# A comparative study of Regulatory systems and Quality management practices in the manufacturing process of different pharmaceutical companies in Nigeria.

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

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**Candidate Declaration:**

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I certify that the dissertation entitled:

"A comparative study of Regulatory systems and Quality management practices in the manufacturing process of different pharmaceutical companies in Nigeria." submitted for MSc in Pharmaceutical business and technology is the product of my own research and references were made in areas where the work of others were utilized.

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**Abstract**

This thesis aims to examine and compare different pharmaceutical manufacturing companies in Nigeria (local and foreign). There will be an examination of regulatory systems and quality management practices in the company and their impact on the quality and availability of medicinal products in the region. The opinion of medical doctors, pharmacists and consumers concerning the products from foreign and Nigerian pharmaceutical companies would also be considered when examining the impact of company quality system on the products. This aim would be achieved by way of conducting quantitative questionnaire survey and qualitative reviews of literature.

A cross-sectional survey with 50 participants including medical doctors, pharmacists and consumers was carried out and literature about the regulatory systems and quality management practices of the were reviewed and the results showed the regulatory system in Nigeria is not effective and the entire pharmaceutical sector of has loopholes that make the system inefficient. The research was also able to identify the factors that influence the quality and availability of medicinal products manufactured in Nigeria which include Socio Economic status of the country, Inadequate laws or poor enforcement of the existing regulations/guidelines for manufacturing of good quality medicinal products, Inadequate funding/support for Nigerian pharmaceutical manufacturing companies, Demand exceeding supply and high cost of good quality medicinal product.

NAFDAC has put in efforts over the years to improve their system but there are still important changes that need to be made. The study recommend that NAFDAC makes the Nigerian Pharmaceutical sector more transparent with its activities and more funding should be made available to the Nigerian pharmaceutical companies. Also should be set up to ensure that the NAFDAC officials carry out their duties effectively and they should be paid properly for it.

Key words: National Agency for Food Drug Administration and Control (NAFDAC) Regulatory systems. Quality management practices, Medicinal products, Good Manufacturing Practices.

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**ABBREVIATIONS**

FDA -FOOD AND DRUG ADMINISTRATION

NAFDAC- NATIONAL AGENCY FOR FOOD DRUGS ADMINISTRATION AND CONTROL

NDLEA- NATIONAL DRUG LAW ENFORCMENT AGENCY

EU- EUROPEAN UNION

ICH- INTERNATIONAL CONFERENCE ON HARMONIZATION

GSK – GLAXOSMITHKLINE PLC

MHRA – MEDICINE AND HEALTHCARE PRODUCTS REGULATORY AGECY.

GMP- GOOD MANUFACTURING PRACTICES

NIPRD- NATIONAL INSTITUTE OF PHARMACEITICAL RESEARCH DEVELOPMENT

OTC- OVER THE COUNTER MEDICATION

API – ACTIVE PHARMACEUTICAL INGREDIENTS

AMRH – AFRICAN MEDICINE REISTRATION HARMONISATION

WHO – WORLD HEALTH ORGANISATION

NEPAD – NEW PARTNERSHIP FOR AFRICAN DEVELOPMENT

ICDRA – INTERNATIONAL CONFERENCE OF DRUG REULATORY AUTHORITY

NIBSC – NATIONAL INSTITUTE FOR BIOLOGIAL STANDARD AND CONTROL

OMCL- OFFICIAL MEDICINE CONTROL LABORATORY

WTO – WORLD TRADE ORGANISATION

QRM – QUALITY RISK MANAGEMENT

# CHAPTER 1: INTRODUCTION

## 1.1 Background of the study

Enhancing quality could be very frequently regarded as an interest that is going to increase value. Upgrading the quality of a product is simply the utilization first-grade raw materials and good strategies in the production of a product. The main aim of enhancing quality is not an easy task although it can be achieved by investing more funds in activities that are designed to prevent manufacture of low quality products like quality assurance instead of funding activities that aid in detection of faulty products after manufacturing. (Poornima, 2017)

An effective regulatory system that achieves good quality is simply a regulatory system that enhances the ability of individuals and establishments to ensure and deal with all safety and quality issues that may arise. This system would involve both he establishment or company and the national regulatory body. For multinational companies the governing regulatory body could be the effective regulatory body in the country where the company is established or it could be governed by the regulatory body from the headquarters of the company.

In recent years, quality has risen to play a big role in the consumer confidence in a products and further influences the consumers choices in using a product especially in the pharmaceutical industry. Also in the past few decades the need has arisen to improve the medicinal products manufactured in Nigerian by way of enhancing the Nigerian regulatory system. However, no notable changes have come up due to different factors especially poor response from the regulators as regards implementation of changes to enhance the system

## 1.2 AN OVERVIEW OF THE REGULATORY AUTHORITIES

Falsified and substandard drugs have always been world problem (WHO.int, 2017) and Nigeria are not excluded as they suffer from the effects till date. This is partially as a result of poor regulation of the production and marketing of medicinal products and partially because of the socio-economic state of the country. People are still found to be self-medicating due to lack of funds and getting the drugs from unlicensed marketers who in turn give them poor quality medicine at a cheap price. Overall, use of substandard drugs are one of the major causes of death in Nigeria. As per research by (Adebayo, 2017) up to one hundred and fifty children died by using wrong formulated medicinal product. In 1995 the use of a particular brand of meningitis vaccine during an epidemic lead to the death of over 2,500 people because the vaccine was reported to have contained impurities This high number of deaths as an issue in Nigeria was what made the pharmaceutical society oof Nigeria to push the government into reacting. Their reaction was the setting up of the Decree no.21 of 1998 banning the manufacture and marketing of fake, adulterated, unlicensed and counterfeit medicines in the open market.

Since the inception of NAFDAC in 1994 however, the situation has gotten better. As of 2001 Dora Akunyili was the director general of the agency and she instituted a great reform. Her aim was to rejuvenate the system and redirect their aim to ensure the safeguarding of the health of the nation. During her time, sale of fake drugs fell to about 16% as of 2006 and marketing of counterfeit and substandard medicine was reduced by up to 80% and the system was seen to effective. (Adebayo, 2017)

Before 1906 when the Pure Food and Drug act was passed, America faced the same problem as patent medicines were being sold in catalogues. Due to this the

only information available about the medicinal product was the label and over hyped slogans for products made available by the marketers. Due to this fact the producers started to exploit the market by using increase levels of cocaine and morphine in the drugs to give users a high as opposed to treating illnesses. Harvey Wiley was the head of the USDA's Bureau of Chemistry was very passionate about ensuring the safety of American food and drugs and so he worked with activist Alice lakey and together they were able to convince the public about the "Pure Food Bill" and soon after, in the year 1906, the bill was signed into the law. This bill is what has grown to become todays Food and Drug Administration. Since then, the FDA has been a very reputable regulatory authority. One of their most notable achievement is the rejection a drug used to combat morning sickness in pregnancy knows as "thalidomide". A drug very well sold in Europe. At the time the safety and efficacy of the medication was not properly tested because it was believed that the drug did not affect the foetus in any way. However, when the drug was given to the FDA for approval to be sold in the US, the FDA required that the company carry out more safety tests. These tests went on to show that pregnant women who used the drug give birth to babies with severe birth defects. This even gave the FDA an upper hand in the world regulatory authorities. (Ben Panko, 2017)

Pharmaceutical companies world-wide have increasingly become more competitive over the years and so different countries have come to the realization of the need to establish regulatory authorities to oversee the activities of these companies. The task of these regulatory authorises are very important and cannot be over emphasized as they ensure that all products meet up to the set requirements as regards the drug development process in that country. All countries with licensed pharmaceutical companies have an established regulatory authority in charge of implementing

guidance and regulations to control the medicine production process. Some of the countries and their regulatory bodies have been listed in the table below.

Table 1.1 Regulatory Authorities around the world

| **Country** | **Name Of Regulatory Authority** |
|---|---|
| Nigeria | National Agency for Food and Drug Administration and Control |
| USA | Food and Drug Administration (FDA) |
| UK | Medicines and Healthcare Products Regulatory Agency |
| Europe | European Medicines Agency (EMEA) |
| India | Central Drug Standard Control Organisation (CDSCO) |
| China | State Food and Drug Administration |
| Uganda | Uganda National Council for Science and Technology |
| Japan | Ministry of Health, Labour & Welfare (MHLW) |

(Geetanjali Sengar, 2012)

The procedure to approve a new medicinal product varies in different countries. For example, in the USA, the food and Drug administration (FDA) is responsible for all activities from drug approval to licensing to inspection of production site.

However, in some other countries the tasked are shared to centralized and state authorities.

As more and more pharmaceutical companies are established, more and more medicinal products are released into circulation giving rise to drug safety and efficacy concerns. It is important to note that the use of any medication comes with a certain level of risk of adverse reaction. However, in most cases the benefits from using the drugs surpasses the risk. Be that as it may, some drugs still cause harm as a result of the drug having some toxic components as seen in drugs from adulterated products as well as counterfeit/fake drugs. These facts lets us know that drug regulation is necessary in order to establish and ensure safety and efficacy of drugs. (Geetanjali Sengar, 2012)

### 1.3 ICH (International Conference on Harmonization)

The ICH is an international organisation started up in 1990's by the European community (EC) which is now referred to as the European Union (EU) in a bid to unite the pharmaceutical market and bolster public health by way of realizing harmonisation by the establishment of technical guidelines, specifications and stipulations for the registration process associated with new products. By creating tis harmonisation, they hope to create a more rationed use of resources and get rid of needless delays as regards development and availability of new medicines. There are 4 divisions of the ICH topics, they include

- Q – quality guidelines
- S – safety Guidelines
- E – Efficacy guidelines
- M – Multidisciplinary Guidelines

This research will focus on the Q – Quality guidelines and the Good manufacturing practice (GMP) guidance for active pharmaceutical ingredients under a certified and suitable scheme for managing quality. The ICH guidelines have been adopted for use by up to 10 countries including ANVISA, Brazil, EC, Europe, FDA, United States, HAS, Singapore, Health Canada, Canada, MFDS, Republic of Korea, MHLW/PMDA, Japan, NMPA, China, Swissmedic, Switzerland, TFDA, Chinese Taipei. (ICH.ORG, 2021)

The information in this document was put together by the ICH in a bid to give directions so as to ensure that the production of active pharmaceutical ingredients is navigated properly and according to the relevant process for managing quality. It is important to note that this guidance does not contain information about the safety of the individuals that take are active part of the manufacturing process. Guidance for these individuals is the duty of the manufacturers and is subject to government laws. (Tietje and Brouder, 2010a)

The guidelines in this case covers all active pharmaceutical ingredients that are being produced by way of chemical synthesis, cell fermentation and extraction from a natural source. Vaccines, blood and plasma derivatives, and whole blood and plasma cells are categorically not included in these guidelines. it gives information concerning the following factors:

- Quality management
- Buildings and facilities
- Process Equipment’s
- Documentation and Records keeping
- Management of materials
- In process control

- Packaging and labelling
- Storage and marketing
- Validation
- Possible recalls. (Tietje and Brouder, 2010a)

Nigeria, however, has not adopted the ICH guidelines for good manufacturing practices. There are 3 regulatory authorities charged with control over drugs, biologicals and medical devices in Nigeria. They include:

- The National Agency for Food and Drug Administration and Control (NAFDAC);
- The National Drug Law Enforcement Agency (NDLEA); and
- The Federal Ministry of Health.

T**he regulatory body responsible for the authorization of drugs, biologicals, and scientific devices in Nigeria is the National Agency for food and Drug Administration and Control (NAFDAC).** It comprises of the NAFDAC Act Cap N1 LFN 2004). The NAFDAC Act permits the organization to control and guide the production, importation, exportation, marketing, sale and utilization of food, medicinal products water and chemicals.

The organization was set up in 1993 in a bid to conquer the growing trade and use of counterfeit, falsified and adulterated drug in Nigeria. This was coming right after the problem grew so big that neighbouring countries including Ghana and Sierra leone band the sale of Nigerian made foods and medicinal products in their country. NAFDAC ensures that all foods and medicinal products manufactured comply with the **NAFDAC GMP standards** in order to ensure that all manufactured goods are of good and high quality

Currently, there is no constant mechanism set up for pricing or recompense of drugs, biologicals and other medical devices in Nigeria. However, the NAFDAC Act empowers the organization to regulate systems to develop, analyse, and advertising products. (Olaniwun Ajayi LP, 2019)

NAFDAC has also established the NAFDAC GMP (good manufacturing practices) for pharmaceutical products which also include its specific pharmaceutical quality systems. The GMP was set up by NAFDAC in a bid to establish consistency in quality standards of all medicinal products manufactured and that they are suitable for use for the intended purpose. The GMP specifies the base standards that all manufacturers must follow in order to establish the quality of the medical products manufactured. These guidelines are applicable to all pharmaceutical and veterinary medicinal products. (NAFDAC, 2019)

This guidance talks about the good manufacturing practices to be applied for use in the manufacturing process including packing and storage of pharmaceutical products for human and animal use. The document also states that it is prohibited to engage in any manufacturing process outside of the regulations in this document and failure to comply with the set standards in the document automatically made the products manufactured substandard or adulterated. In this case such persons involved in the production process is liable to a set out penalty. The NAFDAC GMP gives information about certain factors that are similar to that of the ICH GMP.(NAFDAC, 2019). They include:

- Pharmaceutical Quality System
- Premises and Equipment
- Qualification and validation
- Documentation

- Production
- Materials management
- Quality Control
- Contract manufacture and analysis
- Complaints and product recall. (NAFDAC, 2019)

**The National Drug Law Enforcement Agency (NDLEA**) is an organization that plays the role of getting rid of illegal and narcotic drugs in Nigeria. They are also control the manufacture, marketing, exportation and use of these narcotic drugs. To this effect, they are mostly situated at ports and border crossings

The NDLEA is charged with the task of inspecting, arresting and prosecution as regards offenses related to illegal exportation of hard Drugs. The NDLEA works with other international drug units to find these illegal drugs and destroy them.

