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High Commission of India, Abuja (Nigeria)

Pharma and Alternative Medicine Industries in Nigeria



**A study on the Pharma and Alternative Medicine Industries in
Nigeria**

March 2020

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Section A Introduction

This report, which is a study on the pharma and alternative medicine industries in Nigeria was commissioned by The High Commission of India, Abuja Nigeria.

The study covers the pharma and alternative medicine industries in Nigeria and is expected to be distributed to discerning investors, especially among the Indian nationals and organisations directly or indirectly interested in the pharma and alternative medicine. The objective of the report is to offer high level information to potential investors in the sector and to those interested in offering ancillary services to the pharma and alternative medicine sectors of the economy.

The report is presented in three (3) parts:

- ❑ The Introduction
- ❑ The research findings; Nigeria's healthcare industry, the pharma and alternative medicine sub-sector, the regulatory environment, classes of generic drugs, pharma product registration and importation process etc;
- ❑ Summary of discussions/chats with some of the stakeholders in the industry.

The study covers the following:

- ❑ Overall health infrastructure in Nigeria;
- ❑ Important categories of generic drugs required in Nigeria;
- ❑ The existing regulations for importing pharma products to Nigeria and regulations for registering service drugs (with special reference to discriminatory provisions);
- ❑ Trends in pharma exports of other countries to Nigeria;
- ❑ Trends in Indian pharma exports of Pharma machinery exports to Nigeria and potential of the Nigerian pharma market;
- ❑ Tariff and non-tariff barriers being imposed by Nigeria on Indian pharma products;
- ❑ The analysis actions of other countries facing similar restrictions with respect to Nigeria;
- ❑ Comparison of Nigeria's regulations with other West African countries like Ghana, Benin and Chad;
- ❑ Key players in the Nigeria's regulatory system for health products and their respective roles (including key decision makers);
- ❑ Nigerian regulators for trade and manufacturing of alternative medicines such as Ayurveda, Homeopathy & Others;
- ❑ Inputs from India pharma companies already operating in Nigeria and Indian exporters of pharma products and their proposed suggestions;
- ❑ Any success stories of Indian pharma companies which could be emulated by others.

It is our view that this will elicit interest among potential investors who may then need to commission special investment study in either the pharma or alternative medicine sectors.

Thank you

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Executive Summary

The study on pharma and alternative medicines in Nigeria starts with a brief background of Nigeria, the seventh most populous nation on earth and the most populous black nation with a population of approximately 200 million, occupying an area of approximately 923,768 square kilometres (km²). Although Nigeria's economy remains the biggest in Africa both in terms of the population and vibrancy of the people and the level of endowment, the medical and healthcare infrastructure is generally considered to be low in terms of both human and infrastructure resources. While there are a few top-class/standard healthcare facilities in the country, they are often located in the city centres and usually out of reach of most of the citizens due to the attendant costs.

Due to the relatively low-quality healthcare available, it is not uncommon for those with the financial means to seek for medical care abroad in the name of medical tourism, with the aggregate spending on medical tourism by Nigerians hitting well over US\$1 billion per annum.

Pharma industry

The pharmaceutical industry is broadly grouped into the branded, generic and Over The Counter (OTC). Although there are over 130 pharmaceutical manufacturing companies in Nigeria, Nigeria still imports over 70% of its pharmaceutical need with all active pharmaceutical ingredients (APIs) used in Nigeria being imported, mainly from India and China. In most cases, both primary and secondary packaging materials are obtained locally.

Most of the machinery and virtually all the quality control analytical equipment are imported, mainly from Asia and Europe respectively and for the spares, most import, fabricate locally or buy from local dealers who also have imported same.

The products manufactured by these companies are all essential medicines, including antimalarial, antiretroviral, antibacterial, anticough, analgesic/antipyretic, vitamins, haematinics, antacids, medicines and could be in the form of liquid, capsule, tablet and/or topical formulations.

With a population of about 200 million, Nigeria unarguably constitutes potentially the largest domestic market in Africa. This potential is also increased for the pharmaceutical sector considering the large proportion of the population suffering from both infectious and non-infectious diseases.

Generic drugs

Malaria, HIV/AIDS, and tuberculosis, coupled with widespread malnutrition and poverty, represent a double burden of disease on the population. In addition, heart-related diseases are also on the increase. This explains why Over The Counter (OTC) medicines such as analgesics, antimalarials and multivitamins make up a large share of the market. Other common drugs include Antiretroviral (ARV) drugs, artemisinin combination therapy (ACT), anti-TB and antimicrobial anti-diarrheal drugs. According to Nigeria's Federal

Ministry of Health (FMoH), malaria is responsible for about 60 per cent of all outpatient attendance and about 30 per cent of all hospital admissions in Nigeria.

In terms of local production, the class of analgesics/ antirheumatics/ antipyretics has the largest share due to their affordability and availability in both urban and rural communities, as well as widespread use and misuse of these products for a wide range of symptoms.

Regulatory Matters

Technically speaking, there are various regulatory agencies relevant to the pharmaceutical industry in Nigeria. However, the pharmaceutical industry is essentially regulated by two agencies under the aegis of the Federal Ministry of Health and they include:

- ❑ The Pharmacists' Council of Nigeria (PCN); and
- ❑ The National Agency for Food and Drug Administration and Control (NAFDAC).

The Pharmacists' Council of Nigeria (PCN) regulates the practice of pharmacy and training of pharmacists, including the development of basic pharmacy curricula for degree programmes and mandatory continuing education programmes as well as regulating all premises where pharmacists practice their profession, including manufacturing facilities, retail outlets, and drug warehouses.

The National Agency for Food and Drug Administration and Control (NAFDAC) regulates all drug products and substances, chemicals, bottled water, packaged food as well as inspection of manufacturing premises.

The Traditional, Complimentary and Alternative Medicine (TCAM) is regulated primarily by the Nigerian Medical and Dental Council of Nigeria. The mandate of the council is to regulate the practice of Medicine, Dentistry and Alternative Medicine in the most efficient manner that safeguards best healthcare delivery for Nigerians. Although the Nigerian Medical and Dental Council of Nigeria exists, there are other regulators focused exclusively on the TCAM and they include:

- ❑ The Medical Rehabilitation Therapists Board of Nigeria, which functions as the regulator and licensor of Medical Rehabilitation Therapists in Nigeria and also responsible for regulating and controlling the training and practice of five different Medical Professions; and
- ❑ Traditional Medicine Council of Nigeria, which focuses mainly on facilitating the practice and development of traditional medicine and establishing guidelines for the regulation of traditional medical practice to protect the population from quackery, fraud, and incompetence.

Importation

In Nigeria, there is an existing regulation which states that no drug shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria

unless it has been registered in accordance with the provisions of ACT CAP F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.

The government agency responsible for this is the National Agency for Food and Drug Administration And Control (NAFDAC). The agency has sets of subsisting guidelines designed for local manufacturing or importation, registration and sales of Food items; Pharmaceutical drugs and medical devices; Herbal products and cosmetics; Vaccines and Biologics; Chemicals; Narcotic drugs, psychotropic substances and drug precursors; and Veterinary products.

It is estimated that over 70% of the pharmaceutical drugs used in Nigeria are imported. This has been the trend for well over two decades. Available data shows that the value of pharmaceutical imports into Nigeria has doubled between 2013 and 2018, with a widening deficit from US\$475 million to over US\$780 million. This means that based on current local production and demand, importation of pharmaceutical products will remain key to meeting growing local demand for medicines in Nigeria. Nigeria's import from India of Pharmaceutical products accounts for 31.3% of total pharma with import of medicaments (put up in packings for retail sale) constituting the bulk of the imports, in some cases, accounting for over 90% of total pharma imports.

Import restriction, Tariffs, Trade and non-trade barriers

In Nigeria, there are no limitations or restrictions on market access to the production, distribution or marketing of any product neither is there any law prohibiting the practice of any profession including pharmaceutical products or services except that required for many professional service firms which requires the possession of a minimum professional qualification to practice, which is often to regulate the practice and prevent quacks from practicing. This regulation applies to professionals such as the Medical Doctors/ Dentists, Accountants, Lawyers, Pharmacists, Estate Valuers etc.

For any import into Nigeria, the Nigeria Customs Service (NCS), under the Customs and Excise Management Act (CEMA) 2004, has the legal authority to act on behalf of Nigeria. However, for pharmaceutical products, there are additional requirements from National Agency for Foods, Drug Administration and Control (NAFDAC), the agency empowered by law to regulate the import, distribution, manufacturing of foods and drugs.

The regulation requires that all food, drug, cosmetic, and pesticide imports must be accompanied by certificates from manufacturers and certain national authorities, regardless of origin. These certificates attest that the product is safe for human consumption. Over the years, Nigeria's importation of pharmaceutical products from certain countries was marred by the prevalence of fake, adulterated and substandard products. This prompted the institutionalising of pre-export inspection agents in India, China and Egypt. to control export of substandard drugs to Nigeria. While there are no discriminatory non-tariff barriers on pharmaceutical products from any country, all pharmaceutical imports from China, India and Egypt must be

accompanied by this pre-shipment (pre-export) certificate to ascertain the quality, safety and efficacy of such products. These pharmaceutical imports must provide the Clean Report of Inspection and Analysis before shipment to Nigeria.

The institutionalisation of these pre-shipment agents has created business opportunities for those in these countries.

As a member of the Economic Community of West African States (ECOWAS), Nigeria grants tariff preferences to other ECOWAS member states. While this grants preferential rates to West African member states, it is not considered discriminatory on import of pharmaceutical products from other countries such as India.

Nigeria employs a combination of tariffs and quotas for the double purpose of taxing international trade for revenue generation and protecting local industries from highly competitive imports. Under the Customs and Excise Management Act (CEMA), the Nigerian President has the power to prohibit the importation of any specified goods irrespective of the country of origin. Nigeria has a list of some pharmaceutical products included in the import prohibition or restricted list and has no bearing to the country of origin.

Nigeria's regulations compared with other countries

Every country has regulations regarding the importation, distribution and manufacturing of pharmaceutical drugs. However, when it comes to importation, different countries use different trade and non-trade barriers to either stimulate the economy, protect local industries and/ or drive a definite economic agenda. A look at seven (7) countries (Nigeria inclusive) pharma regulations shows so many similarities in the regulation and legislations governing the pharma and alternative medicines. One key fact in each of these countries is the existence of legislation, regulations and policies that aim to ensure comprehensive control, production, importation, distribution and advertisement of pharma industries/ products.

Although these laws exist, there are minor differences when it comes to:

- Inspection of manufacturing sites/factories;
- Inspection of distribution channels;
- Control of prescription;
- Fast track/ Priority applications for the registration of pharmaceutical products;
- Product samples required for testing before registration; and
- Products for registration e.g. veterinary drugs, water, chemicals, cosmetics etc.

Succeeding in Nigeria as a Pharma company

To succeed as a pharma company in Nigeria, pharma companies should brace up to some of the challenges which may be regulatory in nature (product registration/ import process) or non-regulatory (double taxation, infrastructure and logistics challenge), market challenge etc.

Specifically, these pharma companies should be able to:

- ❑ Follow the money
- ❑ Develop an efficient structure to handle sales-and-distribution networks
- ❑ Build a strong local leadership team
- ❑ Be ready to fight back on fake and counterfeit products
- ❑ Define the opportunities in detail
- ❑ Understand the reality of patient journeys

Section B Introduction

Nigeria, with an area of approximately 923,768 square kilometres (km²), representing about 14% of land area in West Africa is the seventh most populous nation on earth and the most populous black nation with a population of approximately 200 million. Of this number, over 65% of the population is active between the ages of 15-50 years and less than 3% of the population being above 65 years. With a GDP per capita of US\$2,396.30 (December 2018), the Nigerian economy remains the biggest in Africa both in terms of the population and vibrancy of the people and the level of endowment. Over 40% percent of the population lives in the urban areas and 60.0% lives in the rural areas. Its population growth rate is 2.3%.

Administratively, the country has six geopolitical zones, 36 States and a Federal Capital Territory which ranks as a State, and 774 local Government Areas. There are at least 37 major cities and several relatively large rural communities that account for at least 60 per cent of the population but which are highly deprived of essential amenities.

Nigeria shares a 4,047 km border with Benin, Niger, Chad, and Cameroon and has a coastline of at least 853 km. Abuja, located at the centre is the administrative headquarters while Lagos, the former capital, still retains the commercial capital.

Nigeria is one of the most densely populated countries in Africa and plays significant role in influencing the economic activities in the neighbouring countries.

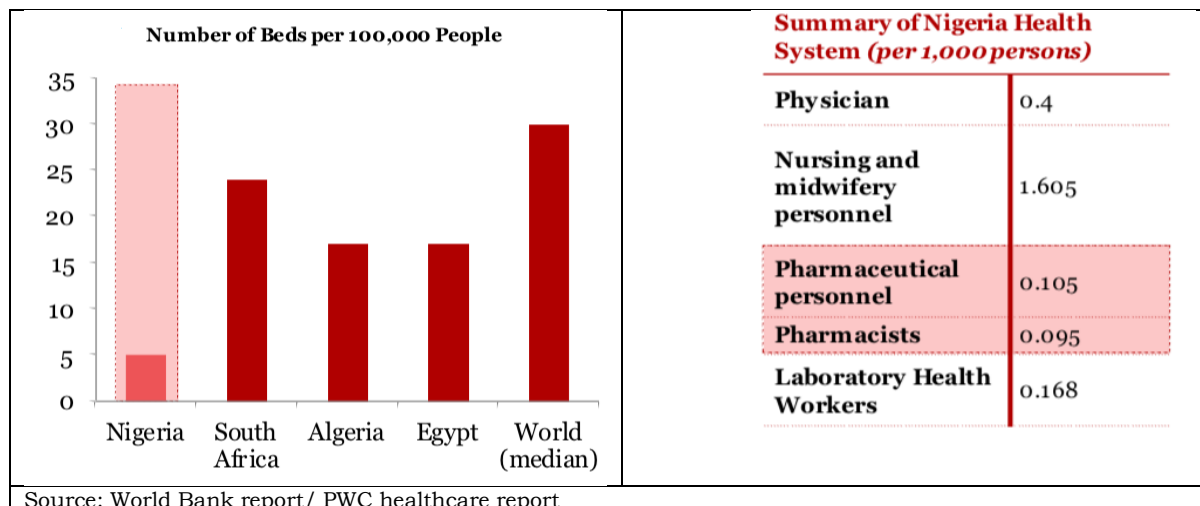
The Nigerian pharmaceutical sector is known to be complex as it involves numerous players such as manufacturers, importers, regulators, wholesalers and retailers, government ministries, professional associations/ societies and a host of other stakeholders.

