captures the consent of the participants before they answer the survey questions. It was made optional for the local drug manufactures/importers to be involved or not in the survey.

CHAPTER 4

4.1 Presentation and Analysis of Research Findings

In this chapter, the answers derived from the survey questionnaire was analysed specifically. The outcome derived from the data assisted the author to determine the impacts of drug importation regulations on local pharmaceutical manufacturing in Lagos Nigeria and in answering the research questions and objectives.

The analysis from zoom meeting with the stakeholders like PSN, PMGMAN and local pharmaceutical manufacturers/importers helped to close the vacuum with the survey questionnaire results, literature reviews and personal viewpoint of the author regarding the local pharmaceutical manufacturing in Lagos Nigeria.

4.2 Demographic Data (Questions 1 – 2)

4.2.1 Response rate:

The survey was distributed to 117 local manufacturers of pharmaceuticals products in Nigeria via the union, Pharmaceutical Manufacturing Group Manufacturing Association of Nigeria (PMG MAN) secretariat for effective reach out. A total of 77 out of the 117 participants responded. Interestingly all the local manufacturers are also importers of pharmaceutical products chiefly from India.

4.2.2 Level of experience:

All the respondents have 10 – 15 years of experience in local pharmaceutical manufacturing and drug importation in Lagos Nigeria.

4.3 Quantitative Analysis

QUESTION 3

To ascertain how importation regulations and other factors have influenced the growth of local pharmaceutical manufacturing in Nigeria, the following factors were considered.

Complex Drug Registration Process

It is interesting to know that 81% of the local manufacturers/importers agreed that complex drug registration process have affected their business negatively, 13% agreed that it has affected their business positively while 6% admitted it to be indifferent. See figure 8a

The analysis shows that majority of the local manufacturer's/importers are experiencing administrative bottle necks and difficulties in NAFDAC drug registration process which have affected their business negatively.

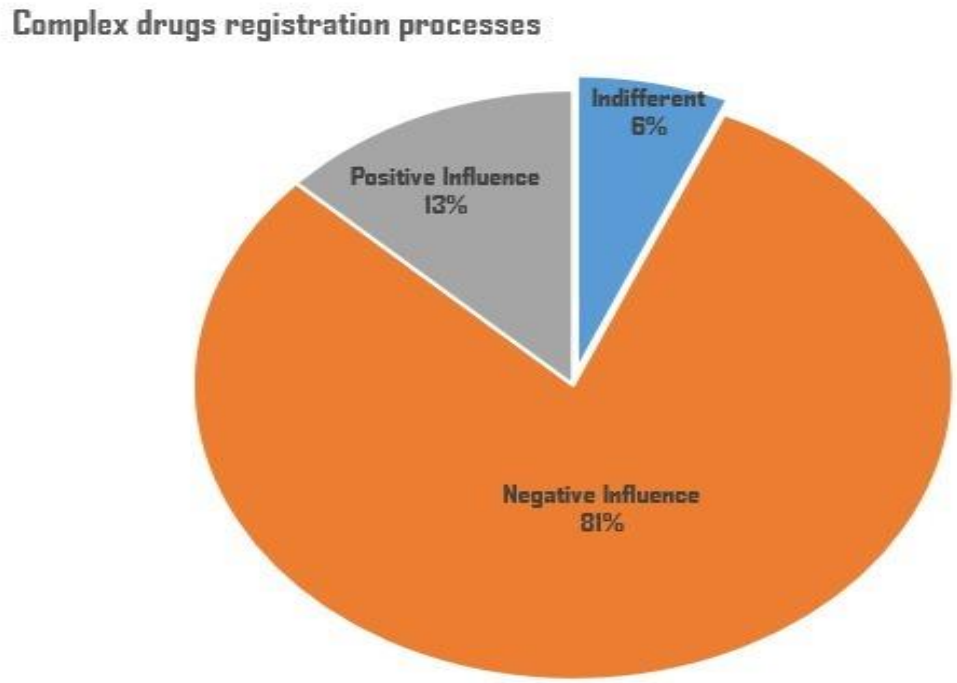

Figure 8a: The impacts of complex drug registration processes on local pharmaceutical manufacturing in Nigeria.

High Taxes and Importation Duties

An overwhelming majority of 93% local manufacturer's/importers admitted that high taxes and importation duties have influenced their business negatively, (4%) of respondents admitted that it has influenced their business positively while (3%) of the respondent admitted it to be indifferent. See figure 8b

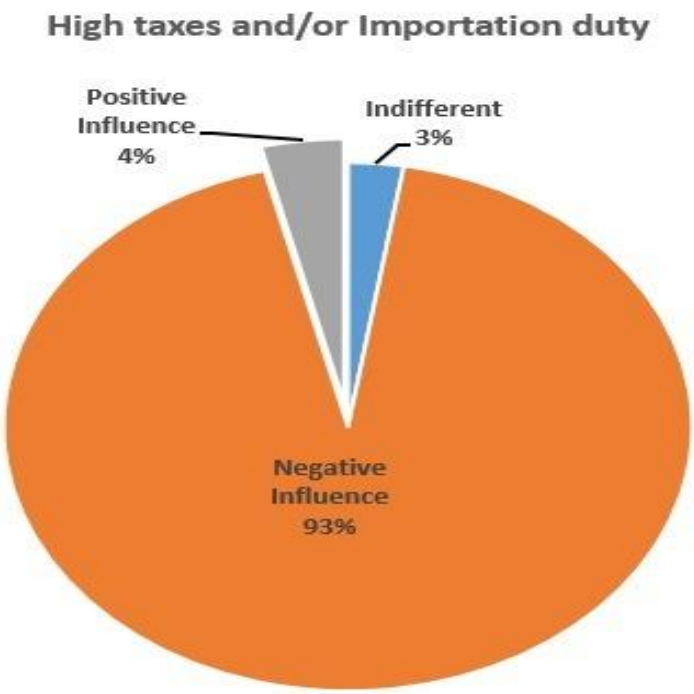

Figure 8b: The effects of high taxes and/or Importation duties on local pharmaceutical manufacturing in Nigeria.

As depicted from the response, 93% of the respondent are affected negatively by high taxes and importation duties. This is a clear indication that taxes from state and non-state actors and importation duties placed on APIs, finished products are very high and affecting the growth of the industry negatively.

Insufficient Regulatory staff in PCN & NAFDAC

On the insufficient staff manpower of PCN and NAFDAC, 51% of the local manufacturers/importers admitted that it has affected them negatively, 44% attributed it to be indifferent while 5% admitted that it has affected their business positively. See figure 8c

The analysis reviews that 51% of the local manufacturers/importers admitted that it has affected their business negatively while 44% admitted it to be indifferent. This confirms that insufficient staff manpower of the regulators is not a major problem for the local pharmaceutical manufacturing industry in Nigeria. In the same vein, it reviews that it does not pose any negative influence on local drug manufacturing in Nigeria.

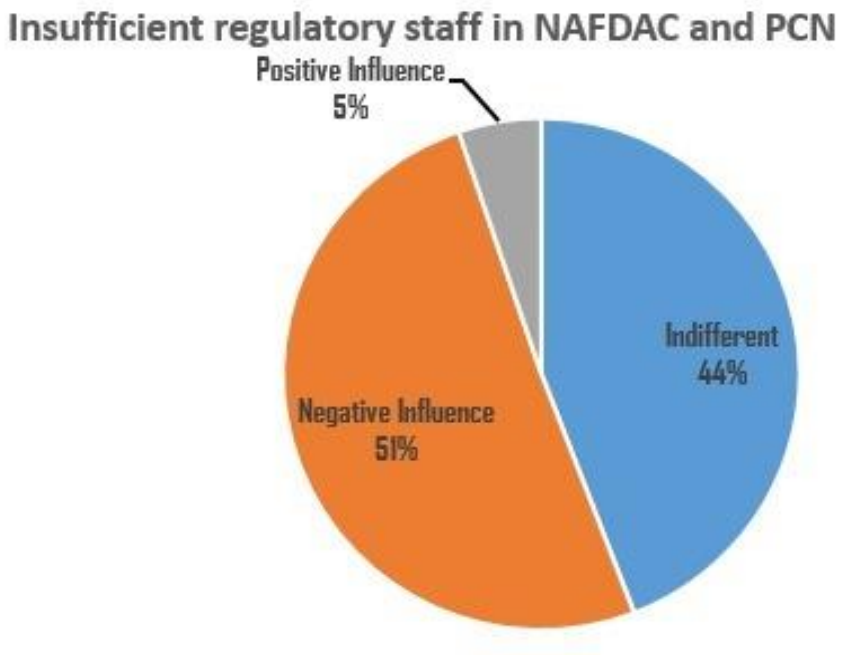

Figure 8c: The effects of insufficient manpower of PCN and NAFDAC on local pharmaceutical manufacturing in Nigeria.

Corrupt Regulatory Officials

Finally, on the corrupt regulatory officials, 86% of the local drug manufacture's/importers admitted that it has affected their business negatively, 10% admitted it to be indifferent while 4% admitted it have positive impacts on their business. See Figure 8d

The above analysis confirms that the high prevalence of corruption from the regulators and government officials responsible for the regulatory of the pharmaceutical industry in Nigeria. Furthermore, it explains that the activities of the corrupt official are affecting the growth of the pharmaceutical industry and providing the enabling environment for fake and substandard drugs in the system.

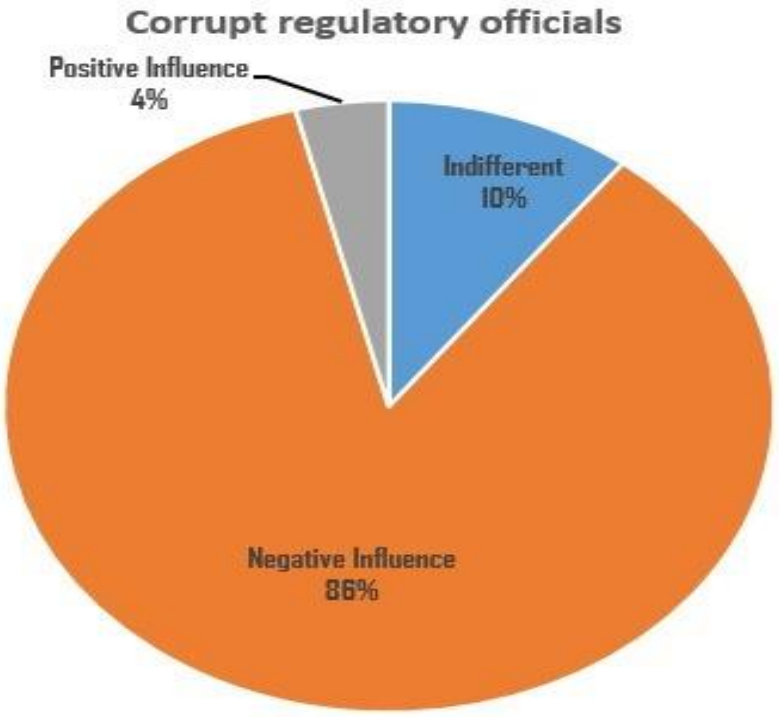

Figure 8d: The effects of corrupt regulatory officials on local pharmaceutical manufacturing in Nigeria.

The above survey's in **question 8** confirms that insufficient manpower of the drug regulatory bodies is not a major problem for the local drug manufacturing, while factors like corrupt regulatory officials, high taxes and or/importation duties and complex registration process are the major factors that is affecting the growth of the local pharmaceutical industries in Lagos Nigeria.

4.4 Nigeria Essential Drug (List question 4-7)

The responses generated from this section were varied and remarkable towards the awareness of drug importation regulations especially EDL.

QUESTION 4

To confirm the awareness of drug importation regulations, the respondent were asked whether they are aware of the EDL and its regulatory policies, a significant number of the participants (81%) indicated that they are aware of the EDL and its regulatory policies, 18% of the respondent admitted to be somewhat aware while 1% admitted to be unaware of the regulation. See Figure 9

This confirms that majority (81%) of the local manufacturers/importers are aware of some of the drug importation regulations especially the EDL because of their daily activities with the regulators in charge of the regulations.