**The Federal Ministry of Health** runs and manages all activities of NAFDAC and NDLEA. They act as the ultimate head which the NAFDAC and NDLEA gets orders and permissions from. The federal ministry of health is also in charge of authorizing and setting up new regulations and guidance in order to ensure that all operations are carried out properly and adequately. The department for Food and Drug services is the section of the federal ministry if health that formulates national policies to control the production and marketing of food and drugs. This section acts as benefactors for the National Institutes of pharmaceutical Research and development (NIPRD) ,NAFDAC and NDLEA. (Health.gov, 2021)

## 1.4 PHARMACEUTICAL COMPANIES IN NIGERIA

In order to properly explore regulations and quality in the pharmaceutical production in Nigeria, I will focus on 2 of the top pharmaceutical companies in Nigeria. One of them would be a Nigerian pharmaceutical company and the other would be a foreign

pharmaceutical company. For the purpose of this research the companies chosen include:

- **Emzor pharmaceutical industry limited** a Nigerian pharmaceutical company situated at Ikoyi, Lagos state that produced different classes of medication including OTC, antibiotics, anti-malaria and others
- **GlaxoSmithKline plc** a UK based company that established a subsidiary in Lagos Nigeria in the year 1971 and stated production of over the counter medications (OTC)

**EMZOR PHARMACEUTICAL INDUSTRY LIMITED**

This is a Nigerian owned pharmaceutical company founded in the year 1984 that deals in production of over 140 pharmaceutical products and medical consumables. Emzor products include various over the counter medication as well as Analgesics, Anti-Malarial, Antibiotics, Antihistamines, Antitussives, and Gastrointestinal. Emzor is the leading brand in production of analgesics in Sub-Saharan region of Africa.

Emzor strives to provide top quality medicinal products to its customers. In order to achieve this the production activities are carried out according to set guidelines. in their bid to ensure continuous learning and innovation they strive to create a conducive environment for all personnel and workers. The company has its own quality policy that aims to promote team work among workers, ensure all policies and guidelines are properly understood and applied and that all policies are constantly reviewed as changes continue to occur. Regulation of the set quality system is also achieved by maintaining a high Health, Safety, and Environmental Standard. (HSE)(EmzorPharma, 2021b). The Emzor HSE, therefore, permits the workers, contractors and consumers to profit from their policy. Emzor guarantees

that they run a safe, responsible and effective operation. They also ensure that there is total and complete compliance with the guidance and guidelines relating to HSE in the country. By doing this they are able to ensure that all personnel work according to safety culture that has been established. (EmzorPharma, 2021a)

The quality management system operated by Emzor also requires working personnel to report any issue relating to all form of malpractice or if the company policy is not followed properly.
The company safeguards these reports and ensure that all reports are strictly confidential and not directed towards personal profits. (EmzorPharma, 2021d)

Due to the fact that Emzor is a Nigerian company, it is controlled and regulated by the national agency for food drug administration and control( NAFDAC) and so the NAFDAC GMP are utilized for their production of medicines for human use

**GLAXOSMITHKLINE PLC**

This is a UK based global healthcare company that has established various offices in different countries around the world including Nigeria. They came into Nigeria in the year 1971 and started the manufacturing process in 1972. With the goal of becoming one of the world's most innovative and trusted health care companies, GSK has set high ethical standards and ensure compliance to them. Their quality management systems focuses on the safety of patients and compliance with the set standards and regulations related to quality as well as the safety of work personnel

The GSK Quality Management System ensures that all information concerning production are well documented and readily available for audition even by health care professionals and other qualified and licensed authorities, this fact is in line

with their values which include: integrity, transparency and patience. The company also creates room for reporting of malpractice. Workers are required and encouraged to report all events that violate the set regulation and standards as well as other personnel carrying out unethical activities.

As an originally UK company, GSK is regulated the Medicine and Healthcare Regulatory Agency (MHRA) and utilized the GMP of international conference of harmonisation (ICH)

### 1.5 Research purpose

The purpose of this research is to examine and compare different pharmaceutical manufacturing companies in Nigeria. There will be a proper examination of regulatory systems and their impact on the quality and availability of medicinal products in the region.

This study will be focusing on comparison of international pharmaceutical manufacturing companies based in Lagos with the Nigerian companies, to identify regulatory bodies and quality management systems with the aim of identifying how effective they are and the outcome of their utilization.

Furthermore, this research will assess the availability of the medicinal products from the pharmaceutical manufacturing companies to consumers in Nigeria, as well as the quality of medicinal products they produce.

### 1.6 Significance of the study

The significant reason for carrying out this research work is due to the fact that quality management systems allow companies in highly regulated industries to constantly apply quality processes in order to supply products which meet

customer expectations and regulatory necessities. The international council for Harmonisation (ICH) offers a comprehensive blueprint at regards production of pharmaceuticals for human use. many different countries have adopted the use of these guidelines for production of pharmaceuticals. Nigeria on the other hand whose regulation of pharmaceuticals is controlled by NAFDAC have not accepted this guidelines but have established their own guidelines for good manufacturing practices. This research will examine the difference in these systems and the outcome of their application.

**1.7 Research Objectives:**

- To determine the impact of regulatory system on the quality of medicines produced by the Nigerian pharmaceutical companies.
- To ascertain the general opinion of the respondents about the of medicinal products manufactured in Nigeria.
- To compare the quality and effectiveness of the medicinal products manufactured the Nigerian pharmaceutical companies to that of the foreign pharmaceutical companies in Nigeria
- To identify the factors that affect the quality and availability of medicinal products in Nigeria

**Research Questions:**

- How can different regulatory systems affect the quality of the medicinal product manufactured by various pharmaceutical companies in Nigeria?
- What is the availability and storage of medicinal products in the local pharmacies?

(Preference of the medicinal products that are manufactured by foreign pharmaceutical company/ Nigerian pharmaceutical company)

- What type of medicinal products do the health care professionals prefer to prescribe for their patients? (medicinal products manufactured by foreign companies/ medicinal products manufactured by Nigerian)
- What type of medicinal products do the consumers prefer to buy?(medicinal products manufactured by foreign companies/ medicinal products manufactured Nigerian companies)
- Cost effectiveness of the medicinal products for consumers from different pharmaceutical companies

**1.8 Structure of the study:**

This study will utilize both qualitative and quantitative methodologies.
The qualitative research would involve collecting data about the different pharmaceutical companies in Nigeria from company websites and also gathering of information about the regulatory bodies and quality management systems in play at these pharmaceutical companies from regulatory body websites, online articles and peer reviewed journals.

The quantitative research would be conducted in form of a survey distributed to health care professionals and consumers. The survey is directed at evaluating the general idea of the respondents about the medicinal products manufactured in Nigeria by the Nigerian pharmaceutical company and the foreign pharmaceutical company. It will also evaluate the quality, availability and preference of medicinal products in Nigeria.
Questionnaires would be given to health care professionals including:

Medical Doctors in Nigeria as they can provide information regarding the preferred medicinal products to prescribe and what possible quality factors influence their choice of prescription. Questionnaires will also be given to Pharmacists that work in large pharmacies in Nigeria. This is because they can provide information about the quality of medicinal products supplied to them by the pharmaceutical companies as well as availability of products from different pharmaceutical companies. Consumers of the medicinal products will also be contacted as they can attest to the effects and impact of the various medicinal products from the different pharmaceutical companies that they have used. I would also be able to gather information about their preferences and what factors influence their preferences.

## 1.9 Conclusion

In conclusion, after the whole comparison among company regulatory standards, the impact of their QM on their products, it is also important to note some key points which include facts that the organization needs to have a defined goal for the development of its products, approaches, organizational structure, and control system and this can be done through the analysis of statistics. The statistics the employer deploys must be documented, and applied on a regular basis. It must have a structured method to persistent development. It should also evaluate outcomes to verify the effectiveness of the technique hired.

Quality management system is a very important part of the pharmaceutical industry which cuts across responsibility against profitability in the sense that the quality and integrity of products delivered or distributed to the consumers must be up to standard regardless of how much resources is being used and also putting into consideration that the safety of the consumers is top priority and as seen in most

pharma company credos. However, some companies manufacture unstandardised products in countries where regulations are not being implemented with the hope of getting away with it as seen in developing countries like Nigeria. NAFDAC and other regulatory agencies have drafted out regulatory measures and policies in order to ensure that pharma companies follow GMP and these polices are in keeping with other international policies (EMA and FDA) in developed countries.

Innovation also has to be encouraged while using a proper technique. The procedures to encourage innovation must address products, strategies, and the organizational structure i.e. QMS. There should be innovation risk assessment which will serve as a preventive movement to mitigate risks that can be inherent in innovation projects in order to ensure that these innovations are maintaining GMP with the goal of ensuring safety and efficacy of products delivered to the consumers. There is a great need for continuous re-evaluation by regular audits (internal and external ) by competent authorities of the quality of pharmaceutical products, upgrades of existing quality management protocols and ensuring licensed and certified active pharmaceutical ingredients and equipment are being utilized.

# CHAPTER 2

## 2. LITERATURE REVIEW

### 2.1 Nature of pharmaceutical industries in Nigeria

There are over 130 pharmaceutical manufacturing companies in Nigeria and since 2011, the number has continued to rise. Some of the companies are Nigerian companies while the others are subsidiaries of large foreign pharmaceutical companies. The foreign subsidiaries noticeably top the charts in quality products manufacturing. These companies are believed to be doing the best they can give the current situation of the country and the restraints they have to face. (DrugXpert, 2019)

Some of the restrains that the pharmaceutical industry in Nigeria faces is brought on by the unstable socio-political environment brought about by high crime rates and corruption in the country. World bank reported that it was impractical for developing countries to go into pharmaceutical manufacturing with the exception of certain countries that has the ability to manufacture the active ingredients required. This fact led to the increased increase in importation of pharmaceuticals and dampened the need to establish pharmaceutical manufacturing companies

There are 3 different pharmaceutical manufacturers that carry out business using various business models they include: Subsidiaries of large pharmaceutical companies that deal with the production of patent protected products, World-wide Manufactures of generics that target advanced markets like US and some medium markets such as China and local producers that make small number of products and traditional medicinal products to serve the local markets. Some hospitals in Nigeria is also known to repackage medicines into smaller packets for distribution to patient this is also part of small scale manufacturing from already finished

products. In recent times, the manufacturing of medicinal products by Nigerian pharmaceutical companies has been on the rise. Even so, the industry still faces certain challenges such as

The high standards set for the manufacturing of Active pharmaceutical ingredients (API) and other raw materials, inadequate research and development brought about by inadequate funding, leading to limitations in innovations, and above all inadequate supply of essentials such as power supply, water tech support for equipment. (Pharmapproach, 2018)

A major characteristic of the pharmaceutical industry is that it is very sensitive and vulnerable to fraud. Most likely to occur in the distribution network. This is because of the health care professionals have more knowledge about the medicinal product then the average patient. This lack of knowledge on the part of the patient can be exploited in order to maximise profit on the side of the professional. Due to the corrupt system in Nigeria, this practice continues and evolves into distribution of adulterated, substandard or even expired drugs and others that could be potentially life threatening. The system is also easily corrupt simply due to human nature. This is because the regulations are set up by the government and is required to be implemented by all production processes. But the whole process is jeopardised by the fact that the regulators bend the set rules for personal profit or the organisations that have paid bribes to boycott these rules

The constant lack of accountability and transparency is also a major factor in the problems of the pharmaceutical industry. This is because the regulators in this case are also the decision makers as regards penalties for malpractice and misconduct and so if a person can pay just enough, they forfeit the penalties

Another major reason for the growing corruption of the pharma industry is the fact that the supply chain is quite long and complicated. Manufactured medicinal products have to pass through a long chain of activities before getting to the consumer. This issue coupled with the fact that there is poor implementation of the set regulation related to marketing and distribution of medicinal products as well as the constantly circulating poor quality and adulated medicines that are hard to detect make the whole process vulnerable to corruption and fraud attacks.
In reality, this is the true nature of the pharmaceutical industry in Nigeria and so if changes must be made and integrity restored to the system, it must be an "all hands on deck" situation. (Olatunji, 2013)

### 2.1.1 AVAILABILITY AND DISTRIBUTION OF MEDICINAL PRODUCTS IN NIGERIA

AVAILABILITY

The availability of medical products in Nigeria is generally poor. Reasons being insufficient funding of community pharmacies by government "out of stock syndrome", unlicensed personnel infiltrating the distribution process and insufficient or defective transportation and storge equipment

In the year 1989, a promulgation decree was made in a bid to ensure the availability of essential medicines but somehow the "out of stock syndrome" continues to plague the industry and country at large. Due to this, a Drug Revolving Fund (DRF) was set up. In 1996. Its aim was to establish a contract with Nigerian manufacturers so that they produced the required essential medicines. This scheme was effective at the time but by 1999 it was eventually terminated. (Erhun *et al.*, 2013)