Section C Health Infrastructure in Nigeria;

Nigeria's medical and healthcare infrastructure is generally considered to be low in terms of both human and infrastructure resources. The quality of healthcare system may not be classified as world class by any standard. Although there are a few top-class/ standard healthcare facilities in the country, the quality of healthcare is also considered low as some of these healthcare facilities often located in the city centres (often for economic reasons) and usually out of reach of most of the citizens due to the attendant costs. Apart from these standard healthcare facilities, there are other healthcare facilities often providing basic healthcare services.

Apart from the fact that top-class healthcare facility may not be easily available in many locations (except the big cities) there are other challenges such as lack of good local facilities, inability to perform procedures locally and high costs charged where services are available.

In terms of bed spaces, Nigeria has a low bed space per 100,000 population when compared to countries such as South Africa, Algeria and Egypt. The bed space per 100,000 population is also below the world's median. Kindly see the figure below.



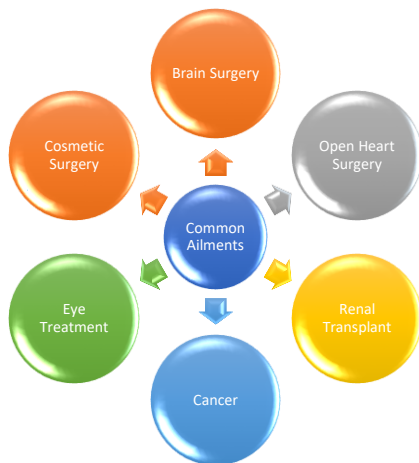
In terms of personnel, Nigeria has one of the lowest healthcare personnel per 1,000 persons. Among the healthcare workers, the Pharmacists and other Pharmaceutical personnel have the lowest personnel per 1,000 persons.

Medical Tourism

Due to the relatively low-quality healthcare available, it is not uncommon for those with the financial means to seek for medical care abroad in the name of medical tourism. While there are no reliable records to show amount spent by Nigerians annually on medical tourism, estimates by various health professionals and High Commissions in Nigeria conservatively put the figure at between US\$1 billion and US\$ 1.3 billion, with India as the top choice for medical tourism by Nigerians. Some of the reports also suggested that an average of US\$15,000 may have been spent by each of the patients. According to the Nigerian Sovereign Investment Authority (NSIA), Nigerians spend \$1 billion annually on medical tourism for a range of care needs of which 60% is reported to be across four key specialities: oncology, orthopaedics, nephrology and cardiology.

Some of the ailments that account for the need for medical tourism include:

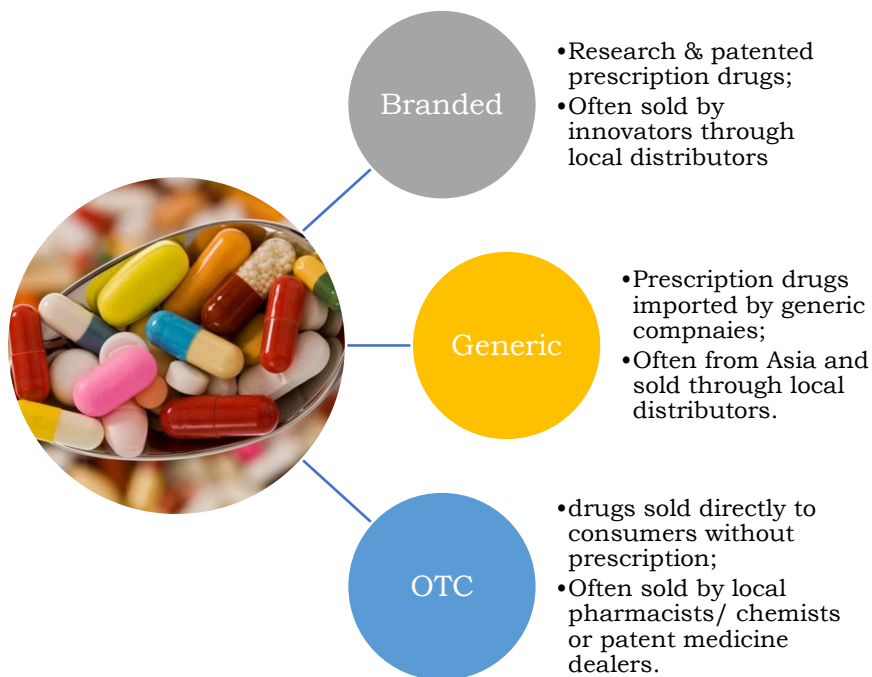
Figure 1 - Common Ailments for Medical Tourism



Pharmaceutical Industry

The pharmaceutical industry in Nigeria is broadly classified into three as shown in the diagram.

Figure 2 - Nigeria's pharmaceutical industry classification



Pharmaceutical Manufacturing

According to the Pharmaceutical Manufacturers' Group of the Manufacturers Association of Nigeria (PMG-MAN), there over 130 pharmaceutical manufacturing companies in Nigeria with less than ten (10) of them quoted on the Nigerian Stock Exchange (NSE).

With a population of approximately 200 million people, Nigeria depends on importation of pharmaceutical products and medical devices to meet local demand of drugs, medical devices and pharmaceutical equipment and machineries.

It is also estimated that over 70% of the pharmaceutical drugs used in Nigeria are imported. This has been the trend for well over two decades. Available data shows that the value of pharmaceutical imports into Nigeria has doubled between 2013 and 2018 (from US\$400 million to over US\$800 million), with a widening deficit from US\$475 million to about US\$780 million.

The implication is that based on current local production and demand, importation of pharmaceutical products will remain key to meeting growing local demand for medicines in Nigeria.

Local Pharmaceutical Production

In Nigeria just like any other country, the determining factor in the pharmaceutical business is usually the disease pattern. This explains the rationale why Over The Counter (OTC) medicines such as analgesics, antimalarials and multivitamins make up a large share of the market. Other common drugs include Antiretroviral (ARV) drugs, artemisinin combination therapy (ACT), anti-TB and antimicrobial anti-diarrhoeal drugs.

The pharmaceutical industry in Nigeria is vibrant, with over 130 pharmaceutical manufacturers employing about 500,000 persons in the manufacturing and distribution chain. The vast majority of jobs are however attributed to the distribution chain. It is also estimated that about 60 per cent of pharmaceutical production in the Economic Community of West African States (ECOWAS) is domiciled in Nigeria.

According to the Pharmacists Council of Nigeria (PCN), there were 128 registered drug manufacturers, 1,534 retail pharmacies, 724 drug distributors and 292 drug importers in Nigeria in 2010. Nigeria has a total of 14,607 public and 9,034 private healthcare facilities (National Bureau of Statistics). However, it has been estimated that there are over 10,000 unregistered patent and proprietary medicine stores, which are thought to sell over the counter (OTC) products only. Most such stores are located in villages and poor communities throughout the country, in areas where fully fledged pharmacies do not exist.

primary health facilities make up about 88% of the health facilities in Nigeria while the secondary and tertiary healthcare facilities make up 12% and 0.25% respectively.

Government owned health facilities account for 67% of the existing health facilities while the privately-owned facilities account for the balance of 33%.

Supply of inputs

All active pharmaceutical ingredients (APIs) used in Nigeria are imported, mainly from India and China. In most cases, both primary and secondary packaging materials are obtained locally. In addition, about 25 per cent of excipients are locally sourced.

Most of the machinery and virtually all the quality control analytical equipment are imported, mainly from Asia and Europe respectively. For the spares, some of the pharmaceutical manufacturing companies either source for their spare parts locally or fabricate it while most of them import directly. In terms of repairs, some of the manufacturing companies that use similar production machines supplied by the same foreign companies in India and in Europe, also join together to contract expatriate engineers and to organize workshops on machine maintenance.

Most of those employed in the local pharmaceutical manufacturing sector are semi-skilled workers who acquire their skills on the job and in in-house workshops organized by the industry. In many cases, expatriates are engaged to train local staff for limited periods of time in specific technical skills but most of the staff engaged by the local drug manufacturers at both management and technical levels are Nigerians.

The local pharmaceutical manufacturing industry is currently able to meet 25 per cent of local demand. Nigerian manufacturers produce liquid preparations, tablets, capsules, ointments, lotions, creams and ophthalmic preparations. The local pharmaceutical industries are able to meet domestic demand for some classes of medicines. According to the Pharmaceutical Manufacturing group of the Manufacturers Association of Nigeria, over 70% of the pharmaceutical products in Nigeria are imported.

The products manufactured by these companies are all essential medicines, including antimalarial, antiretroviral, antibacterial, anticough, analgesic/antipyretic, vitamins, haematinics, antacids, medicines and could be in the form of liquid, capsule, tablet and/or topical formulations.

Potential of the Nigerian pharma market

Nigeria with a population of about 200 million people constitutes potentially the largest domestic market in Africa. This potential is also increased for the pharmaceutical sector considering the large proportion of the population suffering from both infectious and non-infectious diseases. Estimates of the size of the pharmaceutical market in Nigeria vary significantly. However, each of the sources attest to the fact that the size of the total pharmaceuticals and healthcare products market is in excess of US\$600 million annually.

As far as 2009, the Pharmaceutical Manufacturing Group of the Manufacturers' Association of Nigeria (PMG- MAN) estimated the size of the total pharmaceuticals and healthcare products market to be in excess of US\$ 2 billion annually broken down as follows:

Table 1- PMG-MAN estimate of Nigeria's pharma market size

Description	Value
Prescription ethical pharmaceuticals	US\$500 million
Over The Counter (OTC) pharmaceuticals	US\$900 million
Biological products (including vaccines, insulin, interferon, etc.)	US\$100 million
Related healthcare and lifestyle products	US\$500 million

Within the same period, the Business Intelligence Services (BIS) estimated the pharmaceutical market in Nigeria at US\$ 600 million (2010) of which generic medicines accounts for the largest share of US\$ 418 million while Over The Counter (OTC) products make up US\$ 121 million. Patented products account for the balance of US\$ 61 million.

Frost & Sullivan estimated a pharmaceutical market value of US\$ 740 million in 2009. Out of this figure, US\$ 266.4 million were attributed to generic medicines, US\$ 177.6 million to branded products and US\$ 296 million to OTC products (Frost & Sullivan 2010).

Recent studies (2017) however put the estimated market size at US\$706 million with the OTC sector accounting for 43.1%, the Generic sector accounting for 38.9% and Patented products accounting for the balance of 12%.

McKinsey in 2016 also estimated the Nigerian pharmaceutical industry to be worth over US\$1.4 billion (38% non-communicable disease; 62% communicable disease) with the potentials of growing at about 9 percent a year over the next ten years to reach \$3.6 billion by 2026, making it as large as the South African market today. Over the same period, Nigeria could contribute between \$1.9 billion and \$2.2 billion to pharma sales growth with 55 percent of it coming from prescription drugs.

Beyond that, Nigeria also provides 60 per cent of the health products consumed in the Economic Community of West African States (ECOWAS) by volume (PMG-MAN, 2010) and, with an estimated population of about 700 million, the ECOWAS sub-region represents additional market potential.

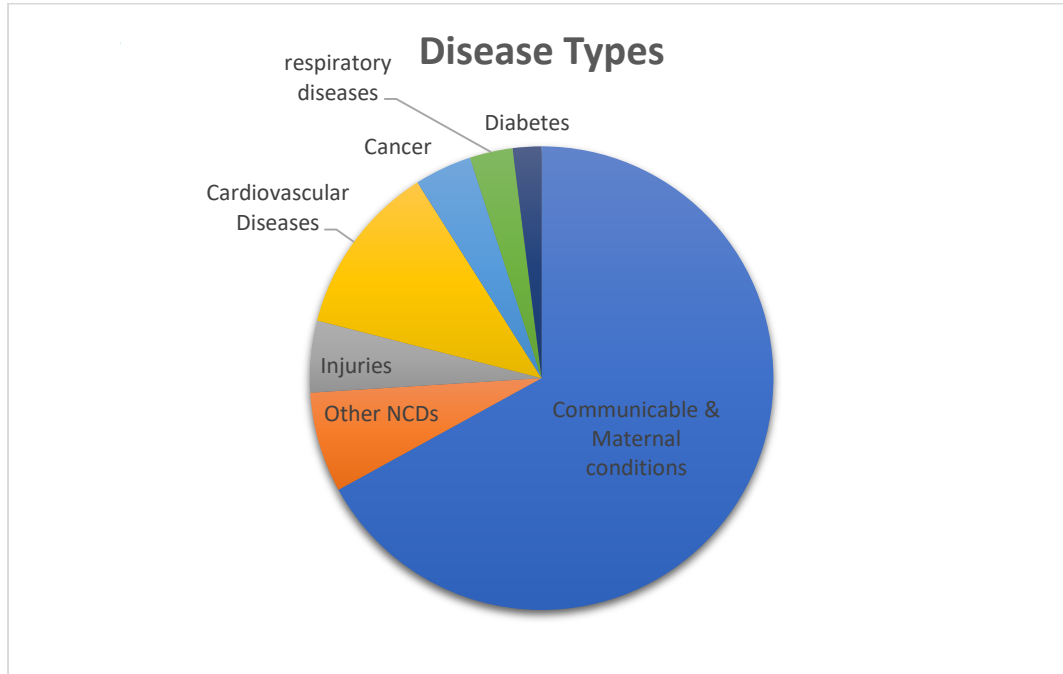
While it is agreed that the market size is well beyond these figures, it is difficult to put the exact size of the market primarily because healthcare spending in Nigeria is predominantly a private affair, with out-of-pocket spending accounting for over 70% of total health expenditure. This is also compounded by the fact that some pharmaceutical manufacturing companies often decline to disclose their production details to third parties either for fear of competitors or for tax management purpose.

Section D Categories of generic drugs required in Nigeria;

As is the case globally, the determining factor in the pharmaceutical business is usually the disease pattern. In Nigeria, Malaria, HIV/AIDS, and tuberculosis, coupled with widespread malnutrition and poverty, represent a double burden of disease on the population. In addition, heart-related diseases are also on the increase. This explains why Over The Counter (OTC) medicines such as analgesics, antimalarials and multivitamins make up a large share of the market. Other common drugs include Antiretroviral (ARV) drugs, artemisinin combination therapy (ACT), anti-TB and antimicrobial anti-diarrheal drugs.