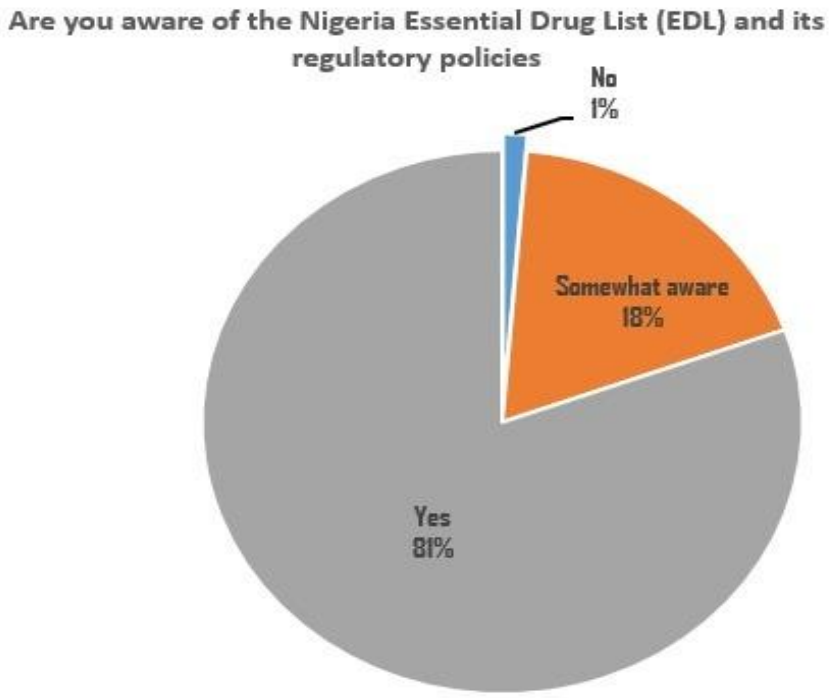

Figure 9: Awareness of the EDL and its regulatory policies by local manufacturers of drugs in Lagos Nigeria.

QUESTION 5

As a follow up to question 4, this was to ascertain further knowledge of drug importation regulations especially the EDL. The local manufactures/importers were asked the stipulated punishment for the importation or manufacturing of drugs not contained in the EDL. Interestingly, 66% of the respondents accurately noted that it is ₦100,000 fine or imprisonment not exceeding 5years, while the rest of the local manufactures/importers (34%) of the respondent got it wrong. See figure 10

The above survey also confirms that most of the local pharmaceutical manufacturers are aware of drug importation regulations especially the EDL and the 34% of the local manufacturer's/importers that got it wrong may not be good in remembering exact figures.

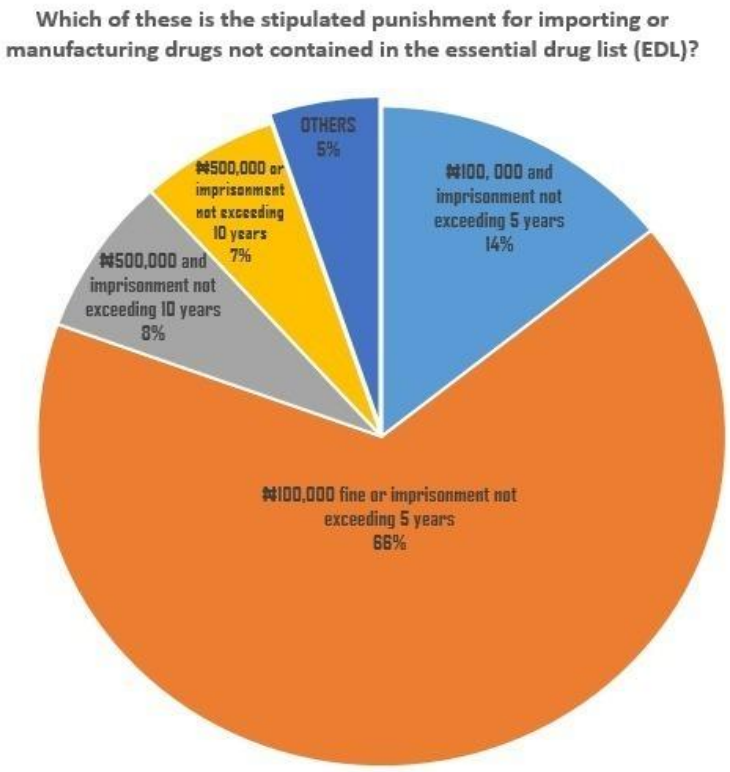

Figure 10: The stipulated penalty for the Importation or manufacturing of drugs not contained in the EDL

Question 6

On another follow up to question 4&5, to confirm if the penalty selected above is sufficient to deter defaulters of EDL regulations, 62% of the local manufacture's/importers admitted that the penalty above for the defaulters is not sufficient to deter defaulters, 22% of the local manufacture's/importers admitted it to be sufficient while 16% agreed that it is indifferent. See figure 11.

The above analysis confirms that the penalty for defaulters of the EDL requires reviews because it is not stringent enough to deter defaulters of the EDL. This is represented in the analysis were majority (62%) of the local manufacture/importers admitted that the already existing penalty to deter defaulters is not sufficient to deter defaulters. On the contrary, it is obvious that the 22% & 16% that admitted the penalty to be sufficient and indifferent respectively may be indirectly benefiting from the EDL regulations.

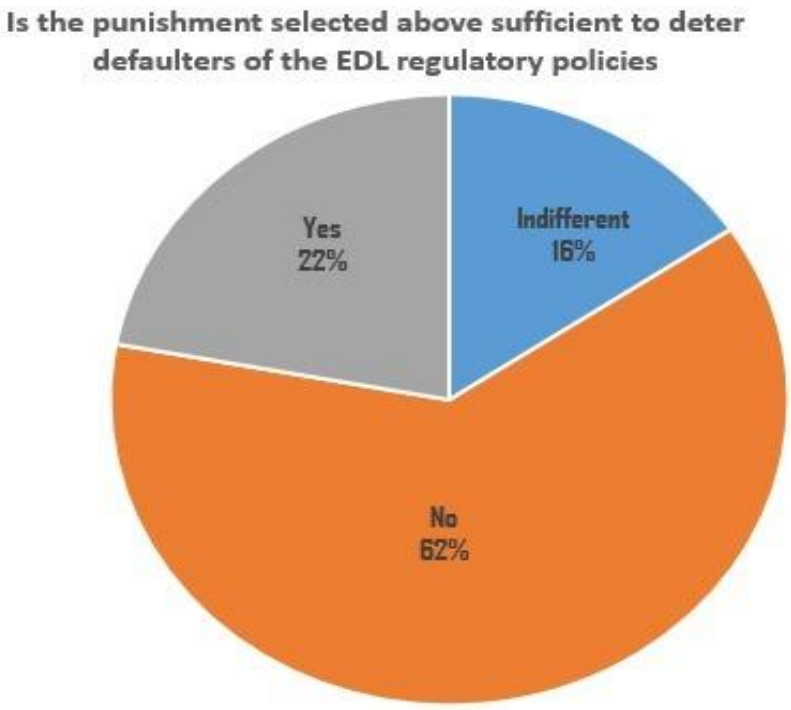

Figure 11: Is the EDL regulatory policy sufficient to deter defaulters.

QUESTION 7

As a follow up to question 6 to confirm the local manufacturers/importers recommendation on defaulters of EDL in order to promote local manufacturing, 44% of the local manufacturer's/importers recommended for a penalty of ₦2,000,000 and 10years imprisonment, while 21% recommended ₦5,000,000 and 5years imprisonment for defaulters, 18% recommended ₦5,000,000 or 5years imprisonment. In addition, 13% recommended ₦2,000,000 or 10years imprisonment for defaulters. In variance, 4% of the local manufacturer's gave other recommendations. See figure 12.

The above survey is in conformity with the initial surveys for the review of drug importation regulations especially the EDL by the local manufacturer's/importers. Secondly, the local manufacturers/importers recommended a more effective penalty to deter defaulters and replacing the existing weak penalty of ₦100,000 fine or imprisonment not exceeding 5years. The penalties they recommended in this survey shows that they want an effective and stringent penalties to deter defaulters of EDL who have negatively affected their business.

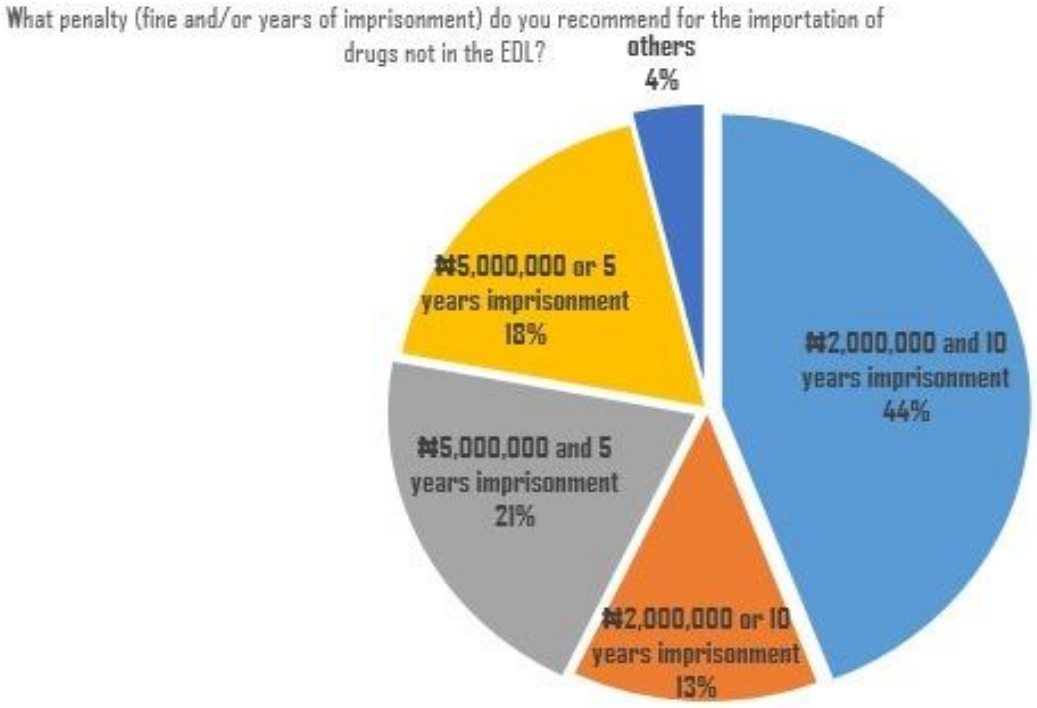

Figure 12: Local pharmaceutical/importers recommendations for defaulters of EDL

4.5: Drug Importation Policies and Penalties (Question 8-13)

QUESTION 8

In order to confirm the local manufacturer's perception on Government implementation of the importation policies for APIs and finished drug products, an overwhelming number of local manufacturers/importers (83%) admitted it be ineffective/inconsistent, while in contrast 17% agreed that it to be effective/inconsistent. See Figure 13

It is evident from the survey that the importation policies for raw materials and finished products are ineffective/inconsistent. The analysis further shows the inability of the Nigerian customs and NAFDAC in the implementation of the importation regulations because of some factors like corruption, personal interest of some of the regulators, manpower etc.

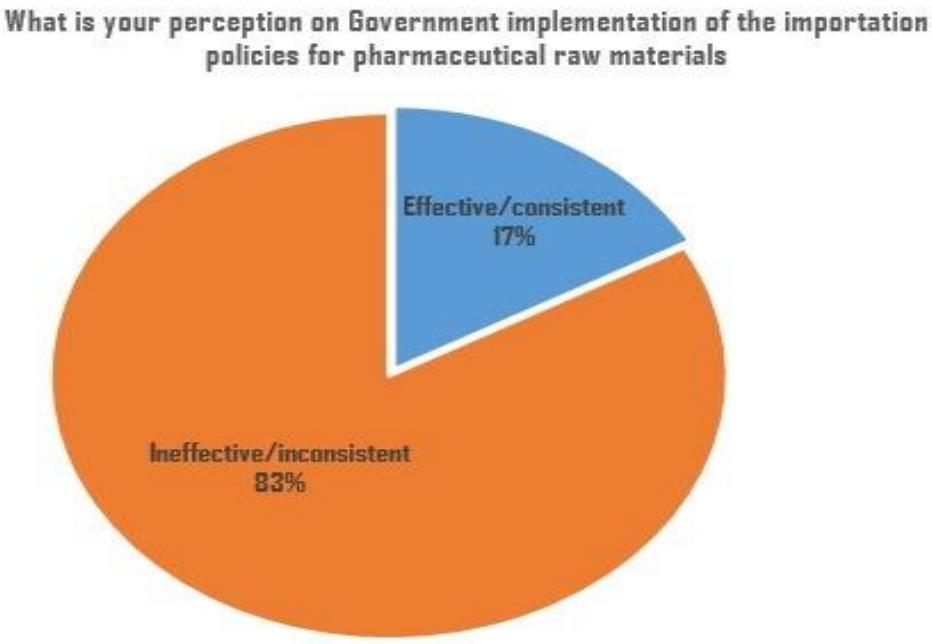

Figure 13: Government implementation of the importation policies for pharmaceutical raw materials and finished products.