DISTRIBUTION

As earlier stated, the distribution and marketing of medicinal products in Nigeria is long and complicated, involving open markets, government owned and private owned hospitals, large community pharmacies as well as unlicensed pharmacies and patent medicine stores. In some cases common petty traders can be seen selling medicines on side walk. Even prescription medicines are sold without a doctor's prescription after being kept under conditions that are not suitable for them reducing their quality and efficacy

Various unlicensed and unauthorised individuals are involved in the marketing and distribution of medicinal products and due to their lack of knowledge about the process and even lack of basic education in most cases, they have no way of telling which drug is fake and which drug is original. The right way involves the sale of medicinal products in licensed and authorised community pharmacies registered with the pharmacist council of Nigeria. The pharmacy is run by a licensed pharmacists (with knowledge of genuine product trademark and good storage of product) all times. (Erhun *et al.*, 2013)

## 2.2 REGULATION OF THE PHARMACEUTICAL INDUSTRY

All areas of the pharmaceutical practice in Nigeria is regulated by pharmacist council of Nigeria Act. The act calls for the registration of all pharmaceutical facilities prior to the start of a pharmaceutical business. The role of the council in this case is to carry out inspections and registration of all pharma marketing and distribution premises and facility. (Ugochi Igwe, 2017)

However, the pharmaceutical practice of manufacturing medicinal products for human use is regulated by the National Agency for Food drug administration and control(NAFDAC). The major role of the agency is the assessment and registration of all medical products manufactured, carrying our post marketing surveillance and

product risk analysis, regulation of all imported medicinal products and control of the product marketing process including promotion. (Ugochi Igwe, 2017)
The NAFDAC falls under the African Medicine Registration Harmonisation (AMRH). The AMRH is an initiative set up in the year 2009 by the African union (AU). The aim of this organisation is to collaborate and assist the regional Economic communities to boast access to high quality medical products that a safe for use and effective in treatment of disease condition. Their plan was to achieve this by way of harmonizing medicine regulations and hastening or accelerating the process of production for essential medicines. This process has h high success rate in the eastern part of Africa. Its growth and development is inevitable with the help of the New partnership for Africa Development (NEPAD) and the WHO. (WHO.int, 2014).

Long before the establishment of the AMRH, the World Health Organisation (WHO) was responsible for proving medicine regulatory support to the different governments and all member states. However, the WHO was asked to bolster the "Harmonisation approach" at the 2008 international conference of drug regulatory authorities (ICDRA). The AMRH was set up in 2009 in response to this request. A close alliance was formed between the AMRH, World bank, NEPAD and WHO. In every case all decisions made must involve at least 2 members of the alliance. Even so, the WHO is the head as regards development of technical standards forms, records and tools  just like in the case if the international Conference of Harmonization (ICH). (WHO.int, 2014)

The AMRH and its initiative is enforced in the Economic Community of west African states (ECOWAS) the Intergovernmental Authority on Development (IGAD) and the Economic Community of Central African State. However, it has

different levels of implementation, functionality and growth in the different countries. The AMRH strive to fix the ancient problem of disjointed medicinal product manufacturing and distribution laws in African countries. To achieve this, they established the "*Model Law on Medical Product Regulation*" this law is expected to establish and assure effectiveness of the set-up regulation and also promote the harmonization as a whole. As of 2014, up to 11 centers of effective regulation has been nominated to carry our regulatory training programs utilizing the present academic establishments that are associated with regulatory agencies. (Ndomondo-Sigonda *et al.*, 2021)

The concept of quality pharmaceutical product manufacturing is based on the set good manufacturing practices for (GMP) e followed by the country. For the Nigeria and Nigerian pharmaceutical industry, the WHO worked with NAFDAC and brought about the "Nigerian Good manufacturing practice (NGMP). To this effect, training programs were also set up for all employees. In order for them to achieve the technical know-how on how to operate. The goal at that point was to improve the quality of the medicinal products manufactured by the Nigerian pharmaceutical companies.

The scope of the GMP is that it describes the GMP as well as all mechanisms to be utilized in the premises for all processes from manufacturing through packaging and even storage of the products. All these to ensure that the medicinal products meet the safety and efficacy requirements that has been set up.

The guideline also gives information about the pharmaceutical quality systems. It states that the a quality system must be put in place that covers all aspects of the production including: organisational structure, use of risk management ethics, resource, compliance and information records management, all personnel

responsibilities and requirement and policies. It also states that the organisation must ensure effectiveness of the set quality systems and finally , that all roles and responsibilities  must be well defined and understandable to the personnel who must be authorised or licensed for the particular role they have been assigned.

The guidelines about quality control state that manufactures must have an established, active and functional quality control department that send constant reports to management on quality of products and processes. Also, that this department should be run strictly by licensed and authorised personnel with the appropriate skill and knowledge. The personnel in charge of the department is must also be allocated a functional, fully resourced and properly funded control laboratory required for testing when deemed necessary. All products must pass though the quality control department and must be approved by licensed personnel in charge before it is released for sale or distribution. Lastly that it is very important for the producers to have a
Sample of the finished product that is released into circulation as well as the API used for its manufacture. The retaining period of the sample collected is at least 1 year after expiration date depending on the stability of the product.

The NAFDAC GMP guidelines for the manufacture of pharmaceutical products also contains vital information about the working personnel, the manufacturing facility and equipment, documentations, qualification and validation criteria among other important issues. It is important to note that these guidelines are only utilized the Nigerian pharmaceutical industry as their governing body is the NAFDAC. (Nafdac.gov, 2019)


Figure 2.1 Components of Good Manufacturing Practices (Vijay Yadav2 *et al.*, 2015)

## 2.2.1THE REGULATORY CAPACITY IN NIGERIA

As a third world country still in the process of development, the socioeconomic status continues to be a major issue. The ability to effectively implement and enforce regulation is on the low side. This is due to various reasons include lack of experience on the part of regulators who are in turn not paid adequately and no form of incentive is given to encourage interest in training programs or talking courses to enhance knowledge. This fact alone led to poor enforcement of set laws. Another issue is the fact that the distribution and supply chain of the medicinal products are in a bad state especially when it comes to the private own businesses

which make up a bulk of them. Distribution and sale in the public sector are achieved through the ministry of health. As for the private sector, the routes are undefined and uneasy to follow due to lack of documentation and possibly unlicensed procedures be carried out. In this case medicinal products can be seen to be sold in the open markets regardless of its quality. The major factor negating the effective regulation of medicinal products in Nigeria and even Africa as a whole is corruption. The transparency international corruption perception report for 2017 made it evident that African countries make up most corrupt of the world. (Ekeigwe, 2019) Supposed regulators are more inclined to collect bribes from faulters instead of bringing them to book. Manufacturers in turn exploit this faulty system in order to save a dime. Funds intended for implantation of an effective pharmaceutical quality system is halved and used as bribe for the corrupt regulators and the other half pocketed. The Public sector is not left out as government funds intended for manufacture of high-quality medical products especially the essential medicines are embezzled or diverted.

The constant lack of accountability and transparency is also a major factor in the problems of the pharmaceutical industry. This is because the regulators in this case are also the decision makers as regards penalties for malpractice and misconduct and so if a person can pay just enough, they forfeit the penalties

### 2.2.2 MEDICINAL PRODUCT LAWS IN NIGERIA

Different laws have been established in Nigeria in a bid to regulate and control the production and sale and marketing of medicinal products in Nigeria. some of those laws include: “The Poisons and Pharmacy Act, Cap 366 of 1990” this act controls the marketing and sale of medicines and gives information about the regulation of various grades and levels of medicines and poisons. “The Food and Drugs Act Cap 150 of 1990” this act prevents the distribution of specific medicines, food products

and cosmetic products. It impedes the importation and exportation of specific medicines and outlaws activities that involve mislabelling, misleading packaging, wrong advertising and even the manufacture of these medicinal, food and cosmetic products in unhygienic or unsanitary conditions. “The Counterfeit and Fake Drugs (miscellaneous provisions) Act, Cap 73 of 1990” this particular act prevents all production and distribution activities that has to do with any counterfeit, adulterated, fake or banned medicines. It also restricts the sale of medicines in the open market without authorization.“ The Pharmacists Council of Nigeria, Decree 91 of 1992” this act invalidate the Pharmacists Act of 1964. It simply states that the pharmacists council of Nigeria is strictly in charge of the following activities. Establishing the required knowledge level of individuals that want to be part of the pharmacy profession, registration of competent personnel to the profession, and constant analysis of the set code of conduct.“ The NAFDAC Decree No. 15 of 199” this particular decree established the National Agency for Food Drugs Administration and Control in Nigeria. “ The drugs and related products (registration) Decree No. 19 of 1993” this decree ensures that medicinal products are not manufactured or marketed except the are registered according to this decree. The decree also details the process involved in the application for registration. (Erhun *et al.*, 2013)

### 2.2.3 REGULATION OF THE FOREIGN PHARMACEUTICAL INDUSTRIES

The regulation of the manufacture of medicinal products for human use is carried out by different regulatory bodies assigned by the country's government.

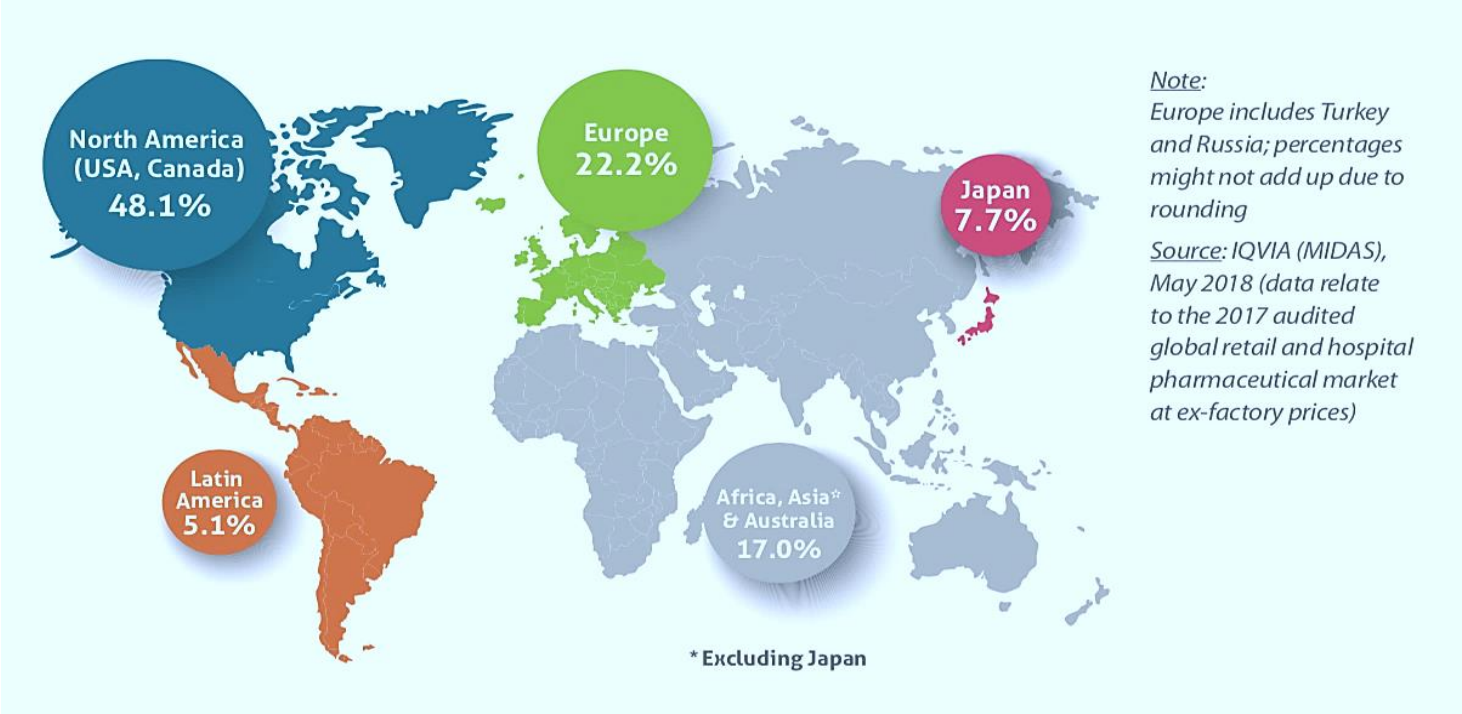


Figure 2.2 World Map showing the United States of America and Europe as the two main countries with the biggest Global Pharmaceutical Market Share

However, the decision to harmonize the regulatory requirements was made by Europe, Japan and the United States and so in the year 1990 at the WHO conference "*The International Conference on the Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)"* was established. It was established due to the realization that continuous establishment of different codes over the years in a bid to regulate the production of medical

products and ensure safety, efficacy and quality only lead to an increase in cost of research and healthcare as a whole.

This harmonization brought about great advantages to the regulatory authorities and the pharmaceutical industry as a whole. Due to the establishment of the ICH guidelines, the replication and repeating of clinical trials reduced greatly and so did the utilization of animals to carry out testing. The ICH regulation also helps to centralize and unify the regulatory procedure as regards the application of a new drug and by so doing, advanced the resources for new drug development and decreased drug development times. (Singh, 2015)

All information about different meetings, policy agreements for the member states are all available on the easily accessible agency website.