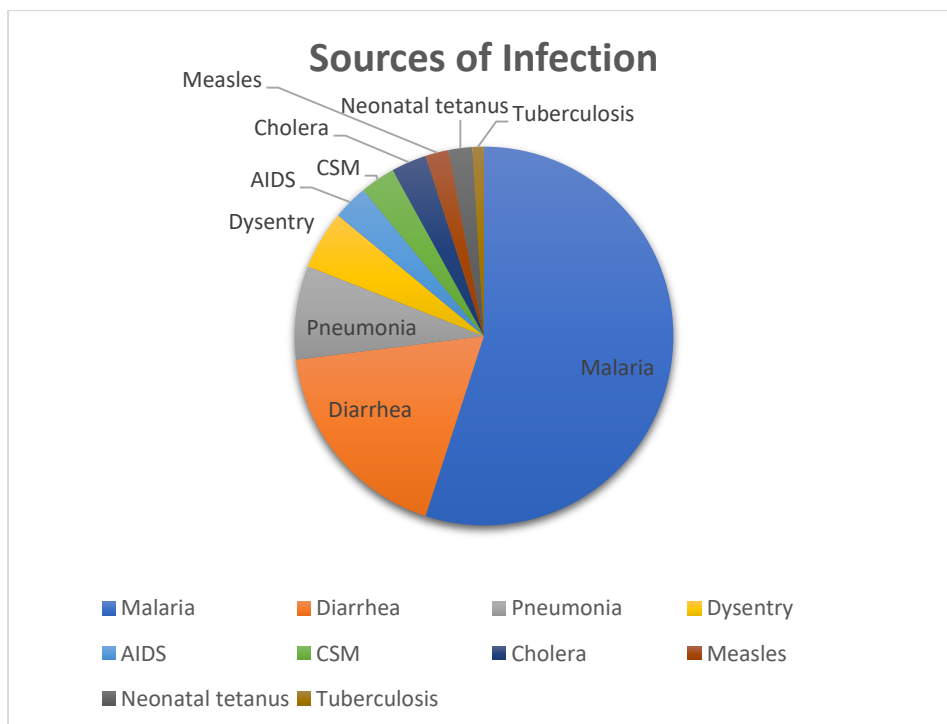
Historical data shows that various diseases and ailment account for high morbidity and mortality in Nigeria. Some of these include:

Figure 3 - Disease Type



In Nigeria, the main sources of mortality include malaria, diarrhea, pneumonia and dysentery.

Figure 4 - Infection sources in Nigeria



The chart below shows some of the important generic drugs required in Nigeria.

Figure 5 - Important Generic Drugs in Nigeria



According to Nigeria’s Federal Ministry of Health (FMOH), malaria is responsible for about 60 per cent of all outpatient attendance and about 30 per cent of all hospital admissions in Nigeria. It also accounts for over 300,000 deaths annually. It is estimated that at least 10 per cent of all childhood deaths are due directly to malaria and up to 25 per cent indirectly.

Undoubtedly, malaria is one of the principal causes of morbidity and mortality in Nigeria and imposes an enormous socio-economic burden on the country. Artemisinin Combination Therapy (ACT) is the first line treatment in accordance with the national malaria treatment guidelines.

In terms of local production, the class of analgesics/ antirheumatics/ antipyretics has the largest share due to their affordability and availability in both urban and rural communities, as well as widespread use and misuse of these products for a wide range of symptoms.

The estimated market share of the various therapeutic classes of medicines locally produced in Nigeria are indicated in the table below:

Table 2 - Drug types and market share

Name	Market Share
Analgesics/Antirheumatic/ Antipyretics	25%
Antibiotics + Antibacterials	15%
Multivitamins + Haematinics	15%
Antimalarial Medicines	14%
Antihypertensives	8%
Cough and cold preparations	5%
Antiretroviral medicines	6%
External/ Topical preparations	5%
Anti TB medicines	4%
Others	3%
Total	100%

It is good to mention that:

- ❑ Some drug manufacturers have diversified into other products such as bottled water, packaged foods, nutraceuticals, and cosmetics with some of them setting up subsidiaries for such purposes.
- ❑ Other therapeutic classes are mainly imported and not produced locally.

Section E Regulatory Environment

1. Introduction

Technically speaking, there are various regulatory agencies relevant to the pharmaceutical industry in Nigeria and they include:

Regulatory Agency/ 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.
Medical and Dental Council of Nigeria	Regulates the practice of medical and dentistry practice, including traditional and alternative practice.

2. The Pharmaceutical Industry

In Nigeria, the pharmaceutical industry is essentially regulated by two agencies under the aegis of the Federal Ministry of Health and they include:

- ❑ The Pharmacists' Council of Nigeria (PCN); and

- ❑ The National Agency for Food and Drug Administration and Control (NAFDAC).

The Pharmacists' Council of Nigeria (PCN) regulates the practice of pharmacy and training of pharmacists, including the development of basic pharmacy curricula for degree programmes and mandatory continuing education programmes. The PCN also regulates all premises where pharmacists practice their profession, including manufacturing facilities, retail outlets, and drug warehouses. Thus, PCN inspects the premises to ensure compliance with Good Manufacturing Practice (GMP) and approves the premises for pharmaceutical manufacturing.

The National Agency for Food and Drug Administration and Control (NAFDAC) regulates all drug products and substances, chemicals, bottled water and packaged food. As NAFDAC also inspects the manufacturing premises to ensure that the facilities are satisfactory for production of the specific products, there is a need for the harmonization of Good Manufacturing Practice (GMP) inspections of manufacturing facilities as well as of human resource development planning by both PCN and NAFDAC.

In 2006, the West African Drug Regulatory Authorities Network (WADRAN) was established with the broad objective of harmonising food and drug regulations within the ECOWAS sub-region.

A. PHARMACISTS' COUNCIL OF NIGERIA (PCN)

The Pharmacists Council of Nigeria (PCN) is a statutory organ of the Federal Government of Nigeria, set up pursuant to decree 91 of 1992 under the supervision of the Federal Ministry of Health for the purpose of the regulation and control of practice of Pharmacy, determining professional standards in Pharmacy and securing the establishment and maintenance of registers of Pharmacists.

The PCN is the main Pharmacy regulatory body in Nigeria responsible for registration and licensure of all Pharmacists, Pharmaceutical Premises (Manufacturing, Importation, Distribution, Wholesale, Retail, Hospital Pharmacies) as well as issuance of Permit to Pharmacy Technicians and registration and Licensure of Patent and Proprietary Medicine Vendors.

Key roles include:

- ❑ Determines what standard of knowledge and skill are to be attained by persons seeking to become Pharmacists in Nigeria;
- ❑ Establishes and maintains a register of pharmacists and secures the publication from time to time of the list of those names as entered in the register;
- ❑ Issues pharmacists Oath and Code of Ethics;
- ❑ Appoints pharmaceutical inspectors to ensure the enforcement of the provisions of the law by inspection and monitoring of premises where pharmaceutical endeavours take place; and

- ❑ Maintains a register of Pharmacy Technicians.

B. NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

The National Agency for Food and Drug Administration and Control (NAFDAC) is a federal agency under the Federal Ministry of Health that is responsible for regulating and controlling the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, chemicals and packaged water in Nigeria.

<http://www.nafdacnigeria.org>

NAFDAC was formed to checkmate illicit and counterfeit products in Nigeria. One of its goal is to eliminate counterfeit pharmaceuticals, foods and beverages products that are not manufactured in Nigeria and ensuring that available medications are safe and effective. The governing council of NAFDAC is headed by a chairman and other members appointed by the president on the recommendation of the Minister of Health. Other council members are:

- ❑ The permanent secretary of the Ministry of Health
- ❑ The director-general of NAFDAC
- ❑ Standard Organization of Nigeria (SON)
- ❑ National Institute for Pharmaceutical Research and Development (NIPRD)
- ❑ The chairman of the Pharmacists Council of Nigeria (PCN)
- ❑ The chairman of the National Drug Law Enforcement Agency (NDLEA)
- ❑ A representative each of the Pharmaceutical Group and the Food and Beverages Group of the Manufacturers' Association of Nigeria.
- ❑ Three people from the general public are also represented on the council.

Functions of NAFDAC

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

- ❑ Regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of drugs, cosmetics, medical devices, packaged water and chemicals;
- ❑ Conduct appropriate tests and ensure compliance with standard specifications designated and approved by the council for the effective control of quality of food, drugs, cosmetics, medical devices, packaged water, and chemicals;
- ❑ Undertake appropriate investigation into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water and chemicals and establish a relevant quality assurance system, including certification of the production sites and of the regulated products;
- ❑ Undertake inspection of imported foods, drugs, cosmetics, medical devices, bottled water, and chemicals and establish a relevant quality assurance system, including certification of the production sites and of the regulated products;
- ❑ Compile standard specifications, regulations, and guidelines for the production, importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water, and chemicals;

- ❑ Undertake the registration of food, drugs, medical devices, bottled water and chemicals;
- ❑ Control the exportation and issue quality certification of food, drugs, medical devices, bottled water and chemicals intended for export; and
- ❑ Establish and maintain relevant laboratories or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions;

NAFDAC envisions that by making these functions known, that its actions will be apparent “in all sectors that deal with food, cosmetics, medical devices, bottled water, and chemicals to the extent of instilling extra need for caution and compulsion to respect and obey existing regulations both for healthy, living and knowledge of certain sanctions or default.

C. Professional Associations

The Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN)

PMG-MAN is the umbrella organization for drug manufacturers in Nigeria and has over 100 local pharmaceutical companies as members although not all indigenous drug manufacturers belong to the Group. In order to qualify as a member, a company must have and utilize manufacturing facilities for the production of drugs and medicines from local and imported raw materials. It must be a member of the Manufacturers Association of Nigeria (MAN) and be duly registered for drug manufacture by the PCN and NAFDAC.

The company must be seen to uphold the principles of Good Manufacturing Practice (GMP).

The objectives of PMG-MAN include:

- ❑ Promoting the manufacture of high quality finished medical products and raw materials in accordance with Good Manufacturing Practice (GMP)
- ❑ Improving the standards of pharmaceutical manufacturing in Nigeria
- ❑ Creating a forum for interaction and understanding between PMG-MAN and organizations within the same field
- ❑ Promoting and influencing drug policy with regard to industrial, labour, social, legal training and technical matters, etc.
- ❑ Developing and promoting the contribution of drug manufacture to the national economy through representations to all relevant government bodies

The West African Pharmaceutical Manufacturers Association (WAPMA)

The West African Pharmaceutical Manufacturers Association (WAPMA) was launched in Ghana in October 2005. Its objective is to promote pharmaceutical business, research collaboration and to serve as a credible body for interaction with ECOWAS and international development partners. Some of its main objective is to:

- ❑ Promote the manufacture, marketing and distribution of high quality pharmaceuticals in accordance with GMP within the West African sub-region.

- ❑ Provide an information network and a system of cooperative assistance with pharmaceutical manufacturing and marketing companies and associations at the national, regional and international levels; and
- ❑ Represent the common interests of its members at the regional and continental levels.
- ❑ Inform its members of trends, developments and implications of any scientific, legal and technical issues impacting the pharmaceutical industry.

Pharmaceutical Society Of Nigeria (PSN)

This is the umbrella association of all Pharmacists in Nigeria and consists of a National Headquarters with chapters in each State of the Federation. Website is: <http://www.psnigeria.org>

Association of Community Pharmacists Of Nigeria (ACPN);

This is a body of all Pharmacists providing Pharmacy services in the Community setting in Nigeria and often includes those involved in wholesale, retail and dispensing of pharmaceutical products in various communities.

Other stakeholders in the pharmaceutical regulatory system for health products include:

- ❑ Nigerian Association Of Hospital Pharmacists (NAHP)
- ❑ Nigerian Association Of Lady Pharmacists (NALP)
- ❑ Consumer Protection Council of Nigeria (CPC)
- ❑ Standards Organisation of Nigeria (SON)
- ❑ National Drug Law Enforcement Agency (NDLEA)
- ❑ National Institute for Pharmaceutical Research and Development (NIPRD)
- ❑ Pharmaceutical Manufacturers Group of Manufactures Association of Nigeria (PMG-MAN)
- ❑ Consumer Association of Nigeria
- ❑ Association of Food, Beverage and Tobacco Employees of Nigeria (AFBTE)
- ❑ Patent and Proprietary Medicine Dealers Association (PPMDA)

3. Traditional/ Complementary and Alternative Medicine (TCAM)

Over the last few decades, there has been a considerable and increasing interest worldwide in Traditional medicine/ Complementary and Alternative Medicine (TCAM) particularly in herbal products. The interest may not be unconnected with the advocacy of The World Health Organization (WHO) on the important role of alternative and traditional medicines in preventive, promotive and curative health, especially in developing countries. The WHO has also been encouraging member states to support traditional medicines to and plan for, formulation of policies with appropriate regulations (WHO, 2001).

Major categories of Traditional/Complementary and alternative medicines (TCAM) in vogue in the developing and developed countries are categorized as:

- ❑ Whole body systems (Ayurveda, homeopathy, Unani, and Traditional Chinese Medicine);
- ❑ Mind–body medicine (meditation, prayer, mental healing);
- ❑ Biologically based therapies (use of natural substances, such as herbs, foods, vitamins, dietary supplements, herbal products);
- ❑ Manipulative and body-based practices (massage); and
- ❑ Energy medicine (Reiki) (Shaikh et al., 2009).

In Nigeria, the traditional medicines have been a strong part of the country’s cultural heritage and have continued to play a significant role in providing health care to a large part of the population. Various studies have shown that over 70% of the Nigerian population have at some point used at least one form of Traditional medicine/ Complementary and Alternative Medicine (TCAM). Despite the statistics, there has been lack of concerted efforts for proper utilization of traditional medicines in the health care system. While a lot of people seem to have embraced the traditional/ alternative medicines, some still view it as an option available to the low and middle income earners, those in the rural settings and those without proper access to modern healthcare facility.

In the last few decades, despite the various actions, policies and statements aimed at promoting Traditional/Complementary and alternative medicines (TCAM) in Nigeria, the level of progress of their implementation has been sluggish primarily because some of these policies have not been able to address the challenges/ concerns related to traditional medicines such as recognition, uniform quality standard, drug availability, education standards, evidence based research, safety and efficacy, rational use, herbal and drug interactions, inadequate understanding of socio-cultural context of their practice and usage, protection of intellectual property rights of knowledge holders, assuring sustainable natural resource use, regulation and capacity building of non-formal practitioners, developing appropriate methodologies for evaluation, resolving conflicts with mainstream medicine.