Question 9

In order to further examine the knowledge of some of the newly importation regulations, the local manufactures/importers were asked the maximum period allotted for importation of newly registered drug products before starting its local manufacturing. Majority (82%) of the participants admitted that it is 10years, while 14% of the participants admitted that it is 5years. The rest of the participants 3% and 1% also admitted that it is 15 years and 20 years, respectively. See figure 14

The survey clearly confirms that most (82%) of the local manufacturers/importers are aware of the new drug importation regulations while the rest (18%) of the local manufactures/importers may not be unaware of it because it is a new regulation.

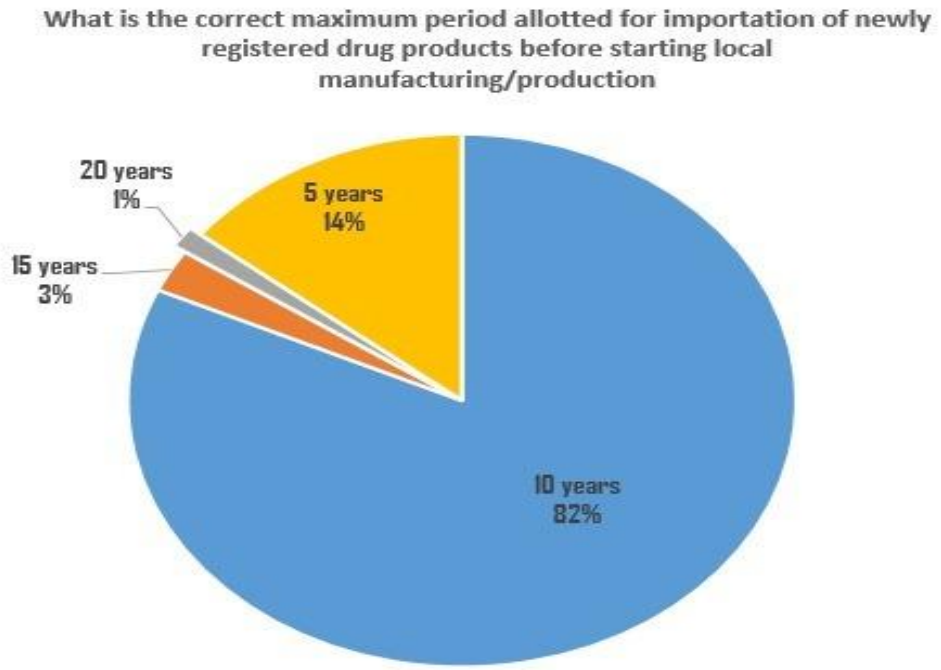

Figure 14: The maximum period (years) allotted for importation newly registered drug products before starting its local manufacturing.

Question 10

As a follow up to question 9 to confirm whether the 10 years placed by NAFDAC on the importation of newly registered drug products is sufficient before its local manufacturing, 60% of the local manufacturers/importers disagreed that the 10years is not sufficient enough to start local manufacturing of the same product, 37% of the local manufacturers/importers agreed that it is sufficient enough while on the contrary 1% of the local manufacturers/importers gave other options. See figure 15

It is evident that most of the local manufacturers/importers are not comfortable with NAFDAC 10 years importation timeline for newly registered drug product before its local manufacturing. This because of the huge funds and logistics required in setting up of production plants and secondly most of them are not willing to start local drug manufacturing because of the government inability to provide the enabling environment and policies that are supposed to protect local drug manufacturing in Nigeria. Furthermore the 37% of the local manufacturers/importers who agreed that the 10years timeline is sufficient enough are the multinationals companies who have already

built the capacity and manpower for local drug manufacturing in Nigeria and willing to start local drug production immediately.

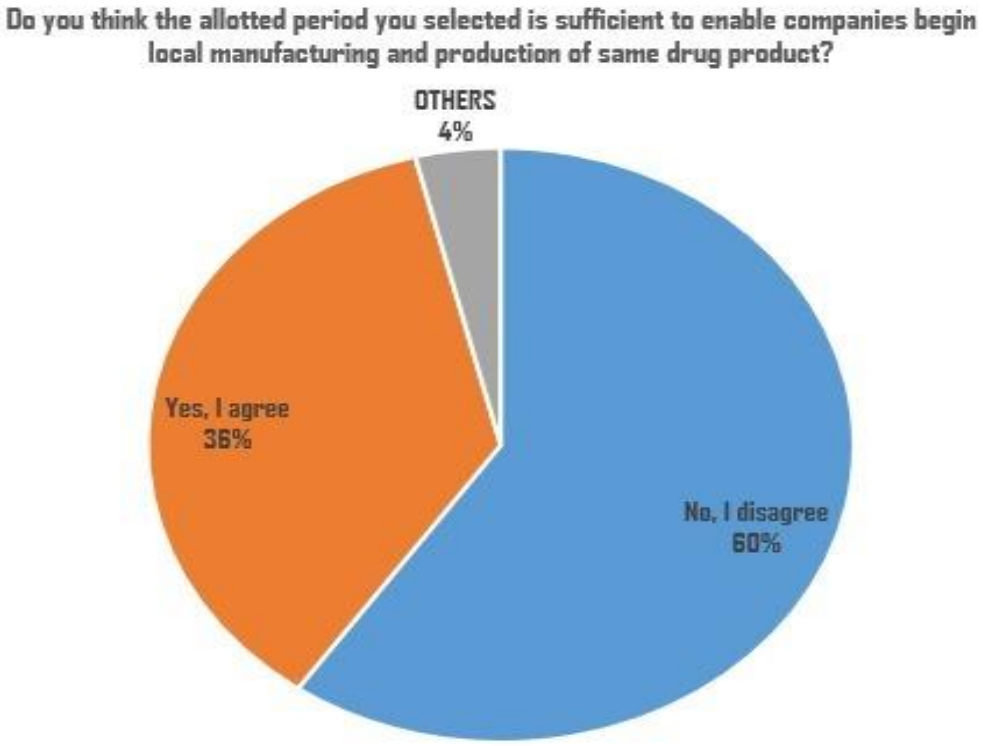

Figure 15: Is the selected period sufficient to enable companies to start local production.

Question 11

As a last follow up to question 10 to get further recommendations of the local manufacturers/importers on the 10 years' timeline to start local production, 65% of participants recommended for 12 years timeline to start local production of the same product imported, 26 of the participants recommended for 7 years' timeline, while 9% recommended for 25 years timeline. See figure 16.

It is also evident from the analysis that most of the local manufacturers/importers want a long-time frame (7-25 years) for the importation of a particular drug products prior before its local manufacturers to enable them to source for funds that is needed for local manufacturing.

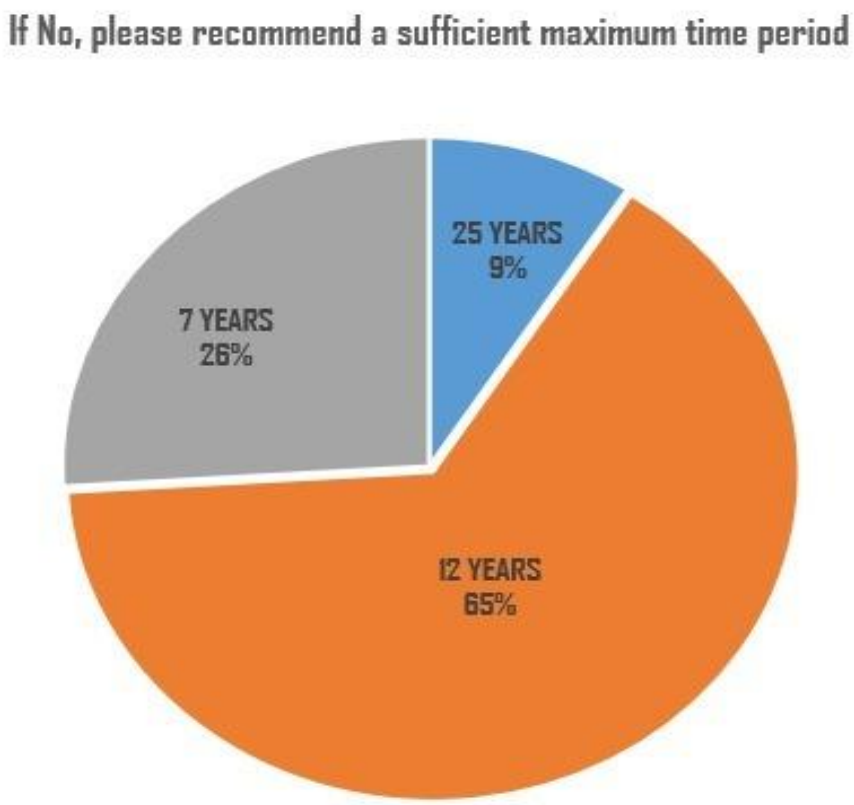

Figure 16: Local manufacturers/importers recommendation on the importation timeline before local production.

Question 12

To further get the recommendations of the participants on the penalty attached to the sale and distribution of counterfeit and fake drug products, majority (49%) of the local manufacturers/importers recommended life imprisonment to deter defaulters, 38% selected 20years imprisonments with an alternative of ₦50,000,000 fine, while 12% selected death penalty, while 1(1%) selected 20years imprisonment. See figure 17

The above survey suggests that the existing regulations on the sale and distribution of counterfeit and fake drugs requires reviews. Secondly the survey shows that the local manufacturers/importers want a more stringent penalties for defaulters who are damaging the image of the industry. Lastly, majority of the local manufacturers/importers (49%) want life imprisonment as prevalent in some other countries like India as the penalty for the sale and distribution of fake and substandard drugs.

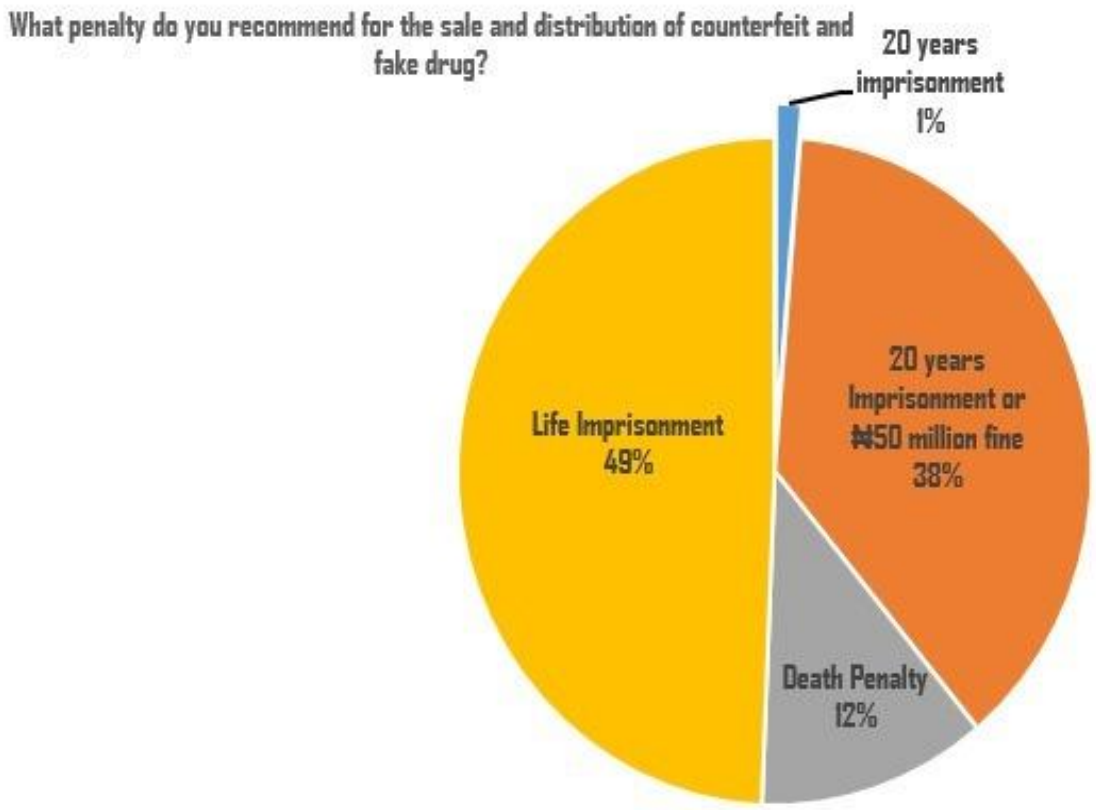

Figure 17: Local manufacturer's recommendations for the penalty on sale and distribution of fake and counterfeit drugs.