The regulation contains guidelines pertaining to Quality, Safety, Efficacy and multidisciplinary guidelines. The quality Guideline in this case includes information about the Good Manufacture practices (GMP) for the manufacture of pharmaceutical medicinal products for human use located on "Q7" and also information about Pharmaceutical Quality Management as see in "Q10" of the ICH guidelines.

In a bid to create a system where regulatory information can be shared, ICH came up with the "*standardized Medical Dictionary for Regulatory Activities (MedDRA)"* this bolters data analysis, and data management. The functioning of the ICH is not limited to the only the member states as their reach goes far deep into many different countries where they carry out training programs, teaching on regulatory and pharmacovigilance issues. Over the years the ICH has also managed to cut down on the cost of putting together a registration dossiers and establishing safety, quality and efficacy of the manufactured and distributed medicinal products. (Singh, 2015)

The ICH Q7 is the part of the guidelines that focus on quality especially on the good manufacturing practices for active pharmaceutical ingredients for human use. This guide ensure that use of API's are carried out under the relevant methods of managing quality. It is also directed towards establishing that all API's to be used meet all set standards for quality.

According to this guideline all activities which include the collecting of materials, production, packing, labelling, storage and distribution of API's is referred to as manufacturing. It is important to note that the terms "current good manufacturing practices" and good manufacturing practices can be used interchangeably. This guidance does not however cover safety for individuals involved in the production process as this is subject government set regulations and also the duty of the producers. The guidance also does not tamper with the capacity of the government assigned regulatory body to set up and authorise distinct registration prerequisites as regards the active pharmaceutical ingredients. (Khagga *et al.*, 2019)

The guide talks extensively about quality management, its principles and it is very specific about the duties and responsibilities of the quality unit. It also contains information about internal audits and to verify compliance with the set GMP as well as product quality reviews channelled towards verifying the uniformity of all processes and procedures. It further talks about the personnel qualifications, hygiene and even consultants. Documentation and record keeping processes as well as storage packaging and labelling of medicinal products being manufactured. (Tietje and Brouder, 2010b). The ICH guidelines are seen to have obviously provided more detailed information about quality management than that of the NAFDAC GMP.

### 2.2.4 THE MEDICINE AND HEALTHCARE PRODUCTS REGULATORY AGENCY(MHRA) AS A FOREIGN REGULATORY BODY

The Medicine and Healthcare Products Regulatory Agency (MHRA) is a UK agency charged with making sure that medicines are effective and efficient. As per latest update since January 2021, UK is out of the European union and this body is the main regulatory body for the country. It was established in the year 2003 when the Medicine Control Agency and the Medicine Device Agency formed a merger. Another merger was formed in 2013 with the National Institute for Biological Standard and Control (NIBSC) and then the whole institutions was revitalized into the now known MHRA.

The structure of the MHRA is set up to include 3 centers. The MHRA Regulatory, The Clinical Practice Research Datalink (CPRD) and The National Institute for Biological Standard and Control. (MHRA, 2013)

The MHRA regulatory is in charge of controlling the manufacture of medicines and production of medical device in the UK. They carry out different processes to ensuring that all information provided are fact based and scientifically proven so that all risk taken are scientifically justified. They are in charge of licensing all medicinal products that are intended for distribution. They also ensure that the clinical trials fulfil all set standards, they constantly review the quality of medicinal products manufactured, they also carry out audits to identify non-compliance and fix all issues.

The Clinical Practice Research Datalink is an institution set up for observational information and interventional research service for the NHS and the MHRA. They work to provide important information used by healthcare professionals and

continuously contribute to the vast collection of data available for the public as a research tool.

The National Institute for Biological Standards and Control (NIBSC) is charged with the control of biologics. They engage in research collaborations and offer biological reference materials. As one of the world leading biological control body, they are charged with discovery and development of up to 90% of the International specifications and requirements that is utilized all over the world to achieve quality assurance as regards biologics. The NIBSC is the Official Medicine Control Laboratory (OMCL) for the UK. They have the responsibility of carrying out tests on biologics in the European union. They formed a strong bond with the World Health Organisation (WHO) and became their international lab for setting standards.(MHRA, 2013).

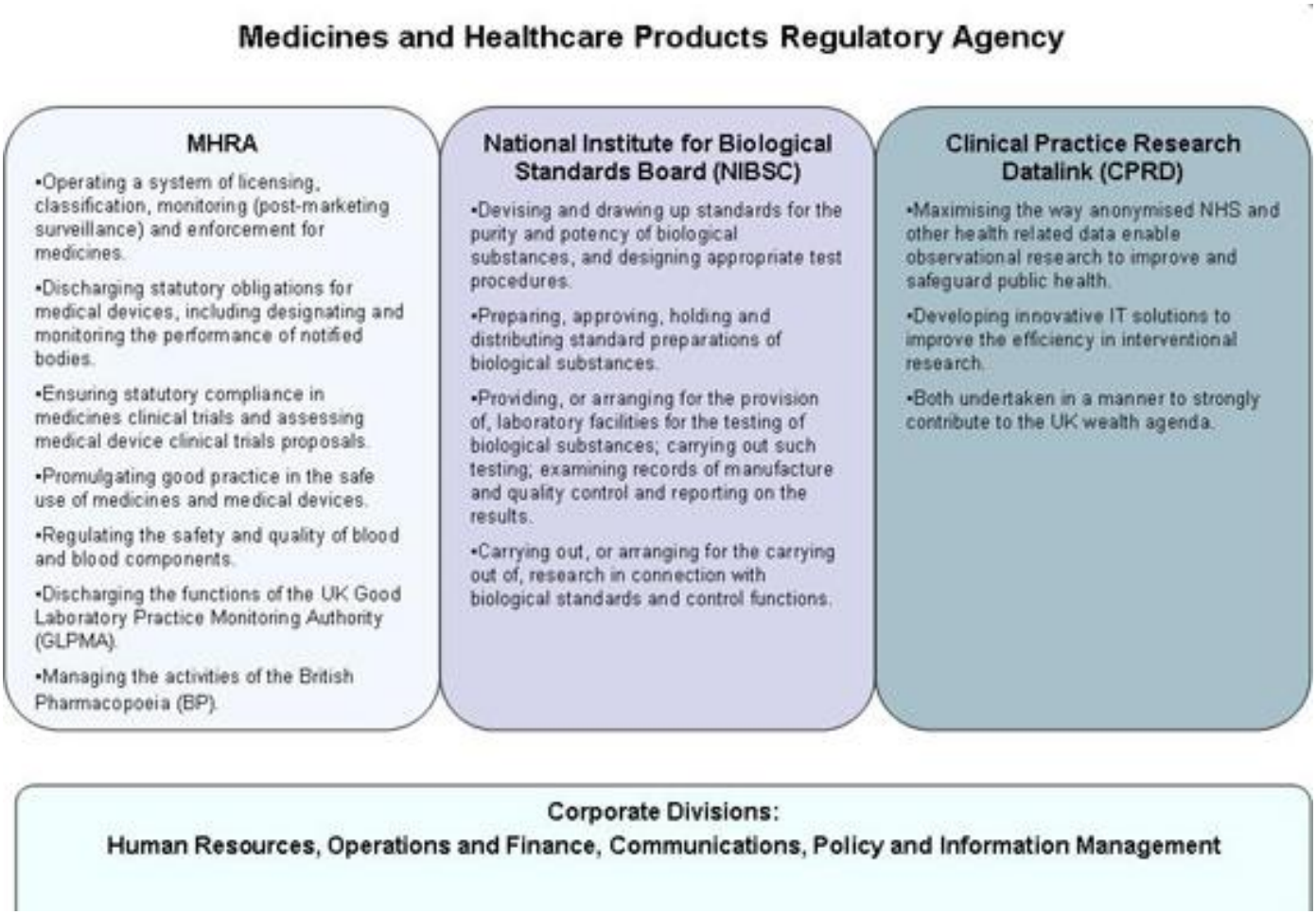

Figure 2.3 showing the main functions of the 3 components of the MHRA (MHRA, 2013)

The MHRA, NIBSC and the CPRD are still continuously performing their individual function. However, in a more synergetic way as a single organisation with the same objectives and aims. They ensure that all medicinal product and medical device introduced into the UK market are up to standard, reliable and safe for use.

### 2.2.5 ATRIBUTES OF AN EFFECTIVE REGULATORY SYSTEM

In order to be able to identify the core attributes of a good pharmaceutical product regulatory system, it is first of all important to determine the characteristics and features of a successful system. according to the World Trade Organisation (WTO), there are 5 main features of a good system, they include, The system must be responsive, the system must be outcome oriented, the system must be predictable, risk proportionate and independent. The **responsiveness** of a regulatory system must go in 2 directions. Firstly, a successful system must be very responsive especially in times of crisis. Secondly, They are must be responsive as regards modification of their codes and guidelines. Outcome Orientation, For a regulatory system to be outcome oriented simply means that, the regulations are set up in a way that doesn't hinder innovative thinking. **Predictability**, this simply means that the framework of the regulatory agency should be clear and easily understandable. The decision making process must neither be irrational or unreasonable. When the regulatory system is predictable, it is easily made available to the general public for use. it contains guidelines and regulations that applied regularly and are fair. A risk proportional system is one that is actively aware of possible risks and ensures proper monitoring of high risk to public health

issues while assigning little monitoring on low risk issues. A **proportional** regulatory system has priorities and works according to those priorities. A regulatory system is **independent** when it was born of both evidenced based study and expectations of the society. (Nap.Edu, 2012)

These core components are the tools of a strong regulatory system. this is because, once all these components are at play, the regulatory system will be able to carry out its main responsibilities which include: Registration of Medicine, safety and efficacy surveillance, quality testing, supervision of producers to ensure compliance of GMP, supervision of marketers and distributors. Determination of product performance by authorization trials. (Nap.Edu, 2012)

## 2.3 PHARMACEUTICAL QUALITY SYSTEMS

The pharmaceutical industry proposed to define drug quality simply with the phrase "*fitness for use*". the phrase simply implies that quality of a medicine is defined by its fulfilment of all set quality traits and characteristics and also regulatory specifications.

Pharmaceutical quality management system was properly described in the ICH guidelines for Technical Requirements for Registration of Pharmaceuticals for Human Use in Q10. This system talked about encouraging the utilization of a risk-based approach as well as science in creating the pharmaceutical quality systems to ensure that they can be used in all phases of the medicinal product Lifecyle. The guidelines unifies the essentials of the GMP regulations and the international organisation for standardisation (ISO). It also integrates the Q8 which is pharmaceutical development and the Q9 which is quality risk management. And so,

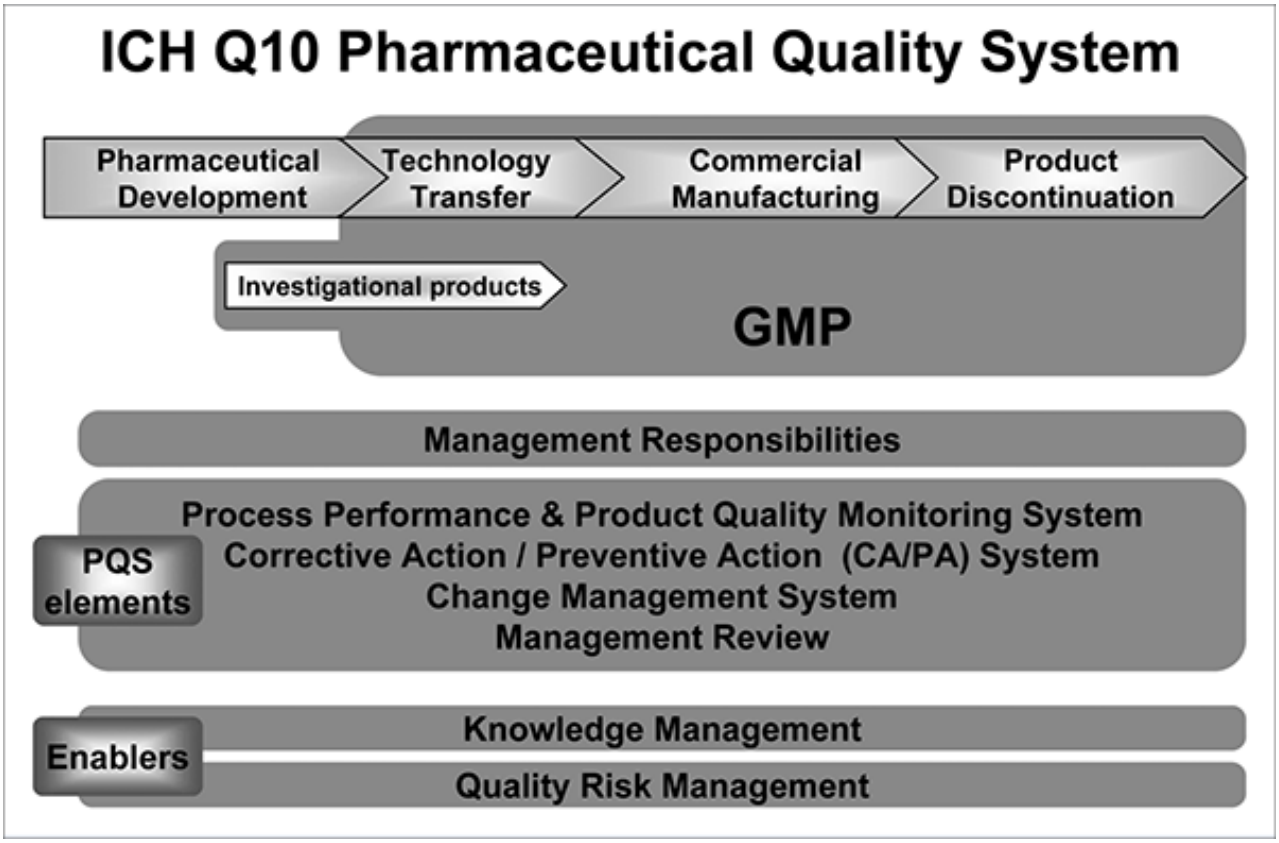

Figure 2.4 Pharmaceutical Quality Systems (ICH Q10) (ISPE.ORG, 2021)

The ICH Q10 (figure 2.4) is like an integrated design that is put together based on the GMP and ISO regulations as well as the pharmaceutical development and quality risk management and that makes up the concept of the pharmaceutical quality system

### 2.3.1 THE PHARMACEUTICAL QUALITY MANAGEMENT SYSTEM

This system can be applied to all and any phase of the life cycle of medicinal product as well as biotechnological and biological products. It is important to take into account that the system must be properly studied so as to recognise the differences in each phase and not he appropriate element to apply.
The guideline has 3 main objectives which include:

- Realization of the intended product
- Adequate handle and control over irregularities
- Constant advancement in all areas.