Although formal legislation promoting traditional medicines dates back to only 1966, informal interaction between the Government and traditional medicine practitioners can be traced back to the 19th century.

The table below shows, from a historical perspective, efforts at regulating the TCAM.

1966	The Ministry of Health authorized the University of Ibadan to conduct research into the medicinal properties of local herbs.
1970s	Continuous research, conferences and training programmes.
1980	Establishment of policies to accredit and register traditional medicine practitioners and regulate the practice of traditional medicine.
1984	The Federal Ministry of Health established the National Investigative Committee on Traditional and Alternative Medicine.

1988	Committee to research and develop traditional and complementary/ alternative medicine was formed by the Federal Ministry of Science and Technology.
1988	The Nigerian Medical and Dental Practitioners Act of 1988 was established. The Act forbids the practice of medicine or dentistry by unregistered practitioners, specifically the issuance of death certificates, performance of post-mortems, or certification of leprosy or mental disability.
1988	Registration requirements for chiropractors and osteopaths are outlined in the Medical Rehabilitation Therapists (Registration, etc.) Decree 38 of 1988
1992	Creation of the National Primary Health Care Development Agency with a broad mandate concerning health matters, including the endorsement of traditional birth attendants.
1994	All state health ministries were mandated to set up boards of traditional medicine in order to enhance the contribution of traditional medicine to the nation's official health care delivery system.
1997	The National Traditional Medicine Development Programme was established.
2000	The Traditional Medicine Council of Nigeria Act was proposed
2017	Centre for research in Traditional Complementary and Alternative Medicine was established.

Regulatory situation

The National Traditional Medicine Development Programme was established in 1997. Since then, the Federal Ministry of Health has been instituting measures to formally recognize and enhance the practice of traditional medicine. These measures include:

- ❑ The constitution and inauguration of the National Technical Working Group on Traditional Medicine;
- ❑ Development of policy documents on traditional medicine, including the National Policy on Traditional Medicine, National Code of Ethics for the Practice of Traditional Medicine, the Federal Traditional Medicine Board Decree, and Minimum Standards for Traditional Medicine Practice in Nigeria; and
- ❑ Advocacy for traditional medicine at all levels and in relevant forums.

Medical and Dental Council of Nigeria

The Medical and Dental professions in Nigeria are regulated by the Medical and Dental Practitioners Act Cap 221 (now Cap M8) Laws of Federation of Nigeria 1990 which sets up the Medical and Dental Council of Nigeria with the following mandates:

- ❑ Regulation of training in Medicine, Dentistry and Alternative Medicine in Nigeria
- ❑ Regulation of Medical, Dental and Alternative Medicine practice in Nigeria.
- ❑ Determination of the knowledge and skills of these professionals.
- ❑ Regulation and control of Laboratory Medicine in Nigeria.

The mandate of the council is to regulate the practice of Medicine, Dentistry and Alternative Medicine in the most efficient manner that safeguards best healthcare delivery for Nigerians.

In 1992, (via Decree No. 78 of 1992), the functions of the Medical and Dental Council of Nigeria were expanded to include supervising and controlling the practice of homeopathy, and other focus of alternative medicine (naturopathy, acupuncture and osteopathy)

The Nigerian Medical and Dental Practitioners Act of 1988 forbids the practice of medicine or dentistry by unregistered practitioners, specifically the issuance of death certificates, performance of post-mortems, or certification of leprosy or mental disability. However, traditional medical activities are protected by a provision in Section 17.6, which reads as follows:

“Where any person is acknowledged by the members generally of the community to which he belongs as having been trained in a system of therapeutics traditionally in use in that community, nothing in [the provisions of the Act dealing with offences] shall be construed as making it an offence for that person to practise or hold himself out to practise that system; but the exemption conferred by this subsection shall not extend to any activity (other than circumcision) involving an incision in human tissue or to administering, supplying, or recommending the use of any dangerous drug within the meaning of Part V of the Dangerous Drugs Act.”

The Medical Rehabilitation Therapists Board of Nigeria (MRTB) Chiropractors and Osteopaths

Registration requirements for chiropractors and osteopaths are outlined in the Medical Rehabilitation Therapists (Registration, etc.) Decree 38 of 1988. The Medical Rehabilitation Therapists Board of Nigeria (MRTB), as inaugurated in 1992 has been functioning as the regulator and licensing of Medical Rehabilitation Therapists in Nigeria and also responsible for regulating and controlling the training and practice of five different Medical Professions in Nigeria namely:

- Physiotherapy
- Osteopathic Medicine
- Occupational Therapy
- Chiropractic Medicine
- Speech Therapy and Audiology Practice.

The implication is that it is illegal for anyone to teach or practice any of the above professions without a valid practicing professional licence, renewable every year.

However, in year 2000, the Chiropractors and Osteopaths migrated into another Board/Council under the Traditional Medicine Act.

Traditional Medicine Council of Nigeria

In 1994, all state health ministries were mandated to set up boards of traditional medicine in order to enhance the contribution of traditional medicine to the nation's official health care delivery system. However, the Traditional Medicine Council of Nigeria Act was proposed in the year 2000 with the following functions:

- ❑ Facilitating the practice and development of traditional medicine;
- ❑ Establishing guidelines for the regulation of traditional medical practice to protect the population from quackery, fraud, and incompetence;
- ❑ Liaising with state boards of traditional medicine to ensure adherence to the policies and guidelines outlined in the Federal Traditional Medicine Board Act;
- ❑ Establishing model traditional medicine clinics, herbal farms, botanical gardens, and traditional medicine manufacturing units in the geopolitical zones of the country; and
- ❑ Collaborating with organizations with similar objectives within and outside Nigeria.

Other stakeholders

The Nigeria Natural Medicine Development Agency

The Nigeria Natural Medicine Development agency (NNMDA) was established in 1997 to enable the Federal Government of Nigeria through Federal Ministry of Science & Technology (FMST) actualize its critical and strategic mandate to research, develop, document, preserve, conserve and promote Nigeria's Natural Medicine (Traditional/indigenous Healthcare systems, medications and non-medications healing arts, science & Technology) and assist facilitate their integration into the National Healthcare Delivery System as well as contribute to the Nation's wealth and job creation, socio-economic growth and development effort.

Since its establishment, the Federal Ministry of Health has been instituting measures to formally recognize and enhance the practice of traditional medicine. These measures include:

- ❑ The constitution and inauguration of the National Technical Working Group on Traditional Medicine;
- ❑ Development of policy documents on traditional medicine, including the National Policy on Traditional Medicine, National Code of Ethics for the Practice of Traditional Medicine, the Federal Traditional Medicine Board Decree, and Minimum Standards for Traditional Medicine Practice in Nigeria; and
- ❑ Advocacy for traditional medicine at all levels and in relevant forums.

Centre For Research In Traditional Complementary And Alternative Medicine

The centre for research in traditional complementary and alternative medicine was established in June, 2017 and aims to support World Health Organization programme in integrating traditional medical practice into public healthcare in Nigeria and around the globe.

Part of its mandate is to support the work of the WHO Traditional Medicine Strategy 2014–2023, assist the Federal, state and local governments in Nigeria develop policies and implement plans that strengthen the role traditional medicine (TM) plays in keeping populations healthy. The centre's activities have been more of organising workshops/seminars, training of orthodox (medical doctors and nurses) and Health workers on the role of traditional medicine in health care delivery etc.

Nigerian Council of Physicians of Natural Medicine (NCPNM)

The Nigerian Council of Physicians of Natural Medicine, registered in 1994 with the Corporate Affairs Commission is primarily involved in:

- ❑ The establishment of training centres with approved syllabus for would-be practitioners of Natural Medicine; and
- ❑ Development and promotion of Natural Medicine, Pharmacy, including drug manufacture from our local raw materials as it relates to practice in Natural Medicine, homeopathy, acupuncture and other specialties.

The Council gave birth to Rational College of Natural Medicine under the Federal Ministry of Health, which offers courses in African Medicine with other Traditional Medicine of other countries such as Acupuncture-Chinese, Homeopathy-Germany, Ayurveda-India, Osteopathic and Chiropractic-England, Naturopathic-Europe.

Although the Council is not a statutory regulator, it claims among others to be involved in:

- ❑ Licensing of Natural Medicine physicians and registration of relevant Practitioners.
- ❑ Regulation and standardization of Natural Medicine practices, health products, remedies, services and goods used in Natural Medicine.
- ❑ Conduction of examinations for intending Natural Medicine Practitioners of all grades in co-ordination with various training institution and upgrading the knowledge of Practitioners, through post qualification training.
- ❑ Organisation of conferences, seminars workshops, exhibition to create public awareness of Natural Medicine.

Regulations for importing pharma products and registering service drugs (with special reference to discriminatory provisions);

In Nigeria, there is an existing regulation which states that no drug shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of ACT CAP F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.

The government agency responsible for this is the National Agency for Food and Drug Administration And Control (NAFDAC). The agency has sets of

subsisting guidelines designed for local manufacturing or importation, registration and sales of:

- Food items
- Pharmaceutical drugs and medical devices
- Herbal products and cosmetics
- Vaccines and Biologics
- Chemicals
- Narcotic drugs, psychotropic substances and drug precursors
- Veterinary products

Although the guidelines designed for local manufacturing or importation, registration and sales of each of the classes mentioned above differs, they follow some basic steps as highlighted below:

- Submission of a letter of application stating the name of the manufacturer; generic/ common name and brand name of the product; product strength and indications. A separate application form shall be submitted for each drug product (i.e. each drug formulation). However, the Application for registration of one dosage form with different strengths may be made on the same application form.
- Obtaining an application form upon payment of the application fee;
- Submission of five hard-covered copies of the application dossier to NAFDAC, including;
 - A comprehensive certificate of analysis;
 - Certificate of incorporation of the applicant;
 - Evidence of trademark and brand name approval from the Ministry of Commerce;
 - Three vetting samples;
 - Current premises licence;
 - Annual licence for the superintendent pharmacist.
- Payment of a registration fee, renewable every five years;
- Request for permission to advertise the product;

It is important to state that for foreign manufacturers:

- They must be represented by local agents with duly registered premises and applications must be accompanied by evidence that a Power of Attorney has been granted to the local agent.
- They must show evidence that they are licensed to manufacture drugs for sale in the country of origin (Manufacturer's Certificate). Such evidence must be by the competent Health Authority of the country of manufacture, and shall be authenticated by the Nigerian Mission in that country.

There are other specific guidelines for products and labelling and these include:

- ❑ All drug manufacturing sites must be inspected and certified fit by NAFDAC before the commencement of production. For imported products, there must be evidence of registration of such products by the competent Health Authority of the country of manufacturer (i.e., Product Licence/Certificate of Registration) and evidence that the sale of the product does not constitute a contravention of the drug laws of that country (i.e. Free Sale Certificate). These documents shall be authenticated by the Nigerian Mission in that country.
- ❑ In the case of an imported new drug substance, there must be evidence that limited local clinical trials have been undertaken, and that such product is registered in the country of origin and also, in at least 2 or more developed countries.
- ❑ No combination drug product shall be registered or considered for registration unless there is proven evidence that such a product has clinical advantage over the single drug available for the same indications(s).
- ❑ The application should indicate the class or type of registration required - whether it is for a prescription only product or an over the counter product.
- ❑ Products found to be of doubtful, little or no therapeutic value and those which are sometimes rather harmful and subject to mis-use, shall not be considered for registration.
- ❑ An applicant shall not be allowed to register a drug formulation in more than one brand name even where different doses of the active ingredient(s) are used.
- ❑ Labelling shall be informative, accurate with the following minimum packaging requirements:
 - Name of product - brand name and generic name where applicable. The generic name must be in similar characters and with brand name.
 - Location address of the manufacturer –
 - Batch number, Manufacturing Date and Expiry Date
 - Dosage regimen on the package
 - Leaflet insert, if prescription product, and hospital packs
 - Indications, frequency, route and conditions of administration
 - Quantitative listing of all the active ingredients per unit dose
 - Adequate warnings where necessary
- ❑ Where a brand name is used, there MUST be a generic name which should be conspicuous in character, written directly under the brand name e.g.:- VENTOLIN "SALBUTAMOL"

- Any drug product which is labelled in a foreign language shall NOT be considered for registration unless an English translation is included on the label and package insert (where applicable).
- Information on indication carried on package and leaflet insert of imported drug product shall not differ from that in other countries, and in particular the country of origin of the product,
- A successful application attracts a Certificate of Registration with a validity period of 5 (five) years.

Documentation required for importation of drug products

Documentation for Registration of Importation of Drug Products includes:

A. Power of Attorney which must be:

- Notarized by notary public in the country of manufacture
- Issued by the manufacturer of product
- Signed by the either the MD, GM, Chairman or President of the Company, stating the name of products to be registered and should indicate 'authority to register product with NAFDAC'.

B. Certificate of Manufacturer and Free Sale

- Authenticated by Nigerian Embassy in the country of origin
- Issued by a relevant Health/Regulatory body
- Indicate the name of manufacturer and products inspected

C. Certificate of Pharmaceutical Products (COPP)

- Issued by the relevant health / regulatory body
- Authenticated by Nigerian Embassy in the country of origin

D. Superintendent Pharmacist License /Premises License - Application letter for Import Permit by the local representative.

E. A letter of Invitation for Inspection of factory abroad.

This is submitted by local representative in Nigeria stating the full location address of the manufacturer.

Section F Trends in Indian pharma exports potential of the Nigerian pharma market

Nigeria Imports from India - Machineries

With the exception of vehicles, machineries account for the largest Nigerian import from India. In 2018, Nigeria imported machineries and boilers worth US\$6.1 billion, representing 14% of the total imports. In that year, machines from India accounted for just 5.8% (US\$354.4 million) of the total machine imports as seen in the next table.