Question 13

As a follow up to question 12, an overwhelming number of the participants (94%) admitted that the selected penalty for defaulters who imports fake and substandard drug products in Nigeria is enough to deter defaulters, while on the contrary 5% of the respondent disagreed that it is not sufficient. See figure 18

The analysis reviews that the stringent penalties selected by the local manufacturers/importers is enough to deter defaulters who are not willing to pay huge amount of money, spend the rest of their life in jail or face death sentence for the sale and distribution of fake and substandard drugs in Nigeria.

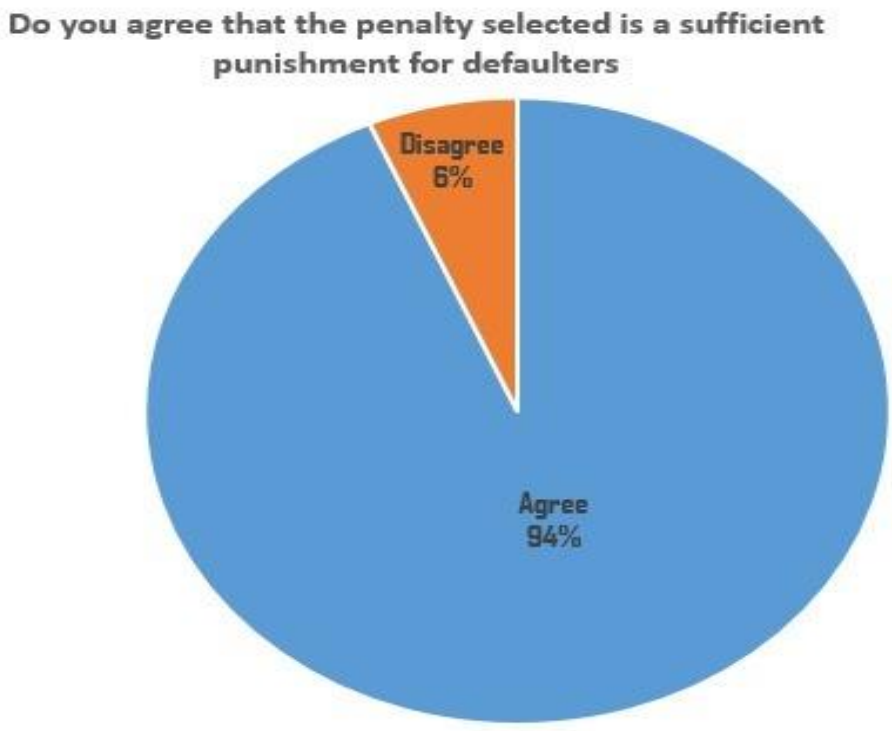

Figure 18: Confirmation on whether the penalty selected is a sufficient punishment for defaulters.

4.6 Contract Manufacturing Organizations (CMOs) Question 14-15

The responses from this section confirms that Nigeria depends majorly the on CMOs from India for the supply of drugs and it was also interesting to know that the CMOs are supplying quality drugs to Nigerians.

QUESTION 14

To be able to know the major exporters of pharmaceuticals to the Nigeria drug market, 52% of the local manufacturers/importers admitted that it comes from India, an encouraging number of 36% local manufacturers also agreed that it comes from both China and India. While 3% agreed that it come from China, India, USA, and Ireland. Furthermore, 5% of the local manufactures/importers admitted that it come from other countries like from U.S.A, Pakistan, Turkey, and Ireland. See figure 19.

The above survey indicates that majority of the drugs sold in Nigeria are chiefly from India then followed by China. This is because India and China have the enabling environment, cheap labour and raw materials that promote drug manufacturing at a lower cost. They also have the required

equipment and facilities for drug manufacturing when compared with Nigeria and some other part of the world.

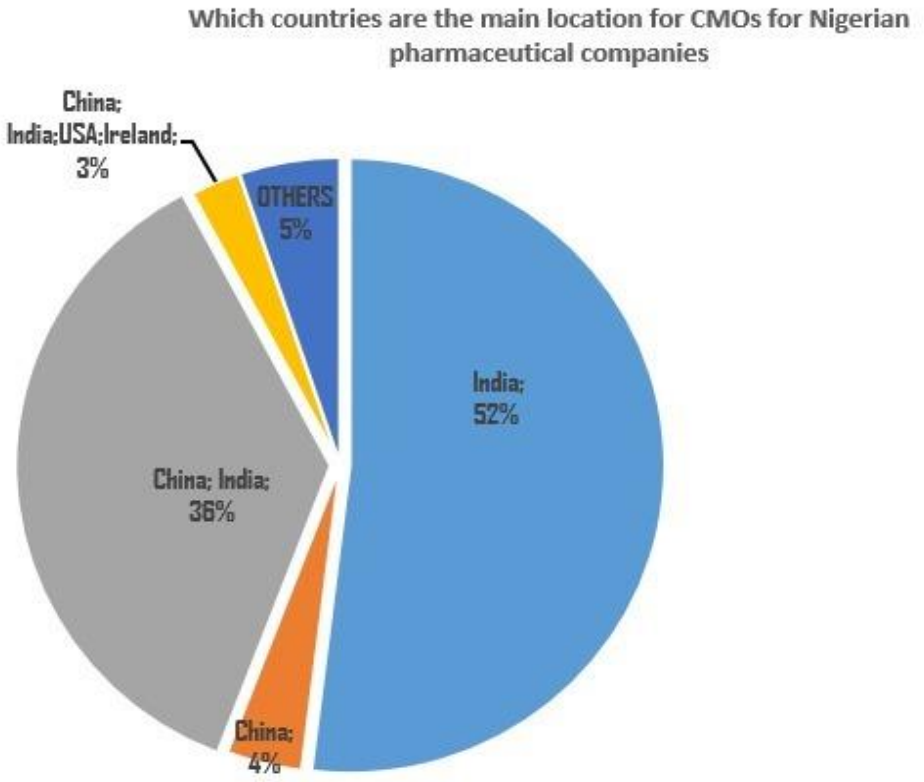

Figure 19: Countries exporting pharmaceuticals to Nigeria

4.7 Recommendations for the growth of local drug manufacturing

The responses generated from this section show the vital roles of the Nigerian government in championing the growth of drug manufacturing in Nigeria.

Question 15

On the analysis of the effects of foreign CMOs on the Nigeria local pharmaceutical industry, majority of the respondent (39%) admitted that it has yielded to the circulation of fake and substandard drugs and affected the growth of their local manufacturing negatively. On the positive effects, they acknowledged that it has led to the availability of cheap/affordable drugs and availability of high-quality drugs. In the same vein, 29% of the local manufacturers admitted that its positive effects include availability of cheap and affordable drugs, availability of high-quality drugs and it have

negatively affected the growth of local manufacturing. On the contrast, the rest of the respondent (26%) are in concurrent with the other options. See figure 20

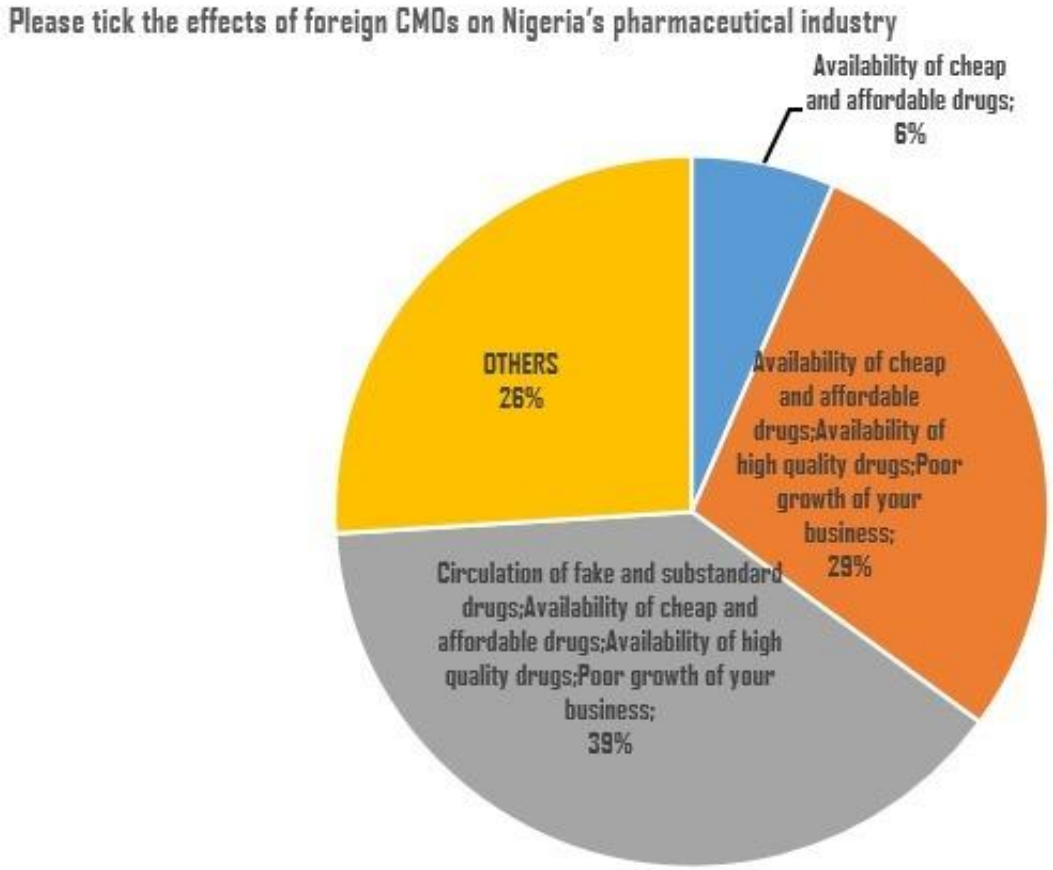

Figure 20: The effects of CMOs exporting drugs to Nigeria.

The above survey shows that the activities of CMOs that exports drugs to Nigeria chiefly from India have yielded to the circulation of fake and substandard drugs and affected the growth of the local manufacturing negatively. This is evidenced in the high rate of fake and substandard drugs in Nigeria that have caused several mortalities and brought less confidence to the health care system in Nigeria.

On the positive angle it has led to the availability of cheap/affordable drugs and availability of high-quality drugs. This is also seen in the availability of cheap/quality drugs like antimalarial, anti-retroviral and vitamins in Nigeria.

QUESTION 16

For the recommendation towards the growth of the local manufacturing, an overwhelming number (99%) of the local manufactures admitted that prosecuting the corrupt regulatory officials is a necessity for the growth of local pharmaceuticals in Nigeria and on the contrast minority (1%) of the local manufacturers/imported disagreed with the survey. See Figure 21a

The survey analysis shows that prosecutions of corrupt regulatory official's is one of the necessities in eradicating corruption in the system and propelling the growth of local manufacturing in Nigeria. It will also discourage corruption and as well, regulators will be afraid of corrupt practices for the fear of been prosecuted and jailed.