The goal here is to ensure that there is a set up system that implements and maintains the distribution of medicines that are of good quality and are up to set standards. Quality risk management (QRM) aids in setting up a functional observational and control mechanism for different procedures that is targeted towards determining the functionality of the process. It also helps in placing focus on areas that need constant improvement as regards quality. This focus in turn gives rise to good outcome of finished products, the methods, designs and documentations used to achieve the functional pharmaceutical quality management system should not be complex so as to facilitate easy understanding of all procedures and processes. It is important to ensure that all quality manuals are in conformance with the organisational policy. (Dubey *et al.*, 2011)

**MANAGEMENT RESPONSIBILITY**

It is very important to establish leadership in the company as regards pharmaceutical quality management this is because the personnel in leadership positions are charged with the responsibility of accomplishing goals that relate to increasing quality. It is expected that all responsibilities and duties should be clear and easy to understand for all personnel involved. The environment should portray a strict obligation towards quality at all times. It is also required for management to take active part in the models, methods and plans as well as implementing and monitoring of the set up pharmaceutical quality systems to ensure effectiveness. If at any point any personnel requires any form of training, it should be promptly looked into, and the need should be met. All supplied resources should be effectively managed in order to ensure adequacies for all departments. There

should be documentation of all processes and communication should be frequent and active. This will ensure that the pharmaceutical quality system in place is managed properly. (Dubey *et al.*, 2011)

## CONTINUOUS IMPROVEMENT IN PROCESS PERFORMANCE AND PRODUCT QUALITY

The quality of a product is highly dependent upon the fitting description of quality features and aspects that is brought to light at the development stage. These ideas and specification must be made available at all sites of production during the production process other issues such as discontinuation of a product, sample retention and retention period, product assessment and review are carried out according to the set regulations.

Basically, the aims of the quality management systems can be achieved by way of "*knowledge management*" and "*quality risk assessment*"

The procedures and processes in the different phases of the medicinal product life cycle are the tools that make up the knowledge archive and directory and should be properly document and the information properly stored to be made available when required. The information about quality risk management is
made available in ICH Q9. It gives information about the principles of quality risk management. As well as the data about how to diagnose and control all risk to the quality. Constant monitoring of product quality continuous innovations are the factors that encourage continuous improvement of process performance and product quality. (Dubey *et al.*, 2011)

## 2.4 QUALITY MANAGEMENT SYSTEMS IN EMZOR PHARMACEUTICALS

Emzor pharmaceuticals limited is a Nigerian owned pharmaceutical company founded in the year 1984 that deals in production of over 140 pharmaceutical products and medical consumables. The regulatory body that control and govern the activities of this company is NAFDAC. This implies that Emzor utilizes the NAFDAC GMP in the manufacture of their medicinal products.

### QUALITY REGULATION AND MANAGEMENT SYSTEM

The main aim of Emzor is to ensure wellness if their consumers. To achieve this they provide world-class healthcare services and manufacture medical products that very cost effective. This creates value for their consumers. Emzor has also managed to set up a business model that is very much in line with the set regulatory requirements. Their business model also aids and encourages innovation and excellence. the company set up a QMS with a framework that is constantly reviewed for possible updates and are properly communicated throughout the company after every update. (EmzorPharma, 2021b)

### HEALTH SAFETY AND ENVIRONMENTAL (HSE) REGULATION AND MANAGEMENT SYSTEM

Emzor maintains high health, safety, and environmental standard which involve risk management. Emzor trains its employees to work in the safest conditions and to act based on risk reduction efficiency in seeking opportunities to reduce risks and errors involved in manufacturing. The company encourages effective communication of health, safety and environmental(HSE) related matters to make

the workplace free from hazards associated with an ability to run a safe and environmentally responsible operation. (EmzorPharma, 2021a)

## WHISTLEBLOWING REGULATION AND MANAGEMENT SYSTEM

The QMS operated by Emzor encourages employees to report any form of wrongdoings that breach the company policy. The report in this case, is expected to be made, not on personal gains but in the best interest of the company and the potential consumers. Any report made  will be properly examined. During the process of investigation, the company will do its best to maintain anonymity for the employee to prevent victimisation. (EmzorPharma, 2021d)

## ENVIRONMENTAL REGULATION AND MANAGEMENT EMZOR SYSTEM

Emzor has emphasized its commitment to environmental safety by establishment of a certain framework that ensures that objectives standards are set that do not fall short of their set Emzor brand policy which is "*WELLNESS FOR EVERYBODY*". They have also show their commitment to safeguarding the environment as regards pollution from pharmaceutical wastes by implantation the an Environmental Management System (EMS). They strive to create an environment that is favourable to everybody by from consumers to employees to stakeholders. They do their best to carry out activities in accordance to local and international standards the best they can, prevent pollution from pharmaceutical waste and mage resources properly. Emzor assesses the environmental outcome of the activities they engage in terms of the socio-economic aspects of operation and make sure that they provide an adequate means of training for all their staff employees and contractors so that they can follow the set guidelines by either the federal, state, or local

government in the environment in which they carry out their operations. (EmzorPharma, 2021c)

The above stated regulations are the ones that Emzor pharmaceutical limited claim to have put in place to ensure quality in their production process. However, there is no further information on the impact of these regulations on the products they manufacture or any proof that these systems are utilized. There is no publication about the quality management system developed in Emzor and other information concerning the quality management system of the company. As per the regulatory body that is supposed to control Emzor which is NAFDAC, there is no information about internal or external audits carried out in the company or in their manufacturing site.

## 2.5 QUALITY MANAGEMENT SYSTEMS AND REGULATIONS IN GLAXOSMITHKLINE PLC (GSK PLC)

This is a UK based global healthcare company that has established various offices in different countries around the world including Nigeria. They came into Nigeria in the year 1971 and started the manufacturing process in 1972. With the goal of becoming one of the world's most innovative and trusted health care companies, GSK has set high ethical standards and ensure compliance to them as their production process is governed by the Medicine and Healthcare Products Regulatory Agency (MHRA) and they utilize the good manufacturing practice guidelines of the ICH in their production process

### THE GSK CODE OF CONDUCT

In GSK, the general belief is believes "it's not just what we achieve that count but also how we achieve it". They believe in taking responsibility or over making

profit. The strive make favourable and proper decisions, so that if any issues arise that can take accountability for their actions. All these to achieved they end goal which is to be one of the world's best operating, credible and dependable healthcare organizations, that is innovative and continuously impact the lives of their consumers.

The values that GSK has set for themselves is the driver of their decision making process. They constantly asceses and review their values to ensure that they are always in the right position as regards their goals and aims. They have also set up standards for themselves to that are aimed at solving certain risk problems that are anticipated bearing in mind the following factors during the decision making. Strick adherence to set guidance and regulations, assess to the tools that aid risk assessment, monitoring and fixing and finally the impact of the decisive decision they have made on their consumers. (Policies, codes and standards, GSK, 2013)

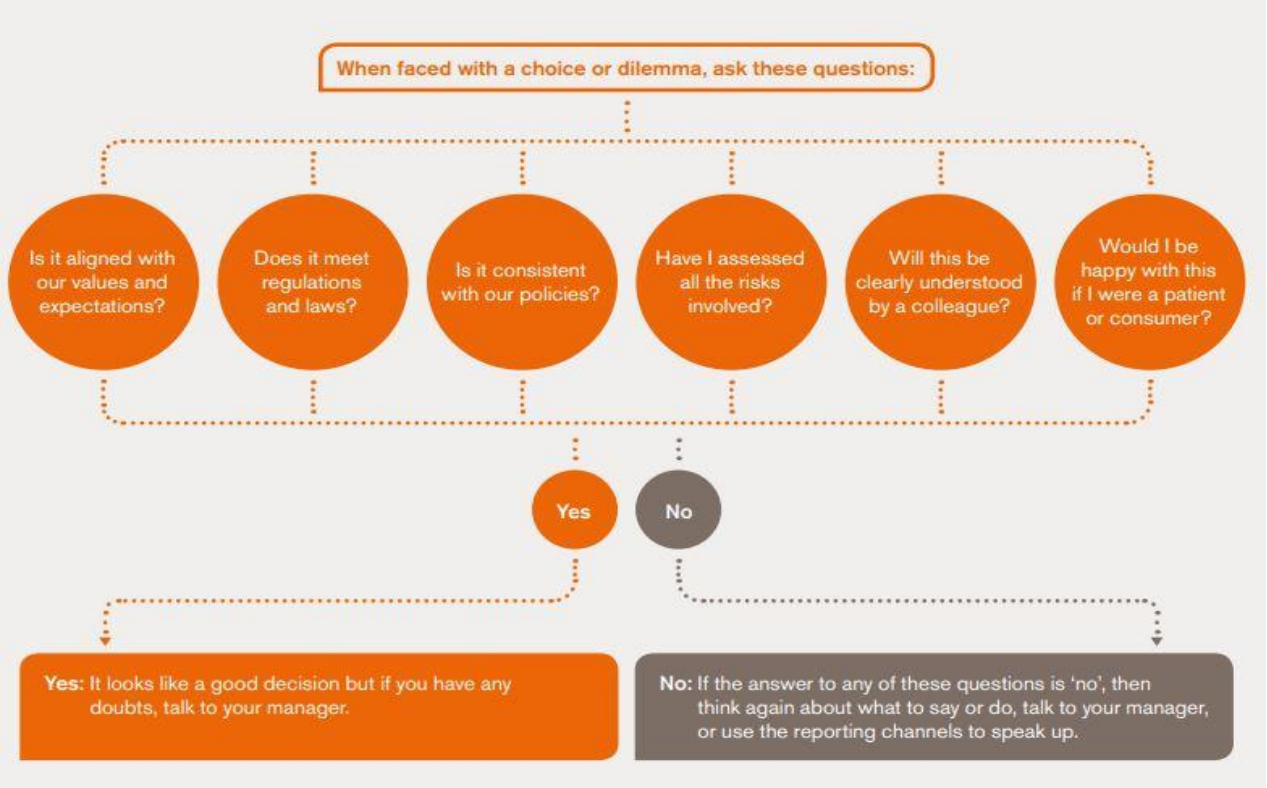


Figure 2.5 Code of conduct at GSK (Policies, codes and standards, GSK, 2013)

The GSK code of conduct is very strict and there are repercussions to not following this code of conduct as an employee. The set standards and policies apply to everyone and failure to abide by them results in disciplinary action against the faulter. Disciplinary action in this case may include but is not limited to suspension, complete dismissal, suspension or rescission of the contract. If the faulter in this case occupies a managerial position, disciplinary action in this case maybe financial recoupment depending on the misconduct and the extent of the misconduct.

Managers at GSK have greater responsibilities as they are in charge of ensuring that the other employees properly understand the code of conduct and work according to it. If for any reason, workers under them violate the set conduct codes,

the mangers are required to report them without hesitation. (Policies, codes and standards, GSK, 2013)

According to (Policies, codes and standards, GSK, 2013), it is important to the company to gain the trust of their consumers and the best way to do this was to target the needs of the people. They were able to achieve this by constantly looking at issues form the through the eye of the patient or consumers. Considering their safety, and giving them all the information they needed to feel safe. GSK has made sure that all the marketing activities are carried out ethically and fulfil all set standards and so all medicinal product promotion that is carried out is legal and comes with proof of functionality. They ensure that all scientific activity carried out is evidenced based and ensure that possible underlying issues are not camouflaged in such a way that it is misleading to the healthcare professionals or the consumers. They strive to ensure that all information made available for public consumption is up to date and valid. They achieve this by constantly working with authorised and licensed scientists and experts. Any concern about GSK products such as information about adverse reactions, side effects, or any safety issues like effectiveness of medicinal product is to be reported to the "Central Safety Department" (CSD).

GSK is totally aware of the counterfeit medicines issues that plague the country. The company understands that these counterfeit products do not contain the active ingredients that fight the illness in the human body and some of them of contain harmful ingredients that have the ability to even worsen a medical condition and so they have taken it upon themselves to report any counterfeit or suspected counterfeit of the GSK products.