Table 3 - Nigeria's import from India - 2008

	Year 2018
Nigeria imports from India in 2018 – Top 10	Value
Vehicles other than railway, tramway	\$577.52M
Machinery, nuclear reactors, boilers	\$354.40M
Pharmaceutical products	\$242.26M
Electrical, electronic equipment	\$135.12M
Plastics	\$109.67M
Organic chemicals	\$100.99M
Mineral fuels, oils, distillation products	\$97.43M
Articles of iron or steel	\$93.46M
Paper and paperboard, articles of pulp, paper and board	\$80.96M
Miscellaneous chemical products	\$62.12M

Sources of data: <https://tradingeconomics.com>; <https://www.ceicdata.com>

Analysis by Matog Consulting

Nigeria Imports from India - Pharmaceutical Machineries

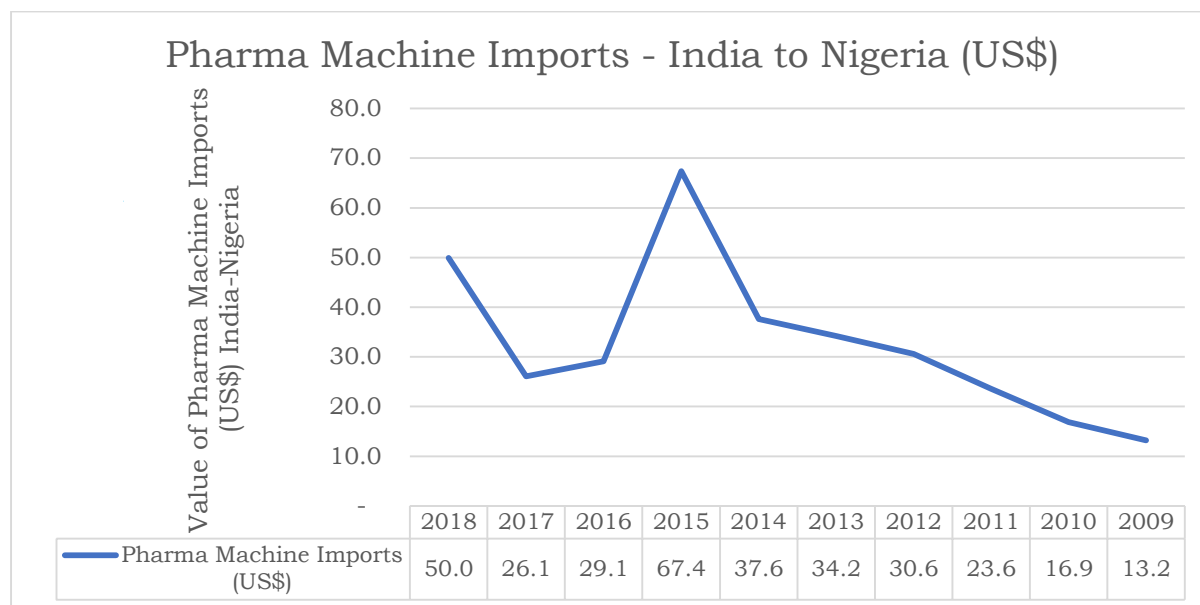
Due to the fungibility of some pharma machineries and equipment, differentiating the machines and equipment imported for the sole manufacture of pharmaceutical products is a herculean task as they are generally given same description. Typical example is a tube filling and capping machine which can be used by a pharmaceutical company for production of topical creams and also by a household/ consumer goods manufacturing company for toothpastes and lubricating oil.

In the same vein, some pharmaceutical companies that have diversified into water production may import non-pharma machineries for bottling purposes while a chemical company engaged in non-pharma production will use same machineries as that of a pharma company.

Between 2009 and 2018, import of pharma machineries from India to Nigeria peaked in 2015 with Nigeria importing US\$67.4 million worth of pharma machineries. This estimate excludes value of spares supplied within the same period.

Kindly see the next chart for the trend in pharma machineries import from India to Nigeria over the ten-year period 2009 to 2018.

Figure 6 - Nigeria's pharma machine import from India



We believe that this is a conservative estimate as it primarily consists of the following:

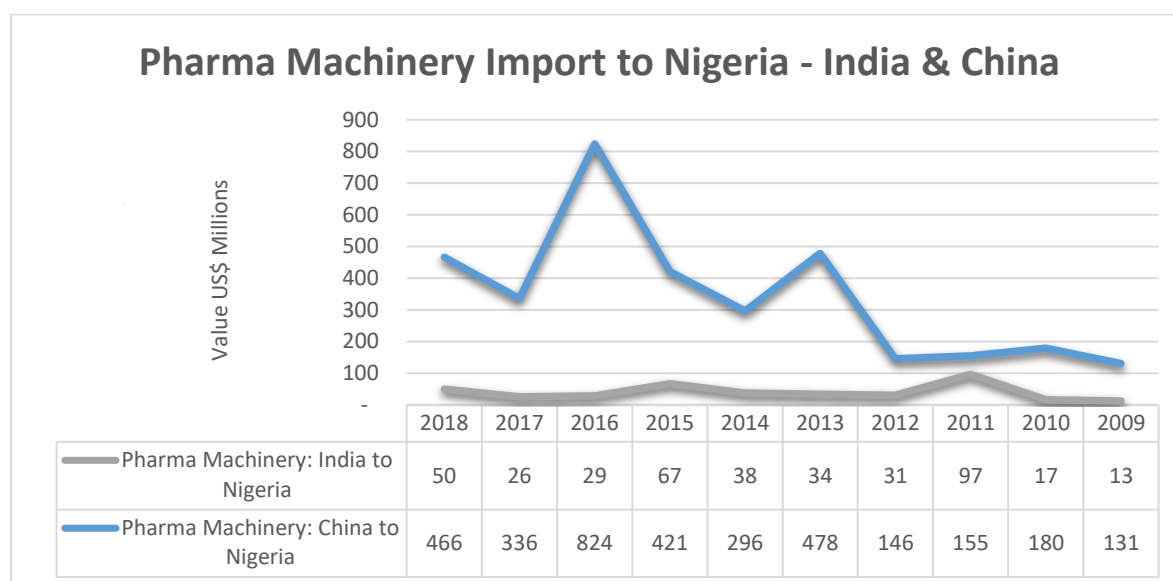
- ❑ Filling machines for liquid and syrups;
- ❑ Capsule filling machine (automatic and semi-automatic);
- ❑ Pharmaceutical tablet making machine (including blistering machines, film coating machines etc.);
- ❑ Cream ointment plant – creamer, tube fillers etc.
- ❑ Industrial mixers – for granules, creams, liquids and powders;
- ❑ Others – granulators, industrial blenders, driers, compactors etc.

Nigeria Imports of Pharmaceutical Machineries – Others

The value of pharmaceutical machineries imported from India to Nigeria is considered relatively low when compared with the value of pharmaceutical machineries imported from either Europe or China.

The chart below highlights value of pharmaceutical machineries imported into Nigeria from China and India over the ten-year period 2009 to 2018.

Figure 7 - Nigeria's pharma machine import - China and Nigeria



Use of machineries along the pharmaceutical value chain

Considering that there are over 130 registered pharmaceutical manufacturing companies in Nigeria, it is good to mention that there is abundant opportunity in Nigeria for the use of pharma machineries. While some of the machines may be designed for the pharmaceutical industries, often than not, they are purchased by non-pharmaceutical companies such as those in confectionary industry and household/consumer goods industry and may be classified as non-pharmaceutical machineries.

Most of the machinery /equipment and virtually all the quality control analytical equipment are imported, mainly from Asia and Europe respectively. For the spares, some of the pharmaceutical manufacturing companies either source for their spare parts locally or fabricate it while most of them import directly.

In terms of repairs, some of the manufacturing companies that use similar production machines supplied by the same foreign companies in India, China and in Europe, also join together to contract expatriate engineers and to organize workshops on machine maintenance.

Section G Trends in pharma exports of other countries to Nigeria;

According to the Pharmaceutical Manufacturers' Group of the Manufacturers Association of Nigeria (PMG-MAN), there over 130 pharmaceutical manufacturing companies in Nigeria with less than ten (10) of them quoted on the Nigerian Stock Exchange (NSE).

With a population of approximately 200 million people, Nigeria depends on importation of pharmaceutical products and medical devices to meet local

demand of drugs, medical devices and pharmaceutical equipment and machineries.

It is also estimated that over 70% of the pharmaceutical drugs used in Nigeria are imported. This has been the trend for well over two decades. Available data shows that the value of pharmaceutical imports into Nigeria has doubled between 2013 and 2018, with a widening deficit from US\$475 million to over US\$780 million.

The implication is that based on current local production and demand, importation of pharmaceutical products will remain key to meeting growing local demand for medicines in Nigeria.

Nigeria's key pharmaceutical import partners include India, China, the Euro Zone (26-member countries) and the US. Nigeria's import from India of Pharmaceutical products accounts for 31.3% of total pharma imports (United Nations COMTRADE database on international trade).

Over the years, import of medicaments (put up in packings for retail sale) constitutes the bulk of the imports, in some cases, accounting for over 90% of total imports.

The table below shows details of pharmaceutical exports to Nigeria by a few countries/ zones.

Table 4 - Pharma exports to Nigeria - Selected countries

By Countries/ Zones	2018	2017	2016
	US\$'000	US\$'000	US\$'000
EU	553,276	728,845	615,434
India	416,637	299,376	352,649
Japan	12,130	7250	18,190
Pakistan	4,370	3,534	3,809
Mexico	3,141	3,025	392
South Africa	3,320	6,405	3,643
Russia	22,350	14,610	4,258

Data for year 2019 not available as at date of report

The bulk of the pharmaceutical exports to Nigeria include:

- Medicaments in packages suitable for retail
- Human or Animal Blood, Antisera and Other Blood Fractions, Vaccines, Toxins; and
- General pharmaceutical goods.

Although Russia's pharmaceutical export to Nigeria is high (US\$22.35 million, as at 2018), it is primarily Human or Animal Blood, Antisera and Other Blood Fractions, Vaccines, Toxins

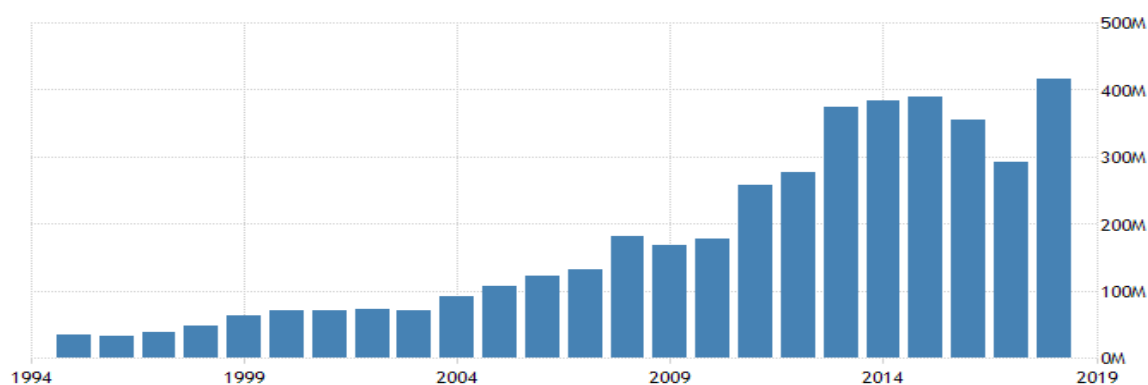
The table below shows details of the key pharmaceutical exports to Nigeria from the Euro Zone and India over a three-year period (2016 to 2018).

Table 5 - Nigeria's pharma import - India and EU

Nigeria's Pharma Imports						
	India			EU		
	2018	2017	2016	2018	2017	2016
	US\$'000	US\$'000	US\$'000	US\$'000	US\$'000	US\$'000
Medicaments (Put up in Packings for Retail Sale)	352,224	246,604	286,990	451,354	556,142	472,961
Human or Animal Blood, Antisera & Other Blood Fractions, Vaccines, Toxins	55,584	46,199	61,400	90,044	154,235	136,234
Medicaments – Others	8,404	5,924	3,800	548	542	150
Pharmaceutical Goods	381	591	361	9,972	16,843	4,924
Wadding, Gauze, Bandages and Similar Articles	12	12	37	777	541	570
Glands, Other Organs; Extracts of Glands or Other Organs	32	46	61	581	542	595
Total	416,637	299,376	352,649	553,276	728,845	615,434

Data Source: <https://tradingeconomics.com>; Analysis by Matog Consulting

In the case of India, the chart below highlights Nigeria's import of pharma products (in US\$) from India over the last 25 years.



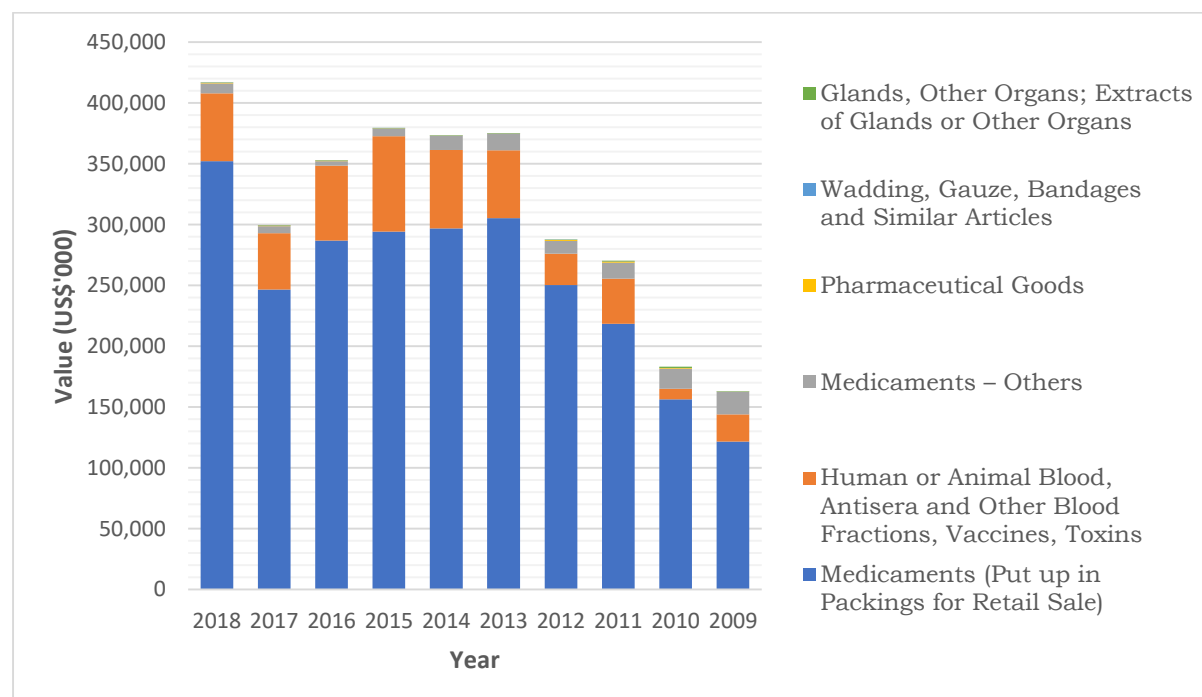
The details of these pharma products (broken down into various groups) over the last ten years is also shown in the next table:

Table 6 - Nigeria's pharma import from India - 10 year trend

Nigeria's Pharma Imports from India										
	2018	2017	2016	2015	2014	2013	2012	2011	2010	2009
	US\$'000	US\$'000	US\$'000	US\$'000	US\$'000	US\$'000	US\$'000	US\$'000	US\$'000	US\$'000
Medicaments (Put up in Packings for Retail Sale)	352,224	246,604	286,990	294,345	296,829	305,419	250,344	218,409	156,315	121,600
Human or Animal Blood, Antisera and Other Blood Fractions, Vaccines, Toxins	55,584	46,199	61,400	78,432	64,607	55,541	25,819	37,100	8,700	22,400
Medicaments – Others	8,404	5,924	3,800	6,303	11,410	13,801	10,316	13,333	16,515	18,413
Pharmaceutical Goods	381	591	361	160	202	45	820	925	520	285
Wadding, Gauze, Bandages and Similar Articles	12	12	37	12	60	65	26	69	28	158
Glands, Other Organs; Extracts of Glands or Other Organs	32	46	61	11	20	66	85	410	1,160	315
Total	416,637	299,376	352,649	379,263	373,128	374,937	287,409	270,246	183,238	163,171

The above is represented graphically in the next chart.