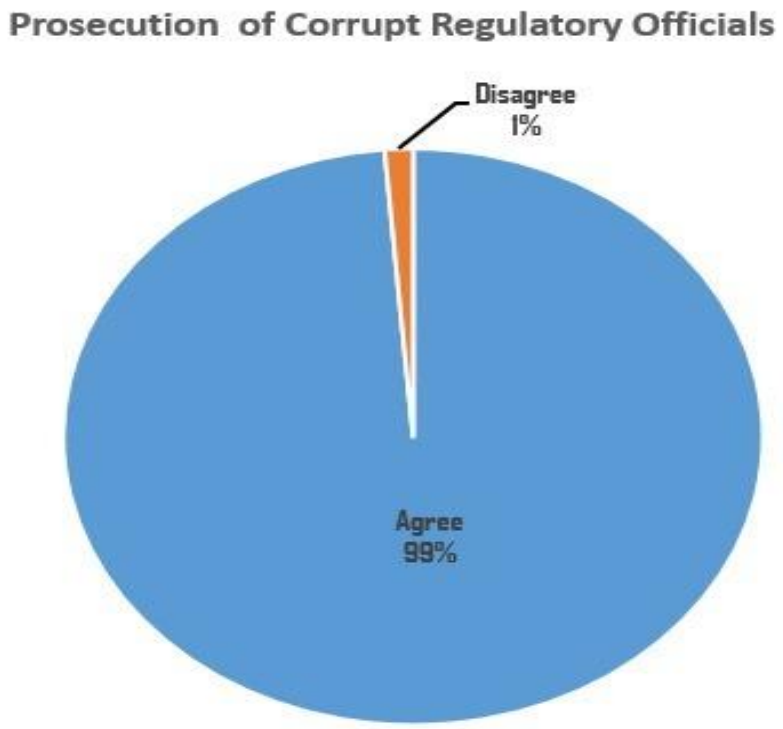

Figure 21a: Prosecution of corrupt regulatory officials in Nigeria pharmaceutical industry

Patronizing of Made in Nigeria Drug Products

The majority (99%) of the local pharmaceutical manufacturers/importers admitted that patronizing made in Nigeria drugs by the government is another factor that will yield to the growth of the local pharmaceutical industries. On the contrary, 1% of the local manufacturers/importers admitted being neutral. See figure 21b

It is evident as seen in the survey that patronizing local pharmaceutical products by the government will result to the growth of local manufacturing. Patronizing local drug manufacturers have led to the growth of the industry as prevalent in the developed countries where government buy mostly drugs produced in their own country. So, if Nigeria government can patronize made in Nigeria products that is made of international standard, then there is hope for the growth of the industry.

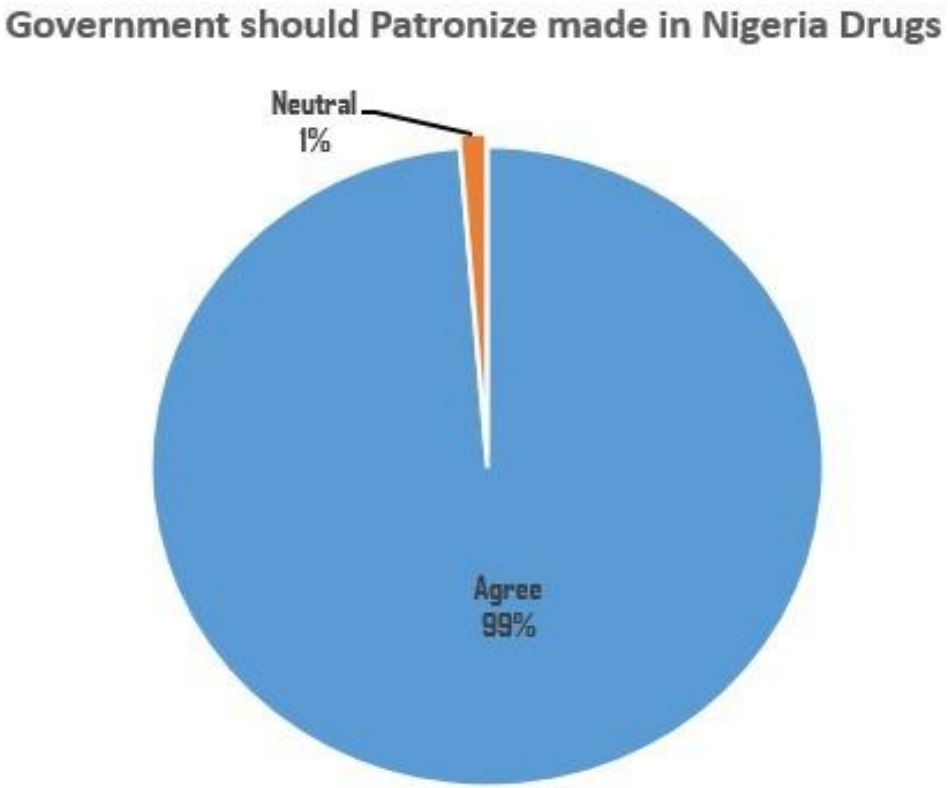

Figure 21b: Patronizing made in Nigeria Drugs

Establishment of CROs by the Government

Interestingly, 99% of the local manufacturers/importers admitted that the establishment of CROs will also encourage the growth of the local manufacturing by encouraging research of novel drugs. On the other side of the coin, 1 of the respondents admitted being neutral. See figure 21c

Furthermore, the survey confirms that the embellishment of CROs will yield to the growth of local manufacturing as recommended.

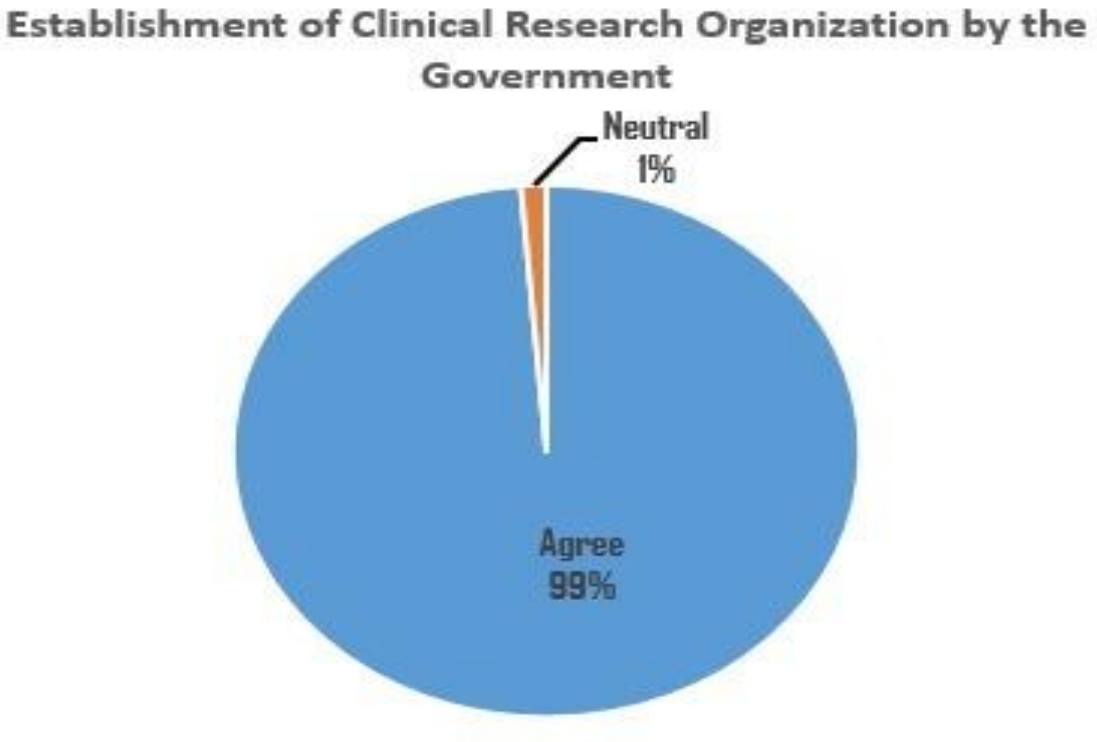

Figure 21c: Establishment of CROs by the Government

Investment in R&D by the Government

It was also interesting to know that all the local manufacturers/importers 100% agreed that investment in R&D by the government is a necessity for the growth of the local manufacturing as evident in the survey. See figure 21d

Research and development have remained one of the catalysts for the growth and development of the local drug manufacturing industry as prevalent in developed countries like USA, Ireland etc. It provides new jobs for the manufacturing industries that depends on the positive outcomes of R&D to grow and make profits. This manifests to the growth of the local drug manufacturing in Nigeria.

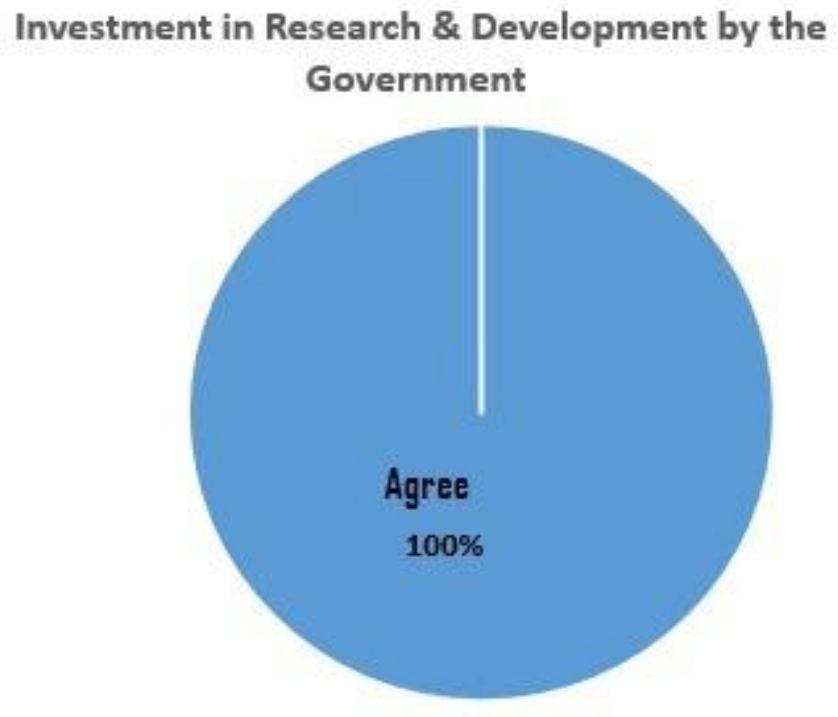

Figure 21d: Investment in R&D by the Government

Provision of Low Loan Interest Facilities by the Government

The entire 77 of the local manufacturers/importers admitted that the provision of soft loan facilities will encourage local manufacturing of drugs in Nigeria as evident in the survey. See figure 21e

The analysis of this survey x-rays the importance of soft loan facilities in the local pharmaceutical industry mostly from the government. It furthers shows that the industry is capital intensive and every drug manufacturer in the industry wants soft loans to boost their business.

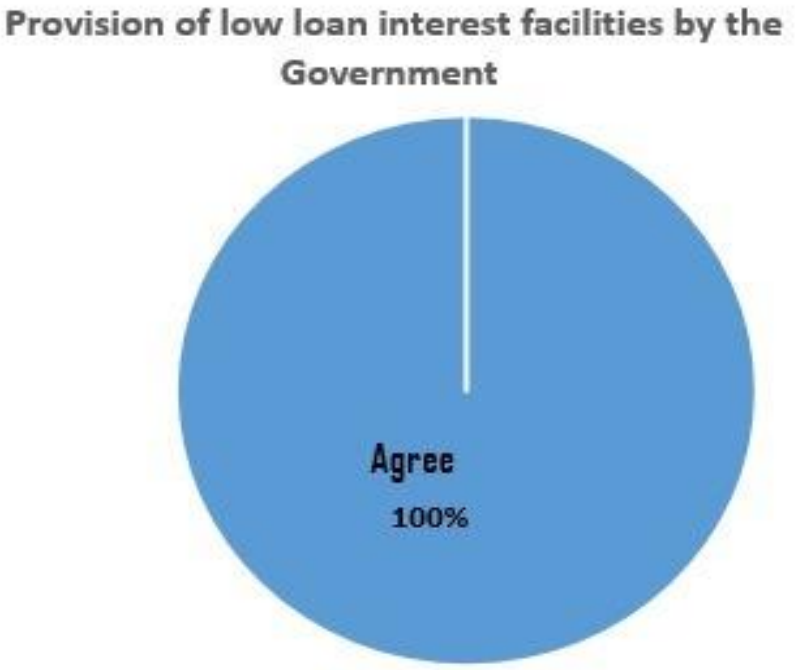

Figure 21e: Provision of soft loan facilities by the Government.