GSK does everything possible to ensure the quality, safety, and efficacy of their products for their patients and consumers. This is achieved buy following the GMP

regulations and ensuring proper documentation of processes with the Quality Management System.
In order to maintain their integrity, they ensure that all data collected is up to date and accurate. They make sure not to take part in any form of corruption or fraud. If any form of illegal action is carried out with their knowledge, it is immediately reported. GSK established the Anti-bribery and corruption (ABAC) foundation principle for their company to establish transparency in all their activities. The system aids in discovery or determent of bribery and corruption.
(Policies, codes and standards, GSK, 2013)

Further research into GSK showed that even with their full proof quality management system, they had still experienced some quality issues. An example can be seen in the GSK consumer healthcare recall of two lots of "children's Robiussin Honey cough and Chest Congestion DM" and "one lot of children's Dimetapp cough and cold". This was a voluntary recall by the company due to incorrect dosing cups in the children's medication. The company consumer healthcare department was concerned about possible overdose due to the incorrect calibration on the drug delivery cup. The company also put out notifications about the possible symptoms of overdose and other side effects in any case where the product couldn't be gotten back. This report was made in February of 2020 and as of June 2020, there had been no reports about adverse events. (GSK, 2020)

The above example highlighted transparency in the system and the effort of the company to ensure quality by setting up a consumer healthcare department that carried out the recall despite the possible loss that they may have to deal with. It is an outright impact of an effective quality system.

## 2.6 Summary of Literature

Upon critical study, evaluation and review of literature from various sources from both Nigeria and other parts of the world, I can obviously see that there is a serious ongoing issue with the pharmaceutical industry in Nigeria. The WHO has made tremendous efforts in a bid to remedy the current situation of the country with respect to the pharmaceutical industry and the quality of medicinal products in the country. The WHO worked with other African countries to form the AMRH. (Ndomondo-Sigonda *et al.*, 2021) discusses the formation of the African Medicine Registration Harmonization (AMRH) and establishment of the "*Model Law on Medical Product Regulation"* They worked with NAFDAC to establish the NGMP and set up academies to train employees about the regulations and enforcement of these regulation. However, the problem runs deep. According to literature, the low socioeconomic state of the country and corruption are the biggest issues that plague the system. regulations have been put in place but upon proper examination of the NGMP, they are seen to be inadequate, not very comprehensive and fail to cover every important aspect of the life cycle of medicinal product effectively. And so even if these regulations are implemented, they are not enough to actually ensure that the medicinal products manufactured are of top quality.
(Olatunji, 2013) highlighted the political issues associated with the pharmaceutical industry and how corruption on the part of the regulators has seriously affected the system. Another issue is the lack of adequate funding of the pharmaceutical industry. It is of utmost importance to invest properly in the facilities for manufacturing and also in the quality management system as these are the tools used to ensure an effective good manufacturing practice compliance. Even so many of the Nigerian pharmaceutical companies fail to invest enough in these crucial aspects due to various factors including embezzlement and diverting of funds in the public sector and inadequate funds due to lack of sponsors in the

private sector. The industry also suffers due to the fact that the individuals in charge of setting up these required aspects decided to cut cost and save money instead of investing in the quality systems. (Ekeigwe, 2019) also properly explained the challenges faced by the country (Nigeria) as regards implementation of the set regulations and highlighted the corruption as the major issue.

Emzor showed lack of transparency in its system as there was no proof of internal or external audits being carried out. NAFDAC also had no reports about inspections of any pharmaceutical manufacturing company sites even though inspection was part of their set guidelines to ensure compliance to the NAFDAC GMP.

GSK on the other had a full proof quality system with constant certification and audits being carried out. Even so, GSK was able to provided information about production errors and recalls bring to light a more transparent and functional system this is easy to trust.

# CHAPTER 3
# RESEARCH DESIGN

## 3.1 Research Philosophy

The research philosophy is simply the conviction and hypothesis that form the knowledge being gathered. The hypothesis of the research is a very crucial aspect of the research as it reflects the unbiased viewpoint of the researcher.
Research philosophies can be that of objectivism or subjectivism.
Objectivism is made up of hypothesis about natural science meaning that the object of an on-going research is always external to the researcher.
Subjectivism on the other hand is form out of hypothesis of arts and humanities. This simply means that assumptions are made from the understanding of repercussions of actions of individuals. (Saunders *et al.*, 2019)

There is a possibility that a specific truth about the recognition of the issues faced in development of data concerning the quality of medicinal products manufactured in Nigeria. The issues faced can be as a result of the process, difference of perception and difference of circumstance. However, it is important to note that identifying issues in the development of knowledge is tantamount to solving the problem. With this in mind relativism and pragmatism will be employed.

The philosophy of this research is positivism.  This type of philosophy was used for this study in order to ensure an objective and critical analysis of all data collected in order to avoid bias and also avoid ethical issues. In this case, all information utilized will be fact based and scientifically proven with no regards to the human bias. The questionnaire was structured following quantitative rules

making sure the questions and options was not leading them. This also helped in the evaluation of information from the participants.

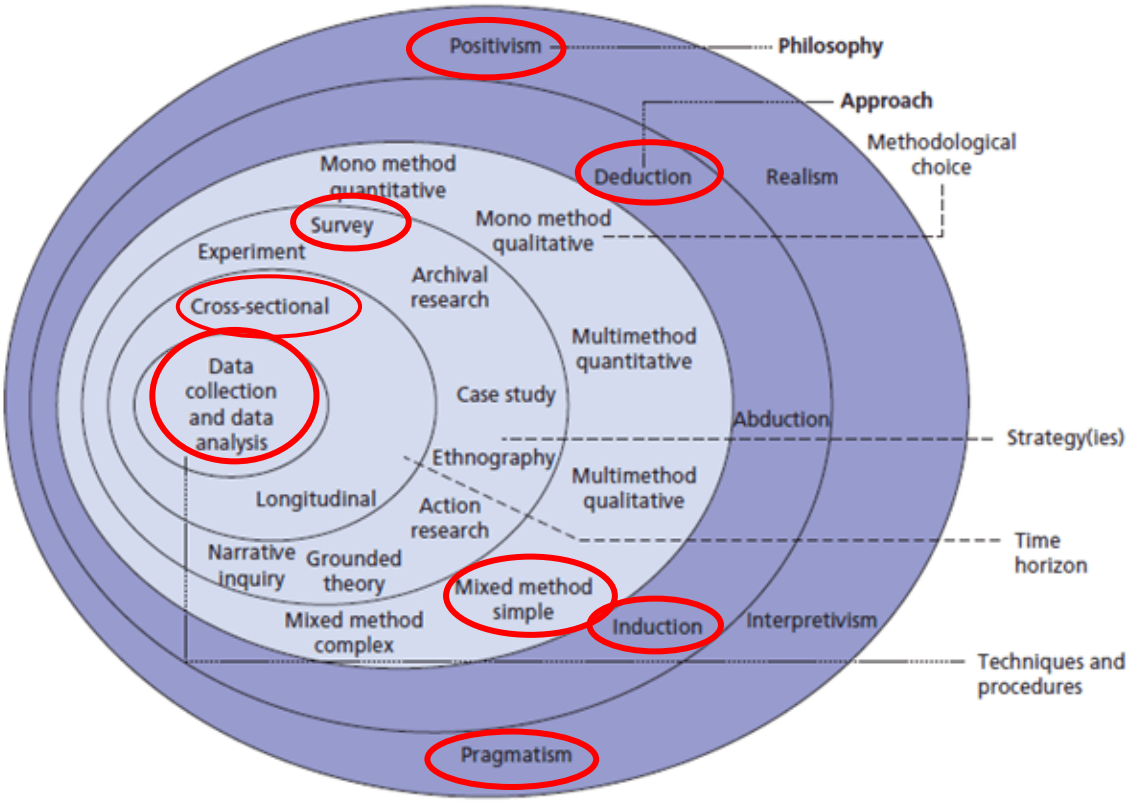


Figure 3.1 Research Onion (Saunders *et al.*, 2019)

Figure 3.2 above highlights the different techniques utilized in this research as they are circled in red.

The respondents were sent highly designed questionnaire in which data were received, reviewed and efficiently interpreted. There was no personal relationships with the participants which rules out unnecessary conflicts and bias. The questionnaire was designed and sent out electronically while also adhering to govern guidelines and recommendations regarding the current Covid-19 pandemic.

So, there was no physical contacts or face to face and this also limited subjectivity and promoted objectivity.

### 3.2 Research Approach

**A qualitative research** methodology involves data gathering and collection by way of audio recording of interviews, video clips, observation of selected groups and other ways by which human behaviours or knowledge about a certain issue based on experience can be assessed.

**A quantitative research** methodology involves assessment of data in numerical from by way of surveys or questionnaire.

**The mixed research methodology** involves the application of both the qualitative and quantitative methods of research.

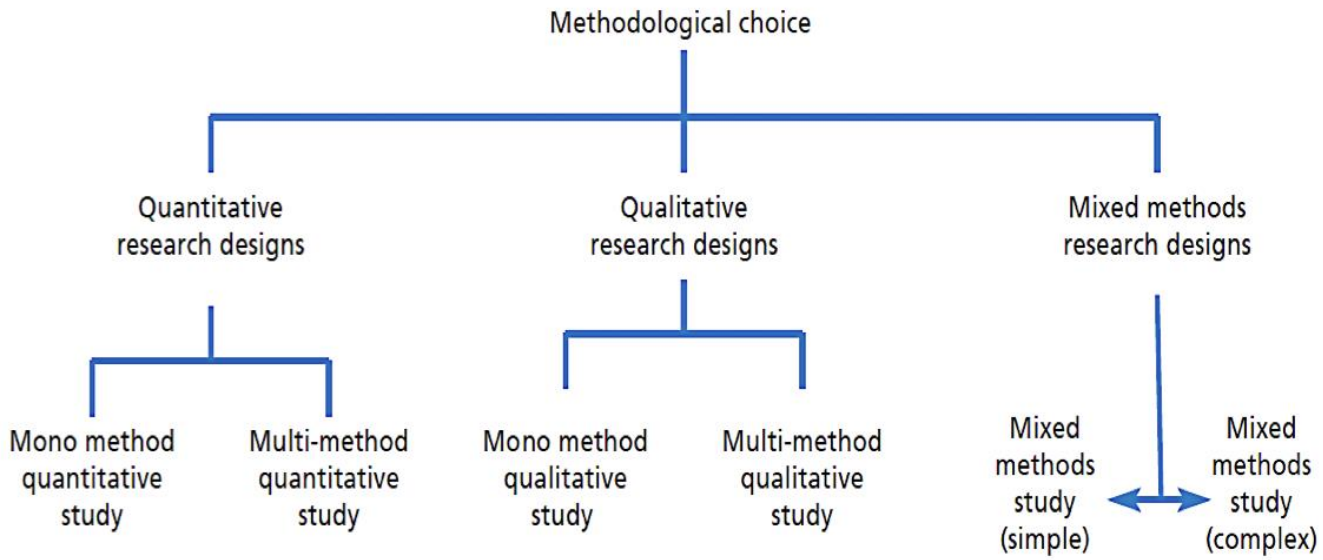


**Figure 3.2 Methodological Approach (Saunders *et al.*, 2019)**

In order to establish the difference in the quality management utilized by pharmaceutical companies in Nigeria and the different regulatory systems utilized

by these companies, the author will utilize both qualitative and quantitative methodologies. The main method here is the mixed research methodology.

The qualitative research would involve collecting data about the different pharmaceutical companies in Nigeria from company websites and also gathering of information about the regulatory bodies and quality management systems in play at these pharmaceutical companies from regulatory body websites, online articles and peer reviewed journals.

The quantitative research would be conducted in form of a survey distributed to health care professionals and consumers. The survey is directed at evaluating the general idea of the respondents about the medicinal products manufactured in Nigeria by the Nigerian pharmaceutical company and the foreign pharmaceutical company. It will also evaluate the quality, availability and preference of medicinal products in Nigeria.
Questionnaires would be given to health care professionals including:
Medical Doctors in Nigeria as they can provide information regarding the preferred medicinal products to prescribe and what possible quality factors influence their choice of prescription. Questionnaires will also be given to Pharmacists that work in large pharmacies in Nigeria. This is because they can provide information about the quality of medicinal products supplied to them by the pharmaceutical companies as well as availability of products from different pharmaceutical companies. Consumers of the medicinal products will also be contacted as they can attest to the effects and impact of the various medicinal products from the different pharmaceutical companies that they have used. The author would also be able to gather information about their preferences and what factors influence their preferences.

All data collected from the different the groups will be put together and analysed properly. The information gathered will be compared to the existing literature in order to create a concluding perspective.

### 3.3 Research Focus

The research focus here will be informative, definitive, explanatory and descriptive in nature.

The informative research will provide adequate information and understanding about the topic. Definitive research will define the actions of participants in specific conditions. Explanatory research aims to establish connections among variables. Descriptive research aims to properly characterize all factors used for evaluation of results.

### 3.4 Research Strategy

The strategy of this study is to examine and compare different pharmaceutical manufacturing companies in Nigeria (foreign and local). There will be a proper examination of regulatory systems and their impact on the quality and availability of medicinal products in the region. In as much as the pharmaceutical industry in Nigeria was critical reviewed in the literature review, there was no comparison with their foreign counterpart with regards to quality and availability in the same country.