Figure 8 - Nigeria's pharma import



Section H Tariff and non-tariff barriers on Indian pharma products;

In Nigeria, there are no limitations or restrictions on market access to the production, distribution or marketing of any product neither is there any law prohibiting the practice of any profession including pharmaceutical products or services. However, most industry sectors especially the professional services require the possession of a minimum professional qualification to practice, which is often to regulate the practice and prevent quacks from practicing. This regulation applies to professionals such as the Medical Doctors/ Dentists, Accountants, Lawyers, Pharmacists, Estate Valuers etc.

For any import into Nigeria, the Nigeria Customs Service (NCS), under the Customs and Excise Management Act (CEMA) 2004, has the legal authority to act on behalf of Nigeria. However, for pharmaceutical products, there are additional requirements from National Agency for Foods, Drug Administration and Control (NAFDAC), the agency empowered by law to regulate the import, distribution, manufacturing of foods and drugs.

The regulation requires that all food, drug, cosmetic, and pesticide imports must be accompanied by certificates from manufacturers and certain national authorities, regardless of origin. These certificates attest that the product is safe for human consumption. With Nigeria's limited capacity to review certificates, carry out inspections, and conduct testing, there are usually delays in the clearance of food and drug imports.

Over the years, Nigeria's importation of pharmaceutical products from certain countries was marred by the prevalence of fake, adulterated and substandard products, to the extent that the estimated fake, adulterated and substandard drugs in circulation was put at over 70%. With Nigeria's threat to place a blanket ban on the import of all drugs from countries that export fake drugs to its shores, the Indian government in partnership with the Nigerian regulators (NAFDAC) reached an agreement to stop the export of fake and adulterated drugs from India to Nigeria by institutionalizing a pre-export inspection agent in India. The pre-export (pre-shipment) agent to control export of substandard drugs to Nigeria. While there are no discriminatory non-tariff barriers on pharmaceutical products from any country, all pharmaceutical imports from China, India and Egypt must be accompanied by this pre-shipment (pre-export) certificate to ascertain the quality, safety and efficacy of such products. These pharmaceutical imports must provide the Clean Report of Inspection and Analysis before shipment to Nigeria.

General tariffs and rates

Effective April 2015, Nigeria started implementing the new ECOWAS Common External Tariff (CET). The comprehensive CET list can be found at: <https://customs.gov.ng/Tariff/index.php>. A fifth band was introduced in the CET at a rate of 35% for specific goods for economic development.

In addition to the CET, national complementary measures can be applied. These consist of an import tax adjustment (IAT) and a supplementary protection tax (SPT). The IAT can be imposed where the most favoured nation duty originally applied by a member state is higher than the duty specified under the ECOWAS CET. The maximum IAT applicable is the difference

between the duty applied by the member state originally and the duty set by the ECOWAS CET. The IAT can be applied for a maximum period of five years from 1 January 2015.

Preferential tariffs

As a member of the Economic Community of West African States (ECOWAS), Nigeria grants tariff preferences to other ECOWAS member states. While this grants preferential rates to West African member states, it is not considered discriminatory on import of pharmaceutical products from other countries such as India.

Trade and Non-tariff barriers to imports into Nigeria

Nigeria employs a combination of tariffs and quotas for the double purpose of taxing international trade for revenue generation and protecting local industries from highly competitive imports. The country's tariffs are determined by the ECOWAS 2015 – 2019 CET Book. The tariff has five bands:

- Zero (0%) duty on essential drugs, active pharmaceutical ingredients (APIs) for ARVs/ACTs, industrial machinery and equipment;
- 5% duty on raw materials and other capital goods;
- 10% on intermediate goods;
- 20% on finished goods;
- 35% on imports into strategic sectors; and
- 50% on finished products with adequate local production capacity.

The effective rates may be higher when excise duties and value added tax are included.

Under the Customs and Excise Management Act (CEMA), the Nigerian President has the power to prohibit the importation of any specified goods irrespective of the country of origin. This may be done to protect its local industries and grow several strategic sectors (especially agriculture) or for revenue generation.

Some of the pharmaceutical products included in the import prohibition or restricted list include:

- Paracetamol tablets and syrups;
- Cotrimoxazole tablets and syrups;
- Metronidazole tablets and syrups;
- Chloroquine tablets and syrups;
- Haematinic formulations; ferrous sulphate and ferrous gluconate tablets, folic acid tablets, vitamin B Complex Tablets (except modified released formulations).
- Multivitamin tablets, capsules and syrups (except special formulations);
- Aspirin tablets (except modified released formulation and soluble aspirin);
- Magnesium trisilicate tablets and suspensions.
- Piperazine tablets and syrups;
- Levamisole tablets and syrups;
- Clotrimazole cream;
- Ointments – penicillin/gentamycin;

- ❑ Pyrantel pamoate tablets and syrups;
- ❑ Intravenous fluids (dextrose, normal saline, etc.);
- ❑ Waste Pharmaceuticals;
- ❑ Ampicillin/ Cloxaycilin combination.

A detailed list of prohibited items can be found at: <https://customs.gov.ng/ProhibitionList/import.php> and https://customs.gov.ng/ProhibitionList/import_2.php.

A prospective importer must also comply with the Import Guidelines, which can be accessed at: https://customs.gov.ng/Guidelines/Destination_Inspection/guidelines.php

As mentioned earlier, almost every good destined to Nigeria, especially in the foods, drug and cosmetics categories, require some sort of inspection and/or certification from government authorities or their appointed third-party contractors. There are potential risks that clearance of goods from the ports may be delayed in the course of detailed inspections, testing and review of the goods. This may add to the cost of the affected goods, especially where demurrages are paid.

With the emergence of local content law, originally introduced to ensure local participation in labour across the value chain of the oil and gas sector, the local content requirements have spread to other sectors to the extent that the government has several import substitution policies which aims to increase local production over imports through subsidies, tariffs, quotas and other barriers to trade. Amongst these measures is a Federal Government directive which stipulates that preference be granted to domestic manufacturers, contractors and service providers in all government procurements. The Executive Order of May 2017 clearly states that at least 40% of expenditure for the procurement of some items shall be on locally manufactured goods. Included in these items is the Pharmaceutical products. This order is primarily for procurements by the Federal Government and not targeted at any country.

There are other unintended actions that has become obstacles to trade especially on importation through the Nigerian ports. Importers often report of erratic application of customs regulations and tariffs, unusual lengthy clearance procedures, high berthing and unloading costs, and corruption. There are also periods when the ports will be congested to the extent that ships reportedly queue up for days, and in some cases weeks and months, before being able to berth and discharge their contents. The delays caused by congestion and the poor condition of the port access roads may inevitably add to the cost of importation. However, it is good to mention that some of these challenges are currently been addressed by The Nigerian Port Authority (NPA), through public-private partnership arrangements.

Duties and Taxes on Pharmaceuticals (Market)

Nigeria imposes duties on imported active pharmaceutical ingredients (APIs) and duties on imported finished products are also imposed. However, there are no duties imposed on medication for HIV, malaria and tuberculosis. Value-added tax (VAT) or other taxes are not imposed on finished pharmaceutical products. A policy is in place to apply VAT on pharmaceuticals, but it is not implemented by customs. A withholding tax of 5% is applied. Provisions for tax exceptions or waivers for pharmaceuticals and health products are in place.

Section I Actions of other countries facing similar restrictions

As mentioned earlier, Nigeria's importation of pharmaceutical products at some point was marred by the prevalence of fake, adulterated and substandard products. Considering that most of the pharmaceutical drugs into Nigeria was from a few countries, the government of these countries entered into a partnership with the Nigerian government (through the regulatory authorities, in this NAFDAC) to establish pre-export inspection agents.

These pre-export (pre-shipment) agents were empowered to control the export of substandard drugs to Nigeria. While there are no discriminatory non-tariff barriers on pharmaceutical products from any country, all pharmaceutical imports from China, India and Egypt must be accompanied by this pre-shipment (pre-export) certificate to ascertain the quality, safety and efficacy of such products. These pharmaceutical imports must provide the Clean Report of Inspection and Analysis before shipment to Nigeria.

The institutionalisation of these pre-shipment agents has created business opportunities for those in these countries.

Section J Nigeria's regulations with other countries

Every country has regulations regarding the importation, distribution and manufacturing of pharmaceutical drugs. However, when it comes to importation, different countries use different trade and non-trade barrier to either stimulate the economy, protect local industries and/ or drive a definite economic agenda.

The level of customs duties is a direct indicator of the openness of an economy to world trade. Import duties, often regarded as a variation of protectionism typically does not apply to countries with which free trade agreements have been concluded.

Tariffs across borders

In Nigeria, the current import duties are perceived as positive by PMG-MAN (for example, zero per cent (0%) on active pharmaceutical ingredients (APIs) for ARVs/ACTs). See previous section (Table X) for details.

The tariff structure within the framework of the ECOWAS Common External Tariff (CET) was designed to discourage imports and stimulate local pharmaceutical production with provision made for tariff free import of industrial equipment and low tariff rates for the import of raw materials such as APIs and higher rates for the import of finished products. The key elements of the ECOWAS CET for inputs and finished pharmaceutical products are shown in table below.

Table 7 - Tariffs on medicines and medical devices in select countries

	Country	Tariff on Medicines	Tariff on Medical Devices
1	Cape Verde	0%	0%
2	Cote d'Ivoire	2.5%	26.5%
3	Gambia	17.05%	17.05%
4	Ghana	17.0%	17.05% and 37.05%
5	Guinea Conakry	2.75%	27.01%
6	Liberia	12.0%	12-14 and 15%
7	Nigeria	26.5%	41.5%
8	Sierra Leone	30.0%	30.0%

Regulatory Environment

Legislation and regulations across select countries.

One of the most significant determinants of safe, quality and efficacious medicines within the regulatory legal framework is the existence of legislation, regulations and policies that aim to ensure comprehensive control, production, importation, distribution and advertisement of pharma products. This section will compare what is obtainable in Nigeria against what is obtainable in neighbouring countries. This important because pharma products produced in one country can easily be bought or exported to the neighbouring country.

Each of the countries have a body responsible for the regulation of pharma products, established by law either as a body corporate or operating as departments of Ministries responsible for health. These bodies will be generally referred to as National Medicine Regulatory Agency (NMRA).

Table 8 - Acts setting up various NMRAs

Country	Title of legislation/ Regulations
Nigeria	<ul style="list-style-type: none"> ▪ NAFDAC ACT N1 Laws of the Federation of Nigeria (LFN) 2004
Ghana	<ul style="list-style-type: none"> ▪ Food and Drugs Law 1992 PNDCL 305B (1992) ▪ Food and Drugs amendment Act 523 (1996) ▪ Pharmacy Act (Act 489) (1994)
Niger	<ul style="list-style-type: none"> ▪ Ordinance No. 97-002 of 10 January 1997 (1997) ▪ Decree No. 97-301/PRN/MSP of 6 August 1997 (1997) ▪ 24 regulatory applications of April 1998 (1998) ▪ 04 regulatory applications of 1999 (1999) ▪ 02 regulatory applications of 2000 (2000) ▪ 02 regulatory applications of 2002 (2002)

Togo	<ul style="list-style-type: none"> ▪ Framework on drug and pharmacy and the text of application (2001) ▪ Public Health Code of the Republic of Togo (15 May 2009) ▪ Elaborated provisions of the code of Public Health (2010) ▪ Regulation No. 6/2010/CM/UEMOA procedures relating to registration of pharmaceuticals for human use in the Member States of the UEMOA (2010)
Liberia	<ul style="list-style-type: none"> ▪ Pharmacy Board Act of 1967 (April 20, 1967) ▪ Public Health Law (1956) ▪ An Act to Establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010 (September 29, 2010)
Benin	<ul style="list-style-type: none"> ▪ Ordinance 75-7 of January 27, 1975, on the Dahomey medicinal products plan ▪ Decree 426 of July 20, 2016, on the authority, organization, and operations of the Ministry of Health ▪ Bylaw 095/MS/DC/SGM/CTJ/DPMED/SA of May 6, 2013, on the authority, organization, and operations of DPMED ▪ Bylaw 239/MS/DC/SGM/CTJ/DPMED/DA/SA of June 17, 2015, on the creation, authority, organization, and operations of the National Committee for Pharmaceutical Products ▪ Bylaw 0343/MS/DC/SGM/CTJ/DPMED/DA/SA of July 10, 2012, on the licensing requirements for nutritional supplements in the Republic of Benin ▪ Bylaw 0311/MS/DC/SGM/CTJ/DPMED/DA/SA of June 13, 2012, on the licensing requirements for cosmetic products in the Republic of Benin ▪ Bylaw #0406 of 2016 establishing the licensing fees and terms of use for pharmaceutical products for human use
Chad	<ul style="list-style-type: none"> ▪ Law 24/PR/2000 – pharmacies ▪ Ordinance 10/PR/1991 - Creation of a pharmacists union