Provision of Tax Incentives and Subsidies

An overwhelming 99% of the local manufacturers/importers admitted that the provision of tax incentives and subsidies for locally produced drugs will encourage local manufacturing and will also encourage more importers of drugs to join local drug production. See figure 21f.

The provision of tax incentives and subsidies by the government is a very important avenue in promoting the growth of the local pharmaceutical industry in Nigeria. This is currently been practiced in countries like India and China and it have made them to be major players in the world pharmaceutical industry.

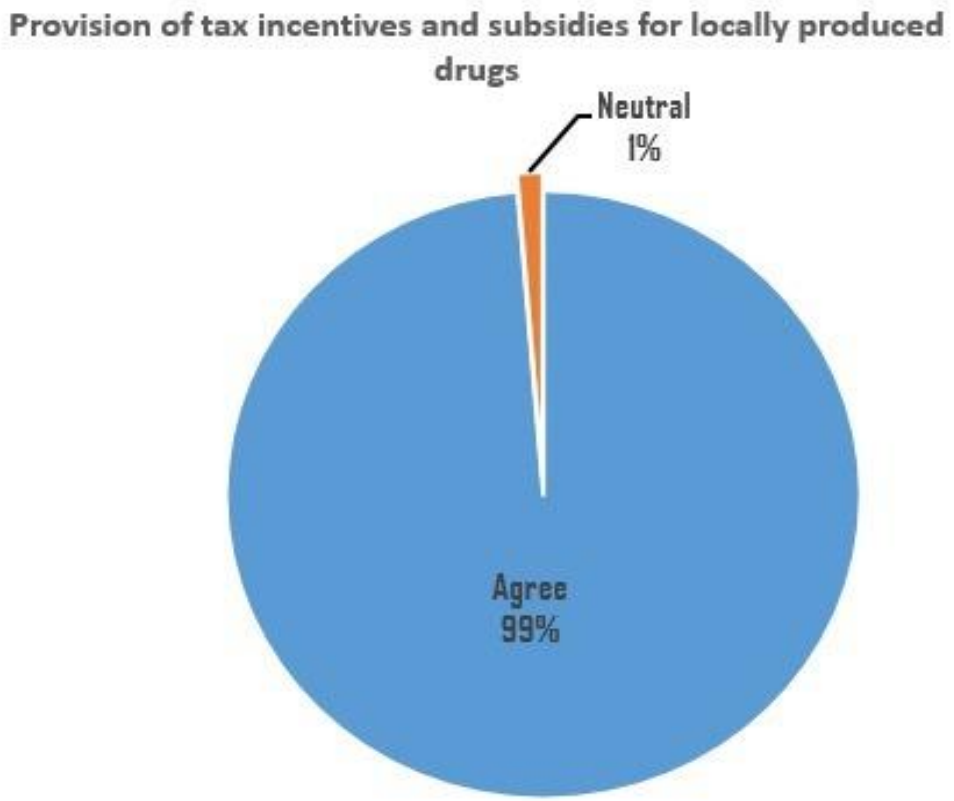

Figure 21f: Provision of tax incentives and subsidies for locally produced drugs.

Review Importation tariff for API and finished drug products respectively

To get the drug manufacturers/importers recommendation on the review of importation tariff for APIs and finished products. It was interesting to know that all (100%) the local manufacturers/importers want the government to review the importation tariff for APIs and finished products. See figure 21g.

The analysis show that all the local manufactures/importers want the government to review the importation tariff for APIs and finished products to favour their business. It is also evident that the local manufactures/importers are interested in the reviews for it to favour the drug importation part of their business that is been discouraged with high tariff by the government. In a similar way, high prices of drugs in Nigeria is associated with exorbitant tariff for API and finished products paid by importers/manufacturers.

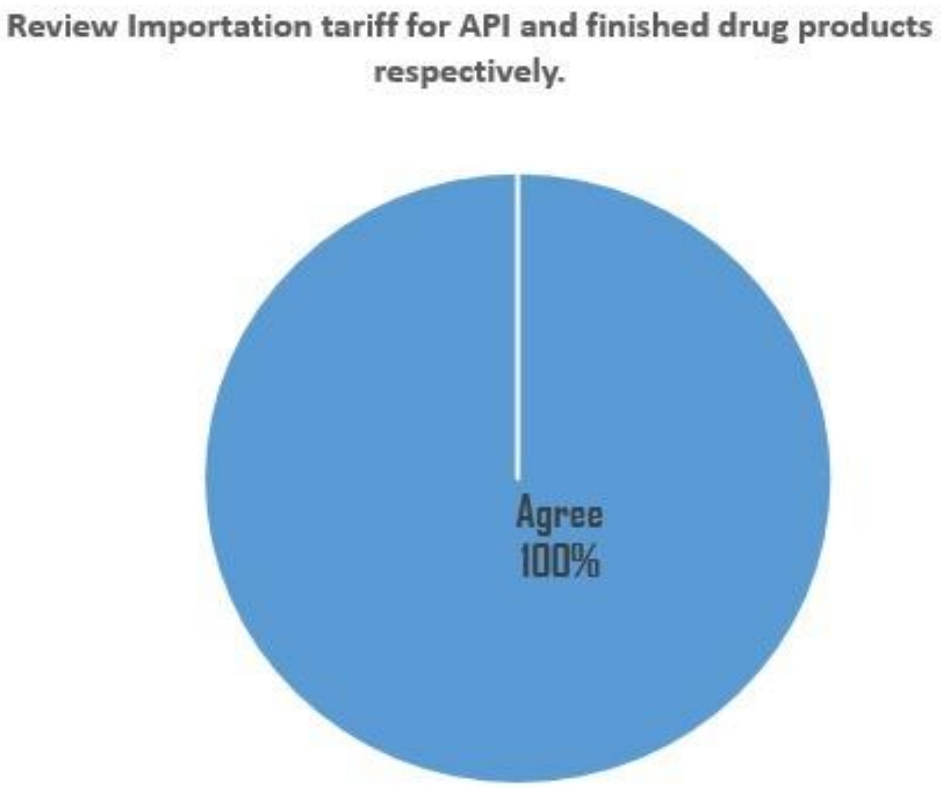

Figure 21g: Review of importation tariff for APIs and finished products

Review of the entire Drug regulations

As a follow up to question 21g majority (66%) of the drug manufacturers/importers agreed that reviewing of the entire drug regulations will encourage the local manufacturing. On the contrast 30% of the respondent disagreed with the above survey while 4% of the participant neither agreed nor disagreed. See figure 21h.

The above survey also shows that the already existing drug regulations is not encouraging local manufacturing/importation. It is evidenced that the regulations are weak and outdated with weak penalties that have encouraged the sale and distributions of fake/substandard drugs in Nigeria. This have resulted to an unfair competition between the local manufacturers/importers who compete with cheap drug with less or no APIs etc.

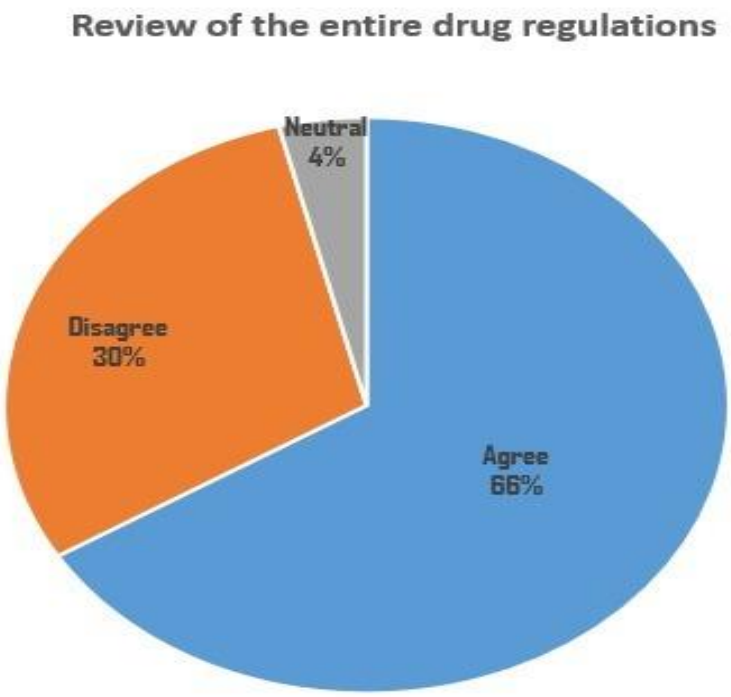

Figure 21h: Review of the entire drug regulations.

The analysis **on question 21a-21h** on the recommendation for the growth of the local manufacturing industry, the vital role of the government in changing the face of local pharmaceutical was x-rayed. The survey shows that without Government contributions in the industry, the journey in achieving efficient local manufacturing of drugs will be distorted. This is because manufacturing of drugs is capital intensive and cannot be actualized effectively by individuals owned companies for a population above 200 million people living in Nigeria. Therefore the local manufacturer's wants the prosecution of corrupt regulatory officials, patronizing of made in Nigeria Drugs by the government, Establishment of CROs by the Government, investment in research & development by the Government, provision of soft loan interest facilities by the Government, provision of tax incentives and subsidies for locally produced drugs, review of the drug regulations and finally review of importation tariff for APIs and finished drug products respectively.

4.8 Qualitative Analysis

4.8.1: Interview with the Pharmaceutical Society of Nigeria (PSN) President (33years in the pharmaceutical industry, with 18 years in local pharmaceutical manufacturing)

The author through the connection of his college alumni association was able to contact and schedule a 40mins zoom interview with the PSN president who shared his previous experience in the pharmaceutical regulatory arm of the government as former manufacturing association of Nigeria (MAN) Chairman, former pharmaceutical manufacturing group manufacturing association of Nigeria (PMG MAN), founding president of Neimeth international pharmaceutical Plc., an indigenous Nigeria pharmaceutical company and currently the PSN president. The aim of the interview is to explore the general view of PSN as part of the regulators of the pharmaceutical industry in Nigeria since 1927.

First and most, it was interesting to find out that the PSN president acknowledged that Nigeria imports 70% of their drugs while 30% are manufactured locally. While literatures reviewed in this research work reported that it is 70% and 25% respectively.

On the impacts of foreign CMOs on local drug manufacturing in Lagos Nigeria, which is one of the author objectives. On the positive impacts, the foreign CMOs have widen the scope of pharmaceuticals available in Nigeria. It has led to the classification of pharmaceutical markets in Nigeria into two sections, first the locally manufactured products and the imported pharmaceutical products. On the negative impacts of foreign CMOs, the CMOs are displacing local products because some of the products from Foreign CMOs are the replica of branded generics that are being produced locally. This creates additional pressure and competitions for the local industry. Secondly, most of the countries by which these products are coming from have a better pricing regime, conducive business environment, production subsidy from the government, benefit of large volume production that make the unit cost of production to be low. The above factors have made it difficult for the local pharmaceutical manufacturing companies in Nigeria to compete favourably with the foreign CMOs from China and India.

It is obvious that the negative impacts of CMOs have limited the growth of local pharmaceutical manufacturing in Nigeria and have remained a major factor that have contributed to the 75% dependency of foreign CMOs from India and China. But on the positive angle, Nigeria have benefited immensely from affordable drugs and availability of different therapeutic classes that have tremendously assisted the medicine need of Nigerians.

To answer the first research question, the author asked the impacts of drug importation regulations on local pharmaceutical manufacturing in Nigeria. The PSN president acknowledged that the importation regulatory framework of the Nigeria pharmaceutical industry has negatively affected the growth of local pharmaceutical manufacturing in Nigeria. First and foremost, the regulation has continued to encourage the influx of foreign pharmaceutical products and thereby limiting the growth of the local pharmaceutical manufacturing in Nigeria. Furthermore, he stated that the local regulations in Nigeria are not sufficient to support local manufacturing in Nigeria. Additionally, he stated that the enforcement of the importation regulations is abysmal both from the fact that the enforcement is lacklustre. Lastly, the frequent taxation from state and non-state regulatory actors. It is evidenced from the analysis that the importation regulations are not encouraging local pharmaceutical manufacturing.