The questionnaire contained detailed information about the research and its purpose. It also stated that the research is an academic research, a dissertation carried out by the author as a fulfilment of the final part of her master’s program in pharmaceutical business and technology. The survey was straight forward and to

the point. It was sent to about 50 participants from different walks of life but targeting mostly medical doctors and pharmacists the other participants were regarded as the consumers.

### 3.5 Primary Data Collection

The questionnaire survey was created with Microsoft forms. It was made up of 23 questions in line with the objectives and questions of the research. The survey was sent to the respective respondents electronically. All respondents were advised to answer to the best of their knowledge and their response was in no way influenced by the author.

The consent of all respondents was duly requested for in the first question of the survey. It was a required question and so the survey didn't continue until it was answered. They were all informed that There was no risk in participation of the survey because their responses would be confidential. Also, there was no collection of identifying information such as name or email address in order to help protect their confidentiality.

The primary data was collected by the use of questionnaire. The questionnaire was given to health care professionals mainly medical doctors and pharmacists. The questions in the survey were structured is such a way as to ascertain their general knowledge and experience with the medicinal products manufactured by different pharmaceutical companies in Nigeria.

The questions in the questionnaire focused on comparing the quality of the medicinal products manufactured the Nigerian pharmaceutical company and those

produced by the foreign pharmaceutical companies in Nigeria. it also sorts to determine the preferred medicinal product by the doctor and the pharmacists to prescribe and how available they were.

### 3.6 Sources

Using the survey created in Microsoft forms, the author was able to gather information from about 50 respondents including 18 doctors, 20 pharmacists and 12 other people considered as the consumers. A cumulative of the data collected was then used to create pie and bar charts to represent figures as regards the survey findings.

### 3.7 Participants of the survey

The author contacted the medical doctors and pharmacists at "Family and Friends private hospital, Lagos which was my previous place of employment. The author also contacted doctors and pharmacists from the Grodno state medical university, which was the authors alma Mata currently working in Nigeria. They were given and explained about the aims and objectives of the research and was able to convince them to take part in the survey. The survey was sent to them electronically. A few of the respondents were contacted via LinkedIn. The other participants (consumers) were contacted on different social media platform.

### 3.8 Inclusion and Exclusion Criteria

The survey for this study was filled in by healthcare professionals mainly medical doctors and pharmacists as they have direct experience as regards the use of medicinal product and its outcome. Consumers also filled in the survey as they can attest to the quality and availability of the medicinal product they have used.

According to the first question in the survey, Persons that did not consent to the study were excluded from the research.

### 3.9 Ethical Concern

An Ethics application form was submitted to Griffith college before the research was carried out to cover all ethical issues. Furthermore, a participant consent form and a participant information form was provided for all a participant explaining the study, explaining why they had been contacted and how to fill in the survey questionnaire. The form also provided information about the possible risk involved with taking part in the study and that all participants had the right to withdraw from the study without consequences. The author provided a proper explanation of the research topic in the first page of the online survey. All questions in the survey were structured in such a way that no personal or identifying information was collected form the respondents.

### 3.8 Conclusion

The primary research for this study involved a survey which was distributed to medical doctors, pharmacists and consumers. the survey was made up of 23 questions. The philosophy of the research in this case was that of positivism. A type chosen to establish that deductions from all facts gathered from the survey and literature review was analysed objectively

All information from the chapter 2 (literature review) of the study and data from the survey was properly examined and put together in order to ascertain the impact of the pharmaceutical quality systems used by the pharmaceutical companies on the quality and availability of medicinal products in Nigeria. A proper analysis of the survey findings will be is presented in the next chapter.

# CHAPTER 4: ANALYSIS AND FINDINGS

In this chapter, there will be a complete analysis of all the information obtained from the questionnaire survey. The information gathered from the survey will help in ascertaining the respondents general knowledge and experience with the medicinal products manufactured by different pharmaceutical companies in Nigeria both foreign and Nigerian. Questionnaire was sent out to different groups of participants by means of email, text messages and other media platforms (WhatsApp, LinkedIn ) in addition periodic reminders were sent which increased the response rate. Response was received form 50 participants which include people from various medical professional sectors as well as consumers.

## 4.1 DEMOGRAPIC REPRESNTATION OF RESPONDENTS

4.1.1 The different group/sections of respondents

**Table 4.1** Distribution of Respondents according to their respective segments

| Respondents | Frequency (Number) | Frequency (%) |
|---|---|---|
| Medical Doctors | 18 | 36% |
| Pharmacists | 20 | 40% |
| Consumers | 12 | 24% |
| Total | 50 | 100% |

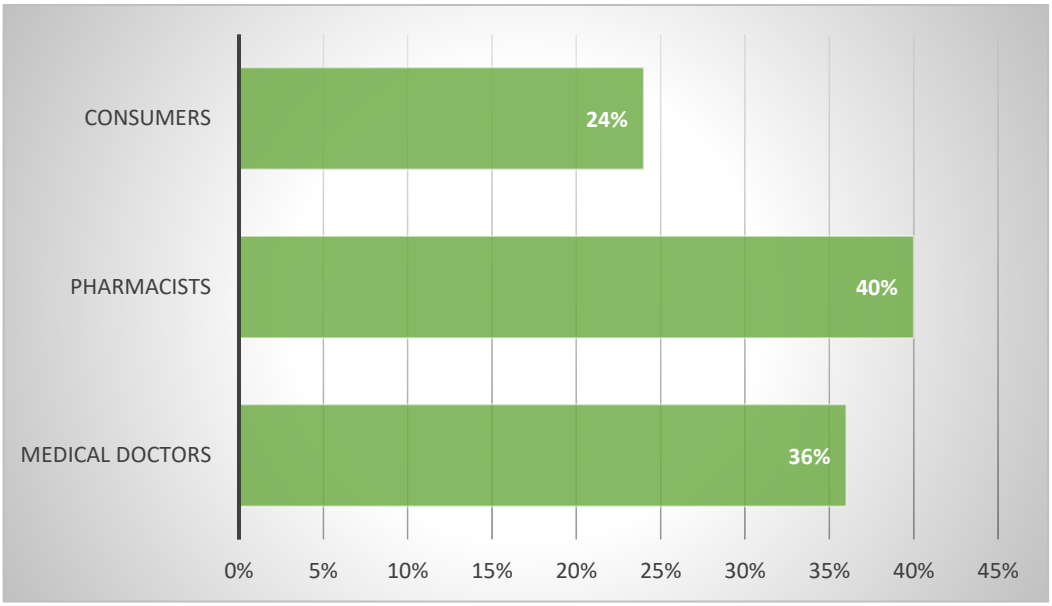


**Figure 4.1** Bar chart representation of the respondents according to their respective segments in %

Table 4.1 and figure 4.1 shows the distribution of the different sectors of individuals that took part in this survey. A total of 50 participants took part in the survey. 20 (40%) of the respondents were pharmacists, 18( 36%) were medical doctors and 12 (24%) were consumers.

**4.1.2** Distribution of participants Age

Table 4.2 Distribution of participants by Age

| Age Group | Respondents (%) |
|---|---|
| 20-29 years | 68% |
| 30-39years | 30% |
| 50+ years | 2% |
| Total | 100% |

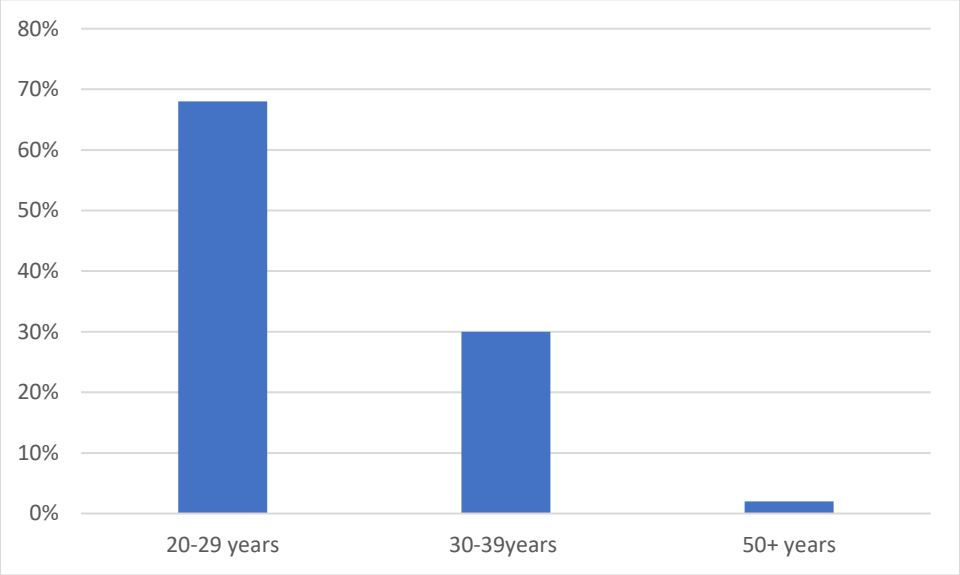


Figure 4.2 Bar chart representation of the distribution of respondents by age

Out of the 50 respondents, 34 (68%) were young adult between the ages of 20 and 29 and 15 (30%) were also young adults between the ages of 30 and 39. Only 1(2%) of the respondent were up to the age of 50.

4.1.3 Distribution of work experience gotten by the years

Table 4.3 work experience of the respondents

| Year of work experience | Respondents (%) |
|---|---|
| <1 year | 24% |
| 1-2 years | 20% |
| 2- 4years | 34% |
| 5+ years | 22% |
| Total | 100% |

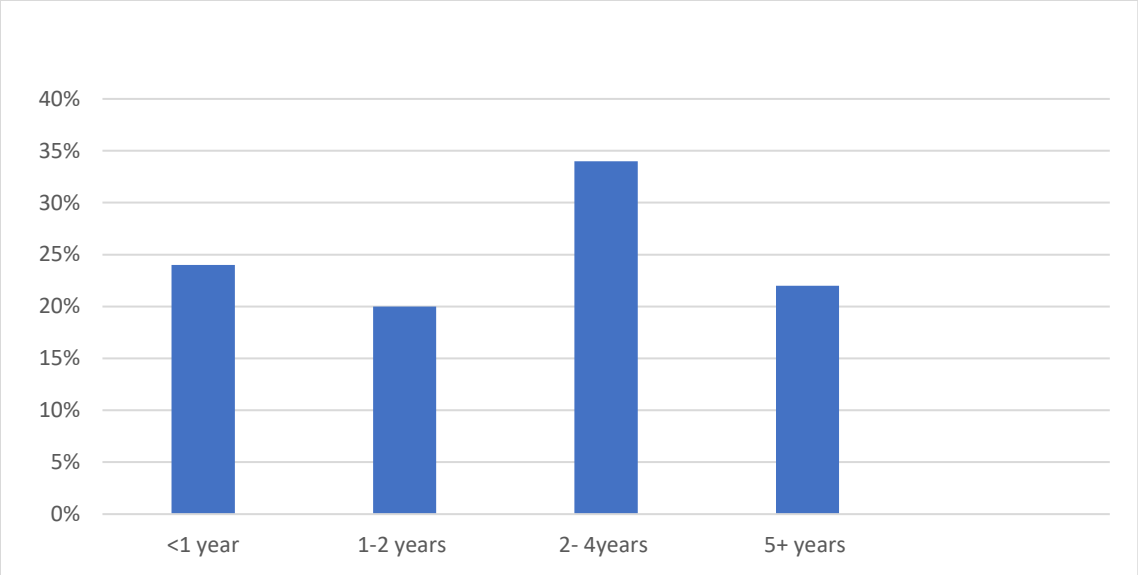


Figure 4.3 Bar chart representation of work experience of respondents

Out of the 50 respondents, 17(34%) have work experience of 2- 4 years, 24% have less than a year of work experience, 22% have work experience of more than 5 years and only 20% have a work experience of 1-2 years.

## 4.2 ANALYSIS OF OBJECTIVE ONE : To determine the impacts of the regulatory systems on quality of medicines produced by the Nigerian pharmaceutical company

According to (Garuba *et al.*, 2009) the process involved in regulation of medicinal products is actually quite complex and so this fact creates loop holes in the regulatory system making it vulnerable and making way for corrupt practices especially in 3 world countries like Nigeria. Due to these loopholes, cohesion to high standards seems almost impossible due to multiple reasons with **lack of transparency** in the pharmaceutical manufacturing industry being the topmost issue. Other issues include weak regulatory control and corruption in the pharmaceutical industry.

Emphasizing more on the lack of transparency in the Nigerian pharmaceutical sector (Garuba *et al.,* 2009) stated that although there was an up to date list of registered medicinal products, it only provide very little to no information about the medicinal products. For the regulators of the set standards, it was noted that there was no data to support the requirements of a specific qualification in order to become a member of the committee. This means that no information was provided about the qualification, work experience, special or technical skill required to become a committee member. Furthermore, the official involved in the entire decision-making process are not mandated to make the guidelines for decision making and even the decision available for the public. Also, there was no guideline to control the meeting of applicants with registration officers. Manufacturing establishments that were located in intensely rural areas take advantage of the fact that regulation of their activities was not readily carried out to engage in production of low-quality medicinal products in order to maximize profit. It was further noted that even when the regulation officers were able to inspect such rural areas, bribes would be offered to cover up sub-standardization of medicinal products by such companies.