Key components of the regulations in these selected countries include:

Table 9 - Key Components of Regulations in select countries

Key regulatory function/ provision	Yes / No	Country	Comments
Establishment of a body responsible for medicines regulation	Yes	Ghana, Liberia, Niger, Nigeria, Togo, Benin and Chad	There is a body responsible in each of these countries.
Licensing of Manufacturers	Yes	Ghana, Liberia, Niger, Nigeria, Togo, Benin and Chad	
Licensing of Importers	Yes	Ghana, Guinea Bissau, Liberia, Niger, Nigeria, Togo, Benin and Chad	
Licensing of Wholesalers	Yes	Ghana, Liberia, Mali, Niger, Nigeria, Togo, Benin and Chad	

Licensing of Distributors	Yes	Ghana, Liberia, Mali, Niger, Nigeria, Benin and Chad	Not mentioned in Togo legislation
Licensing of Retailers/dispensing outlets	Yes	Ghana, Mali, Niger, Nigeria, Togo, Benin and Chad.	In the case of Liberia, this is the responsibility of the Pharmacy Board of Liberia and not the regulatory body
Licensing of Other products/ people	Yes	Mali, Niger, Nigeria, Benin, Togo and Chad.	NGO, Clinics, Private Hospitals (Niger).
Market Authorization/ Registration of Medicines		Ghana, Liberia, Mali, Niger, Nigeria, Togo, Benin and Chad	
Inspection of premises and manufacturing Sites	Yes	Ghana, Liberia, Mali, Nigeria, Togo, Benin and Chad	
	No	Niger	
Establishment of Quality Control Laboratory	Yes	Ghana, Liberia, Mali, Niger, Nigeria, Togo	But controls substandard etc. (Liberia) Upgrading of the laboratory in progress (Liberia) LANSPEX (Niger)
Control of clinical trials	Yes	Ghana, Liberia, Mali, Niger, Nigeria, Togo and Chad	In Togo, this is handled by Bioethics Commission.
Control of counterfeit medicines	Yes	Liberia, Niger, Mali, Senegal. In Nigeria, Ghana and Togo, the authorities go as far as confiscating and prosecuting counterfeit drug producers.	In Niger, the control is not systematic.
Control of imports and exports	Yes	Ghana, Mali, Niger, Nigeria, Togo, Benin and Chad.	In Togo, this is performed by CAMEG
Safety monitoring of products	Yes	Ghana, Mali, Niger, Nigeria, Togo, Chad and Benin.	By the implementation of a national quality control program since 2010 (Burkina Faso)
Control of product promotion and Advertisement	Yes	Ghana, Liberia, Mali, Niger, Benin, Chad Nigeria and Togo	Regulations on publicity and medical representatives (Niger)
Control of other products such veterinary products and chemicals.	Yes	Gambia, Ghana, Mali, Niger, Nigeria, Togo, Benin and Chad	Chad does not regulate herbal products.

Provision for medicines distribution schedules/ categories	Yes	Ghana, Benin, Liberia, Mali, Niger, Nigeria, and Togo.	List of essential medicines (Niger and Chad)
Laboratory reagents	Yes	Burkina Faso	
Control of narcotics and psychotropic Substances	Yes	Ghana, Liberia, Mali, Niger, Nigeria, Benin, Chad and Togo	System of official certificates of conformity to apply the Vienna Conventions (Niger)
20. Mineral Water	Yes	Togo, Nigeria and Ghana	
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	Ghana, Guinea Bissau, Liberia, Mali, Niger, Nigeria and Togo	
Authority to make regulations	Yes	Ghana, Liberia, Niger, Nigeria, and Togo	National Commission of Medicines Ministry of Public Health (Niger). In Benin and Chad, the Ministry of Health is in charge.

It is good to mention the following information among the various countries:

Legislation and regulations

Niger and Togo have policy or legislation that provides a mandate for the country's regulatory agencies to recognize regulatory decisions made by other regulatory agencies. Ghana and Liberia do not have such instruments. For example, in Niger, the relevant frameworks that provide such mandates include the Directives of UEMOA, Regulations of UEMOA and the Decisions of UEMOA.

Liberia, Niger, Nigeria and Togo are currently involved in some regional or continental efforts towards harmonisation of medicines regulation through the following agencies UEMOA, ECOWAS, West Africa Health Organisation (WAHO), African Medicine Forum and the WHO-Technical Regulatory package among others. In Chad, the Medicine Regulatory Authority, *Direction de la Pharmacie, du Médicament et de la Pharmacopée* (Directorate of Pharmacy, Medicines and Pharmacopoeia) is a directorate under the Ministry of Public Health.

Most of country's regulatory agencies are actively involved in various collaboration programmes which promote information sharing, information recognition, joint training, common guidelines and joint assessments/inspection.

Organization and management of regulatory functions

The enforcement of regulatory functions is carried out by each of the country's National Medicines Regulatory Authorities (NMRAs) that discharge day to day

duties. Although each country’s NMRA profile differs, their roles are almost similar with little variation in functions and mode of execution.

Following from the table below, it is significant to note that Most NMRAs execute the functions indicated except for small differences such as:

- Niger and Liberia do not do GMP inspection;
- Niger do not inspect distribution channels;
- Togo do not control prescription

Table 10 - Summary of functions by each National Medicines Regulatory Authority

Function	TOGO	NIGER	GHANA	NIGERIA	LIBERIA	BENIN	CHAD
Licensing of Pharmaceutical Manufacturers	YES	YES	YES	YES	YES	YES	YES
Licensing of pharmaceutical imports	YES	YES	YES	YES	YES	YES	YES
Licensing of pharmaceutical wholesale trade	YES	YES	YES	YES	YES	YES	YES
Licensing of medicine retail/dispensing outlets	YES	YES	YES	YES	YES	YES	YES
Product assessment and registration/marketing authorization	YES	YES	YES	YES	YES	YES	YES
Good manufacturing practice (GMP) inspection	YES	NO	YES	YES	NO	YES	YES
Inspection of distribution channels	YES	NO	YES	YES	YES	YES	YES
Performing medicine quality tests/quality control laboratory	YES	YES	YES	YES	YES	YES	YES
Regulating generic substitution	YES	YES	YES	YES	YES	YES	YES
Control prescribing	NO	YES	YES	YES	YES	YES	YES
Coordination of medicine regulation centrally at national level	YES	YES	YES	YES	YES	YES	YES

Legal and regulatory requirements

Although each of these countries have the mandate to register medicines and pharma products, provisions for waivers in the registration process exist under certain circumstances in Liberia, Mali, Niger, Nigeria, and Togo. There is however no waiver in Ghana. The conditions for waivers vary from country to country. In Nigeria, a waiver is applied for donated drugs which are to be used for specific programmes. For Liberia, in event of crisis or emergency, procedure for registration may be relaxed in line with the protocol of the Ministry of Health and Social Welfare. In Togo, medicines pre-qualified by WHO are given waivers. Senegal has a directive that products without a special permit must have an exceptional delivery by DPL in order to be eligible for a waiver. In Benin Republic, special authorization is required for international aid and clinical trials.

Guidelines for registration of medicines

The relevant guidelines and reference standards for the registration of medicine among these countries varies from country to country. However, reference standards include: WHO and WHO-ICH by Ghana, Re'glement No.06/2010/CM/UEMOA by Niger, WHO Blue Book and WHO documents by Togo. Other countries have standards domesticated to suit peculiar countries. Summary of these standards and the reference materials is shown below:

Table 11 - Guidelines for registration of medicines in select countries

Country / Reference Standard	Name of Guideline
Ghana: WHO WHO-ICH	<ul style="list-style-type: none"> ▪ Guideline for allopathic drug registration [1999] ▪ Guideline for stability testing [1999] ▪ Guideline for conducting BE studies [1999] Guideline for clinical trials [1999] ▪ Guideline for labeling of products [1999]
Liberia	<ul style="list-style-type: none"> ▪ Basic steps for product listing ▪ Application forms and samples evaluation Guideline for samples submission
Niger: Reglement No. 06/2010/CM/UEMOA WHO-GS	<ul style="list-style-type: none"> ▪ Regulation no. 101/MSP/DPHL of 03 April 1998, determining the elements of an application for market authorization [AMM]
Nigeria	<ul style="list-style-type: none"> ▪ Guidelines for drug registration in Nigeria ▪ Guidelines for registration of locally manufactured drug products Guideline for registration of imported products
Togo: WHO Blue Book WHO documents	<ul style="list-style-type: none"> ▪ Memorandum containing the procedures for registration (3/2009)
Benin	<ul style="list-style-type: none"> ▪ Ordinance 75-7 of January 27, 1975, on the Dahomey medicinal products plan ▪ Decree 426 of July 20, 2016, on the authority, organization, and operations of the Ministry of Health ▪ Bylaw 095/MS/DC/SGM/CTJ/DPMED/SA of May 6, 2013, on the authority, organization, and operations of DPMED ▪ Bylaw 239/MS/DC/SGM/CTJ/DPMED/DA/SA of June 17, 2015, on the creation, authority, organization, and operations of the National Committee for Pharmaceutical Products ▪ Bylaw 0343/MS/DC/SGM/CTJ/DPMED/DA/SA of July 10, 2012, on the licensing requirements for nutritional supplements in the Republic of Benin ▪ Bylaw 0311/MS/DC/SGM/CTJ/DPMED/DA/SA of June 13, 2012, on the licensing requirements for cosmetic products in the Republic of Benin ▪ Bylaw #0406 of 2016 establishing the licensing fees and terms of use for pharmaceutical products for human use

Chad	<ul style="list-style-type: none"> ▪ Only two laws pertain to pharmacies in Chad: Law 24/PR/2000 on pharmacies and Ordinance 10/PR/1991 on the creation of a pharmacist's union.
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Requirements for registration and market authorization

Marketing authorization (MA) involves the assessment of scientific information submitted by applicants including the GMP inspection of manufacturing sites for pharmaceutical products. This involves submission of pharmaceutical information, clinical and non-clinical data with a view to ascertain the quality, efficacy and safety of a pharmaceutical product. Depending on the information submitted and the capacity of the NMRAs, additional reference information such as certificate of pharmaceutical product (CPP) and reference data from a Stringent Regulatory Authority (SRA) may be requested by the assessing NMRA.

A certificate of Pharmaceutical Products (CPP) is required in Ghana, Liberia, Mali, Niger, Nigeria, Togo, Benin and Chad. The CPP is required at dossier submission in all the countries for all medicines/products including generic medicines.

Fast track/ Priority applications for the registration of pharmaceutical products.

Ghana, Liberia, Nigeria, have a fast-track policy in place for high priority medicines. Niger and Togo do not have such a policy. The high priority medicines are for HIV/AIDS, TB and anti-malarial. The prioritization policy is freely available to applicants in Liberia, but not freely available in Ghana and Niger. The information is made available on request in Nigeria. In Ghana although the policy is not made freely available nonetheless information is channeled through the Ministry of Health procurement directorate which ensures that the programme managers purchase such information. Applicants for fast track are notified if they qualify in Liberia, however no such information is given in Ghana, Niger and Nigeria. Ghana and Nigeria have mechanisms for targeted registration times based on application type. No such mechanism is available in Gambia and Niger.

Factory inspection

While most of the selected countries undertake the inspection of factories as an important aspect of the medicines registration process. It depends on availability of technical experts who may not be available in the individual countries. Joint inspection is often undertaken to minimize cost of factory inspection.

Ghana, Mali, Benin, Chad and Nigeria have factory inspection policies. In Liberia and Togo policies are still being developed. The policies are freely available to applicants. The policy is published on the website of the regulatory authorities in Mali and Nigeria while it is included in the guidelines/policy document in Ghana, Liberia and Nigeria.

Ghana, Mali, Nigeria, and Togo inspect factories outside their own borders as part of the registration process. Liberia do not have such policies. Manufacturer's track record is a strong indication for factory inspection in Ghana, Mali, Nigeria, and Togo. With the exception of Nigeria, product risk is taken into account if a factory inspection is required. Factory approval by a recognized competent authority is important in Ghana, Mali, while product approval by another competent authority is important in Nigeria and Senegal. In Ghana and Nigeria, inspection will not be done for companies in Europe and USA with valid GMP certificates with low risk products.

Medicine samples tested for registration

An important aspect of medicine registration is the testing of samples to ensure their efficacy. This is done pre and post marketing of the approved medicines.

Ghana, Liberia, Mali, Nigeria, Benin, Chad and Togo test medicine samples before registration and also carries out post-marketing surveillance. Although Niger does not carry out post marketing surveillance, the CSM may require a quality control prior to the issuance of the marketing authorization when it comes to generic drugs. The sample requirement in terms of number, type of batches and packaging vary from country to country. In Benin, unregistered medicines could be imported without testing of samples if they are for international aid or for the purpose of therapeutic trials upon special approvals.

Other products

Apart from human medicines (human pharmaceuticals), the law also provides for the registration of other products in Ghana, Liberia, Mali, Niger, Nigeria, Benin, Chad and Togo. These products include veterinary medicines and Vaccines/biological in Ghana, Liberia, Mali, Niger, Nigeria and Togo. Traditional medicines are registered in Ghana, Liberia, Mali, Niger and Nigeria. Medical devices are legislated for registration in Ghana, Liberia, and Nigeria while cosmetics and prepacked foods are registered in Ghana, Liberia, Niger, Nigeria, and Togo. (Prepackaged foods are not registered in Liberia and Niger. Household chemicals, detergents and water are registered in Nigeria and Ghana. In Chad, herbal products do not fall under the regulation for registration.

Section K Inputs and success stories

Based on interaction with pharmaceutical companies owned by Indian nationals and those that import pharmaceutical products from India, it is clear that there are certain challenges which they encounter in their day to day businesses. These challenges may be grouped into different groups and include:

Regulatory challenges

This may be viewed from pharmaceutical regulatory and non-pharmaceutical regulatory perspective.

Product registration and importation: Registering a new product is often difficult, time consuming and often costly more than the official/ advertised cost. Often, some of these companies do not have a choice than to either outsource the product registration to third parties or pay more to “hasten” the process.

Double Taxation: Although pharmaceutical products are exempt from Value Added Tax (VAT), various arms of the government often come in to demand for various forms of taxation, rates and levies. In one instance, a particular company was made to pay environmental levy to one of the government agencies and sanitation levy to another agency.