On the second research question, the author asked whether the locally manufactured drugs in Nigeria have met the WHO/global standard. The PSN president stated that all the pharmaceutical products produced in Nigeria are approved by NAFDAC and fulfils all the international standards for quality, safety, and efficacy. This is because NAFDAC is not an originator of standards, they borrow standards from the already existing global template since medicine is a global business. But because of the high financial requirement to meet up with the WHO/global standards, it is only 3-4 companies in Nigeria have achieved the WHO/global standards while others are struggling because it is an expensive process. Irrespective of the fact that only few companies have fulfilled the WHO/global standard, local manufactures in Nigeria are producing quality of drugs measurable with international standard for quality, safety, and efficacy. But lacks sophistication in equipment's and production process which are the major prerequisite for attaining the WHO/global standards.

The above interview confirms that few of Nigeria companies have attained WHO/global standards while majority are yet to attain the standards. While the rest are producing quality drugs but lacks sophistication in equipment's as perquisite for actualizing WHO/global standards.

Additionally, to answer the third research question on whether drug importers are aware of the key regulations on drug importation in Nigeria and the need for its implementation. The PSN president stated that from his previous experience in pharmaceutical regulation and currently the PSN president, the pharmaceutical industry in Nigeria are aware of the key regulations on drug

importation because some of the regulations came from advocacy by the manufacturers and importers to make the environment to be conducive for business.

Finally, to be able to confirm directly from PSN as one of the regulators in the pharmaceutical sector and compare the previous literatures reviewed. The author asked whether the importation regulation requires amendment. The PSN president stated that all the pharmaceutical regulation in Nigeria requires holistic review because some of the regulation was carried over from when Lord Lugard was governor of Nigeria.

PSN President Recommendations for the Growth of Local Drug Manufacturing in Nigeria.

The regulators with the cooperation of the Federal Ministry of Health should set up a vision for the local pharmaceutical manufacturing to have a clear picture and direction on the future of the industry. Secondly, setting up the various strategies required to achieve the vision. This will cut across creating the enabling business environment for local manufacturing, establishing a strong regulatory framework, and lastly providing long term funds/supports for the local manufactures with single digit interest rate. Thirdly, implementing the existing drug regulations in Nigeria via partnership and collaboration between the pharmaceutical regulators like NAFADAC, SON, MAN etc. in carrying out their regulatory functions. Lastly, shutting down the open drug market in Nigeria to be able to regulate the activities of substandard and fake drugs smuggled from outside the country. The above recommendations show the vital roles of the government in propelling the growth of local drug manufacturing in Nigeria.

4.8.2: Interview with the Executive Secretary, Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN)

To be able to get the contributions of the pharmaceutical manufacturers group on the impacts of importation regulations on local manufacturing, the author was privileged to have a 10mins zoom interview with the executive secretary of the union.

The executive secretary shared his experience as a manufacturer for more than 15 years and as the secretary of the union. He stated that the importation regulations have impacted positively to the growth of the local pharmaceutical manufacturing with the imports provision list and low importation duty for raw materials. He further stated that the importation regulations are never

the limiting factor to the growth of the local pharmaceutical manufacturing but the inability of the government in implementing the already existing importation regulations remains the problem.

On the union recommendations for the growth of local manufacturing, he stated that Government should start to patronize made in Nigeria drugs, implements the existing importation regulations aggressively, increase the number of products in the import provision list, effective funding of the drug regulators, establishment of policies and incentives to promote local manufacturing, Government should set up basic infrastructures like road, water, power etc. to propel the growth of the industry, and finally provide access to FOREX for the importation raw materials.

4.8.3: Zoom interview with four senior directors of local pharmaceutical manufacturing

The author had zoom interviews with four senior directors of regulatory affairs department from different local pharmaceutical industry with a minimum of 10 years' experience in local pharmaceutical manufacturing in Nigeria. They gave consent for the zoom interview on the condition of an anonymous status.

On the impacts of drug importation regulations on local pharmaceutical manufacturing in Nigeria, the four directors first admitted that there is significant upgrade in NAFDAC operations with process automation that have made applications process to be easy and faster in the importation of APIs etc. In addition to this, the four directors admitted that there is low importation duty for APIs when compared to the 20% importation duty for finished pharmaceutical products. This agrees with previous literatures reviewed in this research work. Sadly, the corruption from some of the custom officials who extorts money from importers have remained a limitation. Thirdly, the four directors acknowledged that the importation of about 70% of drugs from China and India is rooted on the unconducive and harsh business environment that is being experienced by local manufacturers. Finally, they complained of multiple taxation from state and non-state actors from the government.

On the analysis of the above interview question, the four directors agreed that there are fair importation regulations in favour of the local pharmaceutical industry. Sadly, the frequent taxation and ineffective implementation of the stipulated importation regulations have discouraged local manufacturing and encouraging the importation of drugs which requires few taxations.

On the second research question to confirm the influence of foreign CMOs on local manufacturing. The four directors agreed that the foreign CMOs mostly from India and China have the APIs, manpower, machineries, conducive manufacturing environment, good policies, cheap labour, and power. All these factors have resulted to quality affordable drugs coming from India and China and have continued to limit the growth of local pharmaceutical manufacturing in Nigeria. On the contrary, two of the directors also pointed out that the unregulated environment for drugs meant for exports have geared the production of substandard and fake drugs which comes out to be cheap. This result to unfair competition with the drugs manufactured locally.

When the directors were asked for recommendations for the growth of the industry, they suggested that the government should create conducive atmosphere via tax breaks, incentive and soft loans with moratorium, provision of steady power, basic infrastructures, rearrangement of the drug market/drug distribution networks in Nigeria to stop sales of fake and substandard drugs, reduction of the bottle necks in the registration of new drug products, establishment of APIs manufacturing plants, reduction of custom duties, and finally financial empowerment of the drug regulators for effective regulations. They acknowledged the ₦1b loan with single digit interest rate, 3 years repayment period and 1-year moratorium recently approved by Federal Government of Nigeria for the health care sector.

As evidenced from the analysis above, there is fair drug importation regulations in place for the local drug manufactures which have encouraged the importation of APIs. Also, their inability to meet up with the medicine needs of Nigeria is rooted in the frequent taxation from the various government bodies which have affected their business negatively.

4.8.4: Zoom interviews with four Directors of Drug Importers in Nigeria

The author had zoom interviews with four senior management officials from different drug importing firms with a minimum of 15 years' experience in the importation drugs. They gave consent for the zoom interview on the condition of an anonymous status.

The four senior managers acknowledged that they are aware of the key regulations on drug importation in Nigeria which is currently discouraging the importation of drugs than its local manufacturing. For instance, they pay up to 10,000USD against the 1000USD for the inspections of new drug products outside the country.

On whether the CMOs from India and China produce quality drugs, they agreed that most of the CMOs from China produces quality drugs. While substandard and fake drugs are produced intentionally by importers on agreement with the CMOs to maximize profits.

The four senior managers admitted that high importation duties and harsh regulations is a major drawback to the growth of their business. They recommend that the government should support the importation of drugs that the local manufacturers does not have the capacity to produces, the regulators should close the open drug markets to discourage the sales of fake and substandard drugs, provision of soft loans and finally the Nigeria customs should automate their system to discourage bribery and corruptions.

Conclusion

As evidenced by the analysis, most of the local manufacturer's combines local drug manufacturing with its importation for the sustenance of their business since it is more expensive to manufacture drugs than its importation in Nigeria. The local manufacturers, PSN and PMGMAN admitted that the inability of the government in providing the enabling environment for local pharmaceutical manufacturing is among the factor that have discouraged local manufacturing of drugs. In addition to this they admitted that government regulations like high taxes and complex drug regulations have negatively affected the industry.

It is also interestingly to know that both the local manufacturer's, PSN president and PMGMAN secretary interviewed confirmed that most of the Nigeria importation regulations are ineffective/inconsistent and requires holistic review. On the contrary, the local manufacturer's want the government to adopt a more effective and stringent penalties for defaulters of drug importation regulation. For instance, imposing a more stringent penalties of the EDL to discourage the importation of drugs that are not in EDL list to promote local manufacturing of drugs.

Furthermore, majority of the local manufacturer's including the PMG MAN and PSN acknowledged that the activities of the CMOs from mostly India have yielded to the availability of cheap and affordable drugs in Nigeria and have negatively affected the growth of local pharmaceutical manufacturing. According to the PSN president, the CMOs from India have created additional pressure and competition for the local pharmaceutical manufacturing industries in Nigeria who lacks the conducive manufacturing environment as prevalent in India.

On the growth of the industry the PSN, PMG MAN and the local manufacturers recommended that the government have a major role to play by providing the conducive atmosphere for local pharmaceutical manufacturing. The PSN president recommended that the government in collaborations with NAFDAC should set up a goal for the local pharmaceutical industry. On contrary the PMG MAN secretary recommended that more attention should be given to implementation of the regulation than the creation of new policies and regulation.

Further conclusions are available in the next chapter as regard to the research questions stated earlier. Comparisons from the literature review and primary research findings are presented, with the conclusions and reflections on the conducted study.

CHAPTER 5: CONCLUSIONS

5.1 Answering the four main research questions:

1. Are the current regulations on drug importation in Nigeria responsible for the 25% production capacity of the local manufacturers which have made the remaining 75% of the drugs used Nigeria to come from China and India?

As evidenced by the survey and zoom interviews, the drug importation regulations in Nigeria requires holistic reviews because some of the drug regulation was carried over from when Lord Lugard was governor of Nigeria. But it is never a major factor that is responsible for the 25% production capacity of local pharmaceutical industries in Nigeria. As evidenced from the survey and interviews, most of the importation regulations like importation duties for raw materials have been subsidized to promote local manufacturing than importation. Further analysis from the survey and interviews shows that the existing importation regulations are ineffective and inconsistent.

In addition to this, the Nigeria pharmaceutical industry as evidenced from the survey and zoom interviews with the major stakeholder's, is been affected by frequent taxation from state and non-state regulatory actors who frequently visit their factories and inability to comply will result to the shuttling down of the factory. This have continued to be a major factor that discourage local pharmaceutical manufacturing while drastically encouraging importation which has lesser taxation from the state and non-state actors. In the same vein, the local pharmaceutical industries in Nigeria lacks basic infrastructures like power, good roads, water unlike their counterparts from India who has better pricing regime, conducive business environment, production subsidy from the government, benefits of large volume production that propels low unit cost in production.

The analysis shows that the government inability to supports the local pharmaceutical by providing the enabling environment as prevalent in India have resulted to the 25% production capacity of Nigeria pharmaceutical manufacturing industry.

2. Are the foreign contract manufacturing activities in India and China producing quality, efficacious and safety drugs for Nigerians?

The quantitative and qualitative analysis confirms that India and China supply the 70% of the drugs used in Nigeria. The analysis shows that they are supplying quality, efficacious and safety

drugs. The importers admitted that the Chinese and Indian CMOs have the capacity to produce quality drugs as confirmed from the series of drugs supplies that they have executed efficiently for the past two decades.

Further analysis shows that the inability of the Chinese and Indian government to effectively regulate the manufacturing and exports of drugs made for exports is one of the major factors that have contributed to the few fake drugs in the Nigeria market. As evidenced by the survey and zoom interviews, the above factors have created the vacuum for few of Nigeria drug importers to sign contract agreement to produce substandard and fake drugs meant for Nigeria market.

Furthermore, the quantitative and qualitative analysis shows that NAFDAC new regulatory policies like early confirmation of the drug quality, safety and efficacy by NAFDAC employed analyst in China and Indian have continued to discourage the production of fake and substandard drugs for Nigeria market.

3. Do the locally manufactured drugs in Nigeria meet the WHO/global standards for quality, efficacy, and safety?

It is evidence from the survey that all the local pharmaceutical industries in produce safety, quality, and efficacious drugs. This is because all pharmaceutical products produced in Nigeria are approved by NAFDAC who strive to maintain global standards for quality because medicine is a global business. Furthermore, they admitted that the local manufacturers in Nigeria are using the same pharmaceutical ingredients and process that is been used globally.

The interview with the PSN president shows that it is only 3-4 companies in Nigeria that have achieved the WHO/global standards while others are struggling because of it is an expensive process. Irrespective of the fact that only few companies have fulfilled the WHO/global standard, local manufactures in Nigeria are producing quality of drugs measurable with international standard for quality, safety, and efficacy. But lacks sophistication in equipment's which is the major prerequisite for the WHO/global standard for quality.

4. *Are drug importers aware of the key regulations on drug importation in Nigeria and understand the need for its implementation?*

From the responses obtained in the survey and confirmed by the PSN and PMGMAN, it is apparent that the local pharmaceutical manufacturers and importers are aware of the key importation regulations. This awareness is because of the direct interaction with the pharmaceutical regulatory bodies like NAFDAC, PCN, PSN, PMG-MAN. Secondly, it was evidenced in the questionnaire that most of the pharmaceutical are aware of the importation regulations

5.2 Comparing and contrasting results from primary and secondary research.

The above study on the impact importation regulations on local pharmaceutical manufacturing is an encouraging finding when compared to similar studies from the literature review. The secondary research admitted that there are series of available literature towards the impacts of different government regulations and policies towards the manufacturing industry except the pharmaceutical industries. (Ikoni Ogaji and Alawode, 2014)

Garuba et al., (2009) reported that there is corruption in the Nigeria pharmaceutical system especially in drug registration and inspection at the ports of entry in Nigeria. The above secondary research is in conformity with the primary research that explored and confirmed the prevalent of corruption among the regulatory officials which have resulted to the poor growth of the pharmaceutical industry in Nigeria.

The research work conducted by Muanya (2019b) discovered that the drug regulations and its enforcement are weak and outdated with less capacity and structures for its enforcement and responsible for the prevalence of fake drugs in Nigeria. The above secondary research work is in concurrent with the finding from the primary research that specifically discovered that the importation regulations are weak/outdated and lack enforcement.

Several literatures reviewed reported that there are series of CMOs from India and China supplying more of substandard and counterfeits drugs in Nigeria but on the contrast the primary research analysis shows that majority of the CMOs mostly from India supplies quality, safety and efficacious drug products especially to the Nigeria market. (Niaufre 2014, Akunyili 2005)

The secondary research confirms that the negative impacts of CMOs form India and China includes the availability of fake and substandard, embarrassment placing less confidence on the Nigeria

health sector. The primary research discovered that it has only impacted negatively to the growth of local pharmaceutical manufacturing. Akunyili (2005), Bate (2008).

On the positive impacts of CMOs from India and China, the secondary research work admitted that China and India supplies affordable medicines to developing countries like Nigeria because they lower the cost of their drugs in order to compete with the high income trading countries. On the contrary, the primary research agrees with the former but attributed the cheap and affordable drugs from China and India to the favourable business environment created by their government to promote drug manufacturing. Fortunak *et al*., (2016), Hafner and Popp, (2011)

5.3 Concluding thoughts

5.3.1 Contributions and limitations of the Research

The research was completed appropriately, with the generation of data from zoom meeting and survey questionnaire from 77 respondent from different local pharmaceutical industry in Nigeria irrespective of the current pandemic ravaging the world. The data generated from the study was adequately represented in form of tables and charts for clear interpretation and comprehension.

While most research papers focus on the impacts of different government regulations or policies on the manufacturing industry, this research paper focused specifically on the impacts of government importation regulations on local pharmaceutical manufacturing industry in Nigeria. Additionally, this research paper was able to reach out to 77 out of above 116 local pharmaceutical manufacturing industries who are also importers of drugs through the supports and collaboration of their unions (PMGMAN & PSN) who assisted in the distribution of the survey link to the respondent. Secondly, the PSN president and PMG MAN secretary who have been in the industry for 33years and 15years respectively were interviewed to make significant contributions to the local pharmaceutical industry in Nigeria that is yet to manufacture more than 25% of its drugs for a population above 200 million citizens.

The main limitation is the fact that all the local pharmaceutical manufacturers in Nigeria combines their business operation with drug importation to be able to survive the various draw backs associated with local drug manufacturing. So, it will be very difficult to conduct a research work specifically for the local pharmaceutical manufacturing without bias to favour drug importation

which is the major source of income to their business. Other factors like personal bias and inability to recall previous experience in the industry could impact data interpretation.

Finally, without the already established relationship the author has with some of the stake holders in the pharmaceutical industry, data generation for this research paper would be totally impossible because most of the pharmaceutical industries are not willing to share information with outsiders most especially researchers.

The outcomes of this research paper have clearly shown that the major problem that have affected the growth of the local pharmaceutical manufacturing in Nigeria is beyond the importation regulations, irrespective of the fact that it requires holistic reviews. But the problem cut across government inability to provide the conducive environment that propels local drug manufacturing with policies and regulations that will change the face of the industry positively.

5.3.2 Recommendations for future research

Further research work on the pharmaceutical industry in Nigeria should leverage on the government and non-government unions governing the pharmaceutical industry e.g. PSN, PCN, NAFDAC, PMGMAN etc., to reach out to either the drug importers or local pharmaceutical companies for efficient data generation.

Secondly, further research should be carried out with any senior director in the office of the regulatory department of NAFDAC to determine the challenges facing the regulation of the pharmaceutical industry in Nigeria.

Finally, further research should be carried out on the impacts of importation regulations on the importation of drugs in Nigeria to be able to balance local manufacturing and importation of drugs in Nigeria. Since Nigeria depends for the importation of drugs to meet up with their medicine needs.

5.4 Final Conclusions

In concluding this research work and its analysis on the impacts of drug importation regulations on local pharmaceutical manufacturing in Nigeria and after reviewing relevant literatures on the topic within the Nigeria pharmaceutical industry, the author found the process very informative and needful in solving the problem associated with the poor performance of the local pharmaceutical industry that have yielded to the 25% production capacity of the industry.

As deduced from the literature reviewed, “policy reversals and inconsistency in government policies” is one of the limiting factors of local pharmaceutical manufacturing. Secondly the issue of corruption and import duties that sometimes encourages and favours drug importers while suffering the local manufacturers, the government inability to patronize made in Nigeria drugs is also another limiting factor. Apart from inconsistency in government policy, the local producers are facing problems of poor infrastructure, lack of patronage and uncontrolled market space. The above constraints have continued to encourage drug importation than it local manufacturing.

Finally, the growth of the pharmaceutical manufacturing industry depends on the intervention of the Federal Government of Nigeria in providing the infrastructure’s, funds, policies and regulations which remains the key catalyst for the development of the industry and reducing the dependency on CMOs chiefly from India.

Currently, the Nigeria Government have approved ₦100 billion credit supports intervention for the health sector with 5% interest rate per annum valid until February 28, 2021. This is a great intervention especially for the local pharmaceutical industry. More positive actions are required from the government to minimize the over dependency on CMOs from India.

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Appendices

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Impact of drug Importation regulation on local pharma manufacturing in Lagos State Nigeria

Dear Respondent,

I am Mr. Osuchukwu Chisom Lawrence, a post graduate student of Griffith College Dublin Ireland and Innopharma labs. I am carrying out a dissertation on the impacts of drug Importation regulation on local pharmaceutical manufacturing in Lagos State Nigeria as part of requirement for the degree of masters (MSc) in pharmaceutical business and Technology.

The manufacturing of drugs in Nigeria started in 1944 with May and Baker Nigeria Plc. And currently Nigeria has more than 115 local pharmaceutical companies producing drugs in Nigeria. Irrespective of the increment in the number of drug manufacturers, the local pharmaceutical manufacturing industry in Nigeria has the capacity to meet only 25% of the local demand while the remaining 75% are derived from the importation of drugs predominantly from China and India.

To be able to address this issue, the author will study the positive and negative impact of the existing drug importation regulation on local pharmaceutical manufacturing in Lagos State Nigeria and the key challenges facing the industry. The study will equally evaluate whether drug regulation in Nigeria have contributed positively or negatively to the growth of the pharmaceutical industries in Nigeria.

Furthermore, the author will study the negative and positive influence of the foreign contract manufacturing organization on local drug manufacturing and quality of drugs in Nigeria. Recommendation will equally be given for the growth of the local pharmaceutical manufacturing in Nigeria.

The survey is made up of 16 multi choice questions in six sections that will take 5 minutes to complete with anonymous participants feedback's as a default setting from Microsoft forms. This makes the participant identity not to be seen by the researcher. Be rest assured that all data generated will be handled according to the Regulation (EU) 2016/679 of the European Parliament general data protection regulation.

Thanks in anticipation.

For further information please contact chisomosuchukwu@gmail.com (Researcher)
Rex Coghlan [rex.coghlan@griffith.ie]
Research Faculty
Dr. Prosper Anaedu [anaedup@innopharmalabs.com]
Research
Supervisor

* Required

1. Participant Agreement *

- [ ] I agree to voluntarily participate in this research study and give consent to have my responses used for this purpose

Next

Never give out your password. Report abuse

* Required

2. Please identify the category of your business? *

- ◯ Local Pharmaceutical Manufacturer
- ◯ Drug Importer
- ◯ Both

3. To what degree does these factors influence your pharmaceutical business? *

	Negative Influence	Positive Influence	Indifferent
Insufficient regulatory staff in NAFDAC and PCN	◯	◯	◯
Corrupt regulatory officials	◯	◯	◯
High taxes and/or Importation duty	◯	◯	◯
Complex drugs registration processes	◯	◯	◯

Back Next

* Required

Nigeria Essential Drug List [EDL]

4. Are you aware of the Nigeria Essential Drug List (EDL) and its regulatory policies? *

- Yes
- No
- Somewhat aware

5. Which of these is the stipulated punishment for importing or manufacturing drugs not contained in the essential drug list (EDL)? *

- ₦100,000 fine or imprisonment not exceeding 5 years
- ₦100, 000 and imprisonment not exceeding 5 years
- ₦500,000 or imprisonment not exceeding 10 years
- ₦500,000 and imprisonment not exceeding 10 years
- Other

6. Is the punishment selected above sufficient to deter defaulters of the EDL regulatory policies? *

- Yes
- No
- Indifferent

7. What penalty (fine and/or years of imprisonment) do you recommend for the importation of drugs not in the EDL? *

- ₦2,000,000 or 10 years imprisonment
- ₦2,000,000 and 10 years imprisonment
- ₦5,000,000 or 5 years imprisonment
- ₦5,000,000 and 5 years imprisonment
- Other

Back Next

* Required

Importation Policies and Penalties

8. What is your perception on Government implementation of the importation policies for pharmaceutical raw materials (APIs) and finished drug products? *

- ◯ Effective/consistent
- ◯ Ineffective/inconsistent
- ◯ Non-existent/very poor

9. What is the correct maximum period allotted for importation of newly registered drug products before starting local manufacturing/production? *

- ◯ 5 years
- ◯ 10 years
- ◯ 15 years
- ◯ 20 years

10. Do you think the allotted period you selected is sufficient to enable companies begin local manufacturing and production of same drug product? *

- ◯ Yes, I agree
- ◯ No, I disagree
- ◯ Other

11. If No, please recommend a sufficient maximum time period?

- ○ Other

12. What penalty do you recommend for the sale and distribution of counterfeit and fake drug? *

- ○ Death Penalty
- ○ Life Imprisonment
- ○ 20 years Imprisonment or ₦50 million fine
- ○ Other

13. Do you agree that the penalty selected is a sufficient punishment for defaulters? *

- ○ Agree
- ○ Disagree
- ○ Indifferent

Back Next

* Required

Contract Manufacturing Organizations (CMOs)

14. Which countries are the main location for CMOs for Nigerian pharmaceutical companies? (select all that apply) *

- [ ] China
- [ ] India
- [ ] USA
- [ ] Ireland
- [ ] Other

15. Please tick the effects of foreign CMOs on Nigeria's pharmaceutical industry? (select all that apply) *

- [ ] Circulation of fake and substandard drugs
- [ ] Availability of cheap and affordable drugs
- [ ] Availability of high quality drugs
- [ ] Poor growth of your business
- [ ] Other

Back Next

16. Please do you agree or disagree with the following recommendations for the growth of the pharmaceutical industry? *

	Agree	Disagree	Neutral
A. Prosecution of Corrupt Regulatory Officials	○	○	○
B. Government should Patronize made in Nigeria Drugs	○	○	○
C. Establishment of Clinical Research Organization by the Government	○	○	○
D. Investment in Research & Development by the Government	○	○	○
E. Provision of low loan interest facilities by the Government	○	○	○
F. Provision of tax incentives and subsidies for locally produced drugs	○	○	○
G. Review of the entire drug regulations	○	○	○
H. Review Importation tariff for API and finished drug products respectively.	○	○	○

Back Submit