Infrastructure and Logistics

Included in infrastructure and logistics support are factors that aid production and movement of pharma products from the manufacturers/ importers to end users and includes electricity/ power availability and supply, access roads/ rail network, port facilities, water supply and availability of market for sales of products.

Some of these are discussed briefly in the next section.

- ❑ **Power and Energy:** The role of power and energy in the mining process cannot be over emphasised as absence of power is a real challenge and threat to storage of pharma products.
- ❑ **Access Roads:** For most of the rural areas, good access road, all year round, is a requirement as absence of it will impede movement of pharma products from manufacturing plants to market/ rural areas.

Market challenges

This includes:

- ❑ High level of substandard, counterfeit and fake drugs;
- ❑ Presence of local and unregistered drugs/ herbs etc.

To succeed in the industry, some of the following “secrets” may be adopted:

❑ Follow the money

While this may sound strange, it is an economic reality. It is estimated that approximately 50% of all pharmaceutical purchases/ consumption is concentrated in the top five Nigerian cities, and per capita spending in big cities can reach almost twice the national average. Some of the reasons why the consumption is high in these cities is the superior logistics and infrastructure support in the cities when compared to the rural areas.

❑ Develop an efficient structure to handle sales-and-distribution networks

Of the over 80,000 pharmaceutical products retailers in Nigeria, approximately 4,500 of them are registered pharmacies, and more than 70 percent of revenue potential lies in unregistered and informal outlets served by some 200 wholesalers. While the pharmaceutical companies may not have

the resources to reach out to all the retailers it will be good to develop excellent marketing strategy with the wholesalers that should include:

- ❑ Stringent metrics for compliance and performance;
- ❑ Well-defined priorities for markets, health centres, distribution channels, and customers;
- ❑ Attractive financial and non-financial incentives; and
- ❑ Adequate marketing resources.

To succeed, pharma companies should adopt the aforementioned steps so as to extend their reach in the unserved/ underserved cities, health centres and customer segments.

❑ **Build a strong local leadership team**

Production of quality products does not always guarantee business success. Leadership, especially at the top is equally important. To succeed in Nigeria as a pharmaceutical company, you will need committed leadership, preferably a team with deep knowledge of both industry and local environment. With good leadership, structures that will align all interests should be put in place and this includes dedicated investment budgets, autonomy to make routine day-to-day decisions, and local support for critical functions such as marketing and finance.

For the (non-pharmaceutical) middle-management skills, the companies will be competing for talent with other sectors (banking, telecommunications, oil and gas etc.) in some cases, candidates with basic skills may be recruited and trained. To succeed in Nigeria, these companies must attract local talent by promoting a meritocratic culture with global career tracks, investing in diversity, building trusting local relationships, and offering globally competitive financial packages.

❑ **Be ready to fight back**

Considering that the retail network in Nigeria is predominantly informal, it will not be out of place to have fake, counterfeit and sub-standard drugs sold side by side with the original/genuine drugs. This means that to be successful, pharmaceutical companies must be ready to adapt and change tactics and possibly deploy means and ways to counter counterfeiting of its products. Some pharma companies have continued to deploy various security seals and mobile authentication service to check mate this.

❑ **Define the opportunities in detail**

Drilling down into opportunities at the level of health centres and sales-and-marketing channels enables a company to make smart choices about where to allocate resources. Using a clinical sales force to serve hospitals and account managers to serve government tenders and large accounts has proved not very effective in overcoming barriers in patient access and infrastructure. An approach geared to specific products, channels, and healthcare providers is likely to prove more effective. It will not be a bad idea to develop product portfolio that meets the contrasting needs of affluent patients, who face a growing burden of noncommunicable illnesses such as

heart disease, and poorer patients, who disproportionately suffer from infectious diseases such as typhoid.

❑ **Understand the reality of patient journeys**

Traditional market-entry models are unlikely to prove effective against the hurdles presented by awareness, access to primary healthcare, generics substitution by retail pharmacists, and product availability and affordability in Nigeria.

The suggestion is that pharma companies should instead study local patient journeys and develop bespoke solutions. For example, for hypertension in Lagos, it is estimated that more than four-fifths of patients are unaware of their condition, while among the one-fifth with a diagnosis, fewer than half regularly check their blood pressure. Two-thirds of patients visit a retail pharmacist rather than a medical professional as their first port of call, but three-quarters of Lagos's retail pharmacies and proprietary and patent medicine vendors are unregistered and are often staffed by technicians lacking the knowledge, skills, and tools for effective diagnosis. These pharma companies may start by carrying out focused detailing with retail pharmacists, providing blood-pressure kits, training staff in diagnostic methods, and hosting screening sessions in priority cities.

To succeed as a pharma company in Nigeria, the pharma companies should:

- ❑ Define their strategic objective of operating in Nigeria. These objectives should align with the organisation's global priorities taking into cognizance the local conditions in Nigeria.
- ❑ Define their geographic focus; this means which states/ cities/ towns they want to focus taking into cognizance socio-cultural/ economic powers
- ❑ Define the key health providers; this is by asking who are the key buyers, and how much value do they drive?
- ❑ Identify an efficient product portfolio. Which health centres/ distribution channels are the most attractive to target, given the bouquet of existing products and those in the pipeline?
- ❑ Understand their patient journey. How can we address the pain points that limit patient access to healthcare and medicines in each disease area?
- ❑ Identify optimal route to market. What sales-and-distribution model would best open up our path to the patient?
- ❑ Go into innovative partnerships. What are the big ideas and stakeholder partnerships that will drive step-change growth?
- ❑ Clarify their business case. What sales growth and returns can we expect from our investment?
- ❑ Review their in-house skills and talent. What organization and skill gaps exist, and how can we fill them rapidly?
- ❑ Create their road map. What tactical levers can we pull to capture quick wins, and what key performance indicators, targets, and milestones should we use to measure success?

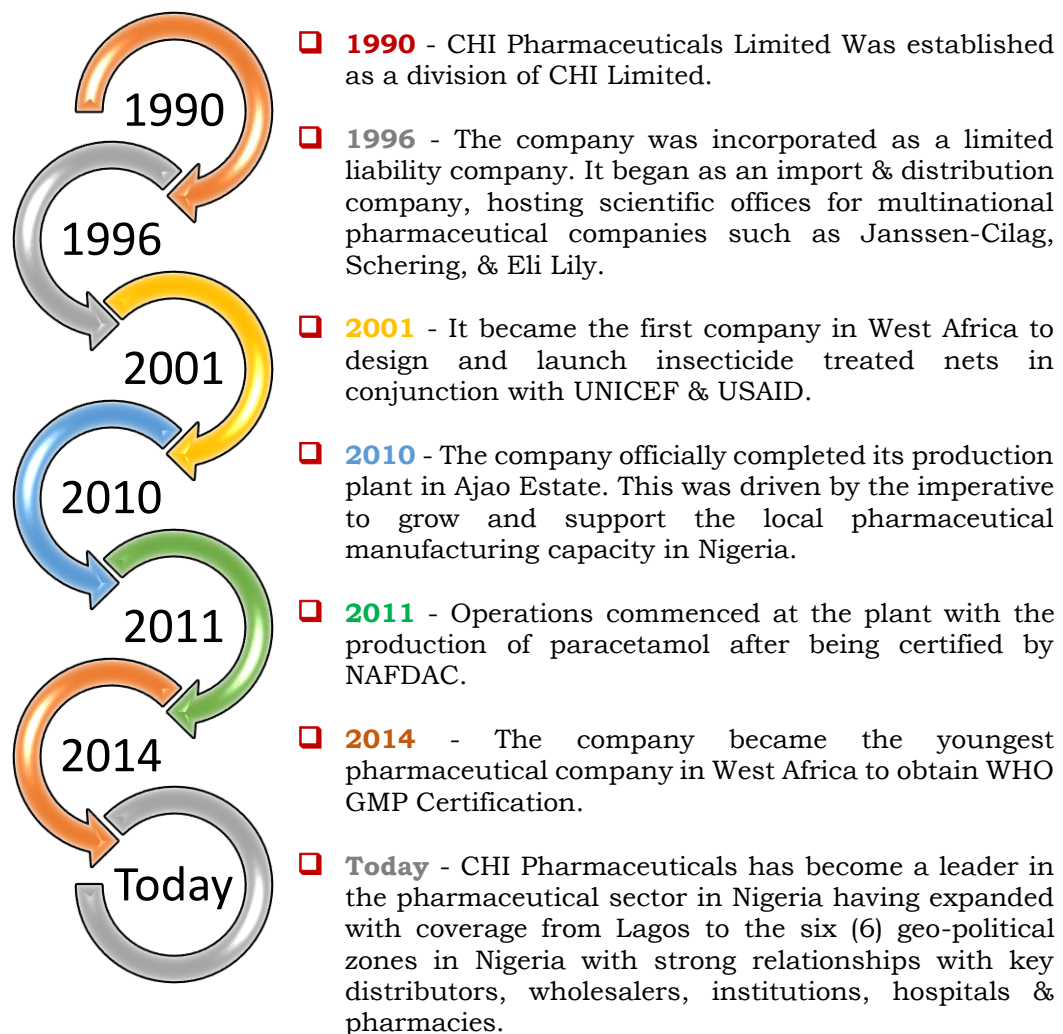
Nigeria still offers exciting growth opportunities for multinational pharma companies, but short-term success is by no means assured. Gaining market share requires a clear grasp of city potential, government context, distributor landscape, and healthcare providers. Those companies that master local dynamics and devise bespoke solutions will be best placed to develop winning strategies.

The story of Chi Pharmaceuticals

CHI Pharmaceuticals is one of the leading pharmaceutical companies in Nigeria. The Company started as a division of CHI Limited in 1990 and have expanded today with coverage across Lagos, the commercial nerve centre of Nigeria and all the six geo-political zones of Nigeria. It's products is in high demand across the West African sub-region.

The success story of Chi Pharmaceuticals is graphically illustrated below:

Figure 9 - Chi Pharmaceuticals - Historical perspective



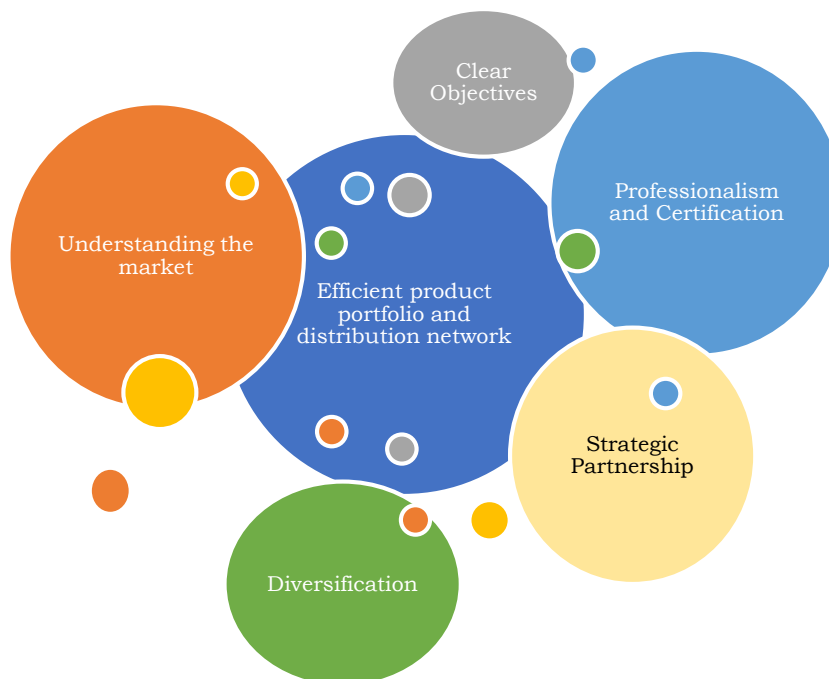
The story of Jawa Pharmaceuticals

Jawa Group of Company, established in 1998 is one of the top pharmaceutical products manufacturing, distribution and marketing company in Nigeria operating from Lagos with administrative offices spread across the country with over 400 highly-skilled, professional, experienced, trained and certified staff.

The company which started just five products in 1998 has over 50 products covering mainly multivitamins, antibiotics, anti-ulcerants and GI disorders, anti-malaria, anti-histamines, antiseptics and pain management, oncology and intra-uterine contraceptive device and antihelminthics.

The company's success is hinged on the following factors:

Figure 10 - Jawa Pharmaceuticals - Success factors



❑ **Strategic Partnership**

Entered into marketing arrangement with various pharmaceutical manufacturing companies in India with the goal of delivering quality products and catering for most of the therapeutic segments.

❑ **Understanding the local market and taking advantage of the opportunities**

Expanded into the critical care and ethical products market with launch of new division which specializes in different therapeutic segments like Anaesthetics, Antibiotics, Total Parenteral nutrition, and Antimalarials. Expanded its horizons into newer therapeutic segments and newer molecules like superior antibiotics, anti-malarials, anti-cancer, gastrointestinal anti-diabetic and cardio-vascular drugs, anti-depressant, anti-inflammatives and sutures.

❑ **Clearly defined objective**

The company has a clearly defined objective of not only providing world-class quality medicines at the most affordable cost for Nigerians and non-Nigerians but also ensuring availability of such innovative and economic formulations at every nooks and crannies of Nigeria and beyond.

❑ **Diversification**

The company is horizontally and vertically diversified.

It has over 50 products covering mainly multivitamins, antibiotics, anti-ulcerants and GI disorders, anti-malaria, anti-histamines, antiseptics and pain management, oncology and intra-uterine contraceptive device and antihelminthics.

In 2011, the company expanded into the Animal Health Care Business under the name of Kattle Care Limited with the aim of bringing more farm wealth through better animal health.

❑ **Efficient product portfolio and distribution network**

Although the Company's operational office is in Lagos, it has administrative offices across the nation which ensures that its products reaches every nook and cranny of the country and beyond.

❑ **Professionalism and Certification**

Apart from being a member of the Pharmaceutical Manufacturing Group of Manufacturers' Association of Nigeria (PMG-MAN), the Company has received the following awards / accreditations:

- ISO Certification: ISO 9001:2008 Certified (SON)
- NAFDAC GMP Certificates in Year 2011
- Best Antibiotic manufacturer in Nigeria in Year 2008-2010.
- Africa direct marketing merit award as best antacid in Nigeria



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High Commission of India, Abuja (Nigeria)