The research about transparency in the Nigerian pharmaceutical sector (Garuba *et al.,* 2009) also noted the main weaknesses in the inspection of the companies that carry out the manufacture of medicinal products. The main issue was the unavailable of guidelines conflict if interests. This is a problem as at least two individuals carry out inspection of one site. These guidelines can aid in the process as a difference of option can exist at any point of the inspection. Respondents of the research also pointed out the problem of company executives offering gifts to inspectors in return for good inspection results. The respondents also noted that some companies established a partnership agreement with the inspectors. In this

case, how can a company partner give a bad report about the company? (Garuba *et al.*, 2009)

These issues with the supposed established system are the reasons for the lack of information about the level of implementation of regulations and the impact of regulations on the products manufactured by the Nigerian companies. All evidence points to the fact that these standards are set but not implemented effectively or at all.

The company website for Emzor pharmaceuticals limited had no information about audits or inspections carried out in the manufacturing site. It also had no information about product quality issues in the past even 20 years. Further investigation into the case also showed that this information was also not available on the NAFDAC website as they deemed to not be public records. This fact makes the whole pharmaceutical sector questionable as the regards the level of implementation of set regulations

## 4.3. ANALYSIS OF OBJECTIVE TWO: To ascertain the general opinion of the respondents about the medicinal products manufactured in Nigeria.

4.3.1 According to the question (*What is your opinion about the quality of pharmaceutical products manufactured in Nigeria*)

Table 4.4 Showing the participants response to the question about the quality of pharmaceutical products manufactured in Nigerian.

| Participant's response | Result (%) |
|---|---|
| Poor | 28% |
| Neutral | 62% |
| Good | 10% |

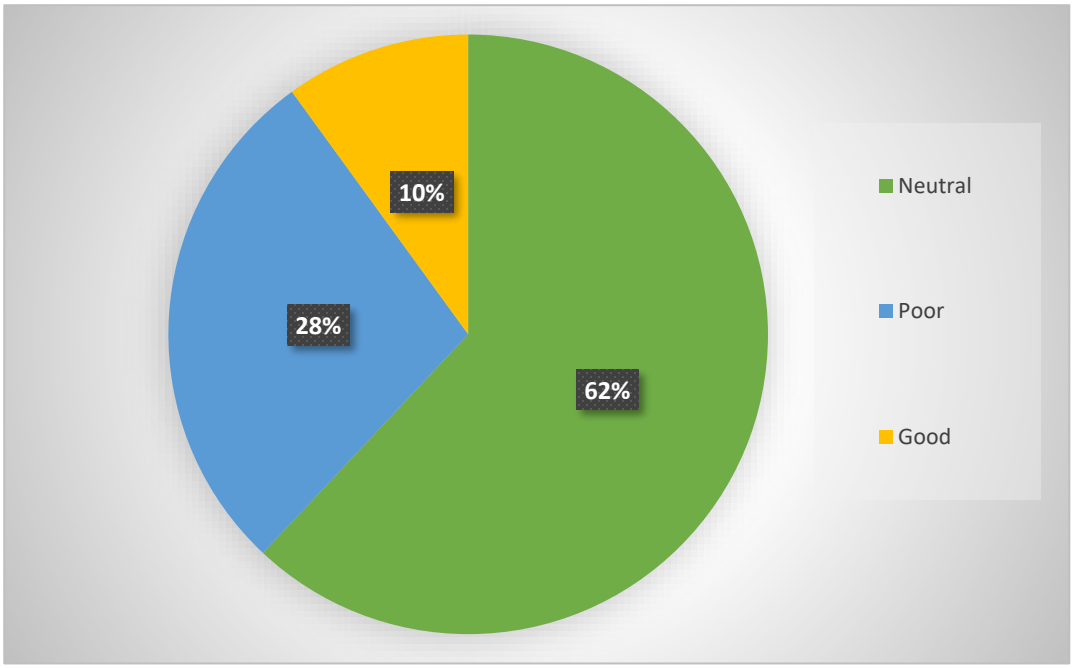


Figure 4.4 Pie chat representation of the participants response to the question about the quality of pharmaceutical products manufactured in Nigeria

Out of the 50 respondent, 31 (62%) which was majority did not have any opinion and answered Neutral, 14 (28%) answered that the Nigerian medicinal products is of poor quality and only 5 (10%) said that the Nigerian medicinal products were of good quality. Implying that the general consensus among the health care professionals and consumers based on experience is that the Nigerian medicinal products are not of top quality.

4.3.2 According to the question (*Do you agree or disagree with the statement that medicinal products produced by Nigerian pharmaceutical companies in Nigeria are of better quality than medical products produced by foreign pharmaceutical companies*)

This questions were asked to ascertain the respondents perception about the quality of medicinal products manufactured by Nigerian pharmaceutical company as compared to the medicinal products manufactured by the foreign pharmaceutical companies. This perception would be formed out of their experience with the use these medicinal product.

**Table 4.5** Showing the perception of respondents about the quality of medicinal products manufactured by Nigerian companies in comparisons to the products manufactured by foreign companies

| | |
|---|---|
| Agree | 3 (6%) |
| Neutral | 10 (20%) |
| Disagree | 36 (73%) |
| Total | 100% |

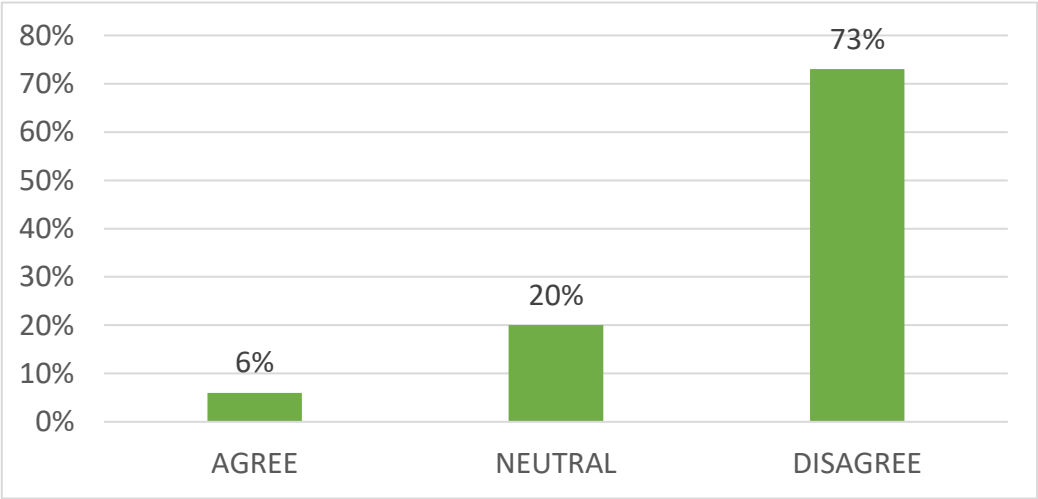


Figure 4.5 Bar chart representation of the perception of respondents about the quality of medicinal products manufactured by Nigerian companies in comparisons to the products manufactured by foreign companies

Table 4.5 and Figure 4.5 shows that out of the 50 respondents , 36 (73%) of the respondents disagreed with the statement that medicinal products produced by Nigerian pharmaceutical companies in Nigeria are of better quality than medical products produced by foreign pharmaceutical companies while only 3 (6 %) agreed with the statement. 10 (20% ) of the respondent had a neutral response.

**4.3.3.** According to the question (Do you agree or disagree with the statement medicinal products produced by foreign pharmaceutical companies are of better quality than medicinal products produced by local pharmaceutical companies)

Table 4.6 showing the perception of the respondents about the quality of medicinal product manufactured by the foreign pharmaceutical company.

| | |
|---|---|
| Agree | 72% |
| Neutral | 24% |
| Disagree | 4% |

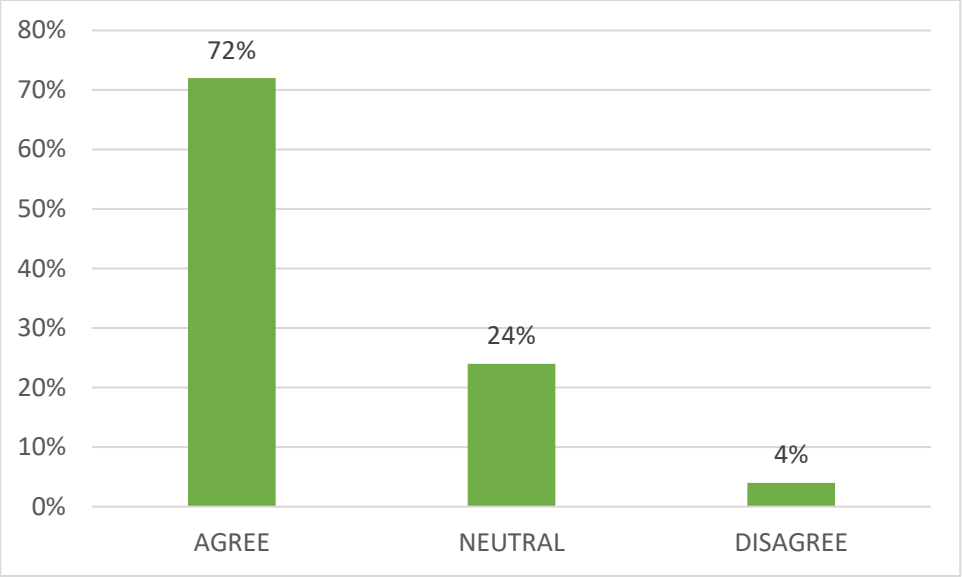


**Figure 4.6** Bar chart representation of the perception of the respondents about the quality of medicinal product manufactured by the foreign pharmaceutical company.

Table 4.6 and Figure 4.6 shows that out of the 50 respondents, 36 (72%) agreed with the statement that medicinal products produced by foreign pharmaceutical companies are of better quality than medicinal products produced by local pharmaceutical companies while only 2(4%) disagreed with the statement. 24% were neutral on the matter

The response implies that a majority of the respondents are of the belief that the medicinal products from foreign pharmaceutical companies are of better quality when compared with the medical products manufacture by the Nigerian pharmaceutical companies

**4.3.4** According to the question (*As a health care professional what medicinal products would you prefer to prescribe for your patients?*)

This question was asked specifically for healthcare professionals (HCP), to ascertain their preference as regards prescription for their patients based on experience about the quality and effectiveness of medical products they use.

**Table 4.7** showing the response of the healthcare professionals about the product they prefer to prescribe

| *As a health care professional what medicinal products would you prefer to prescribe for your patients* | Frequency (%) |
|---|---|
| Foreign pharmaceutical product | 40 (95.24%) |
| Nigerian pharmaceutical products | 2 (4.76%) |

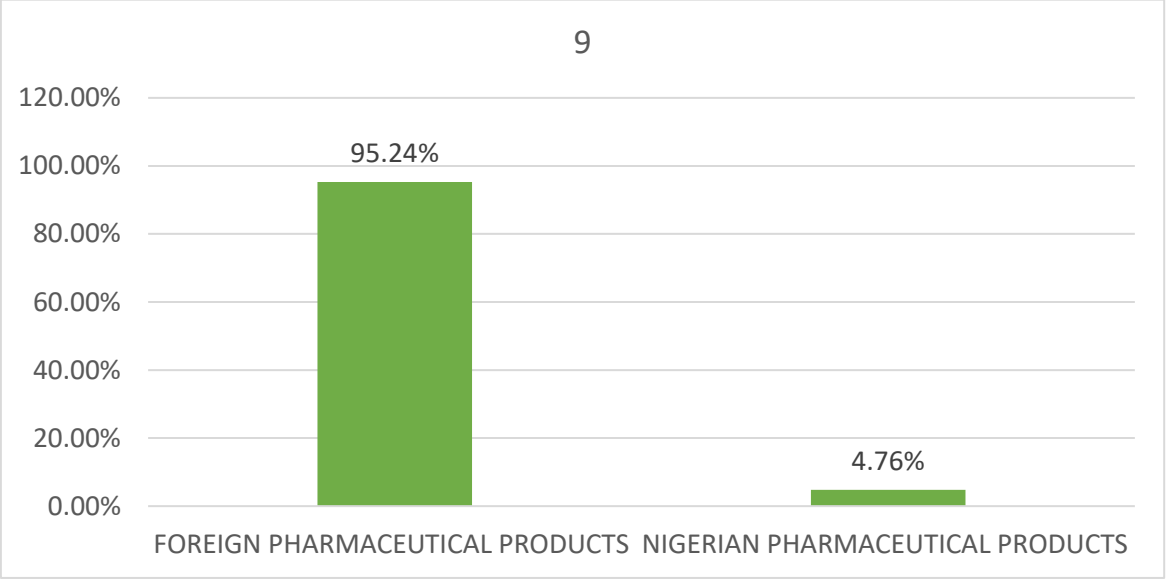


**Figure 4.7** Bar chart representation of response of the healthcare professionals about the product they prefer to prescribe

Table 4.7 and figure 4.7 shows that out of the 18 medical doctor respondents, 16 (95.24%) preferred to prescribe medicinal products from the foreign pharmaceutical companies while only 2 (4.76%) preferred to prescribe medical products from Nigerian pharmaceutical companies.

The response implies that a majority of the health care professionals in their experience prefer to prescribe foreign pharmaceutical products.

**4.3.5** (*In your experience, what medicinal product are consumers more inclined to buy*?)

This question was asked to ascertain the consumers preference between Nigeran and foreign medicinal product from the perspective of the pharmacists.

**Table 4.8** Showing the response of the pharmacists about the preference of the consumers as regards choice of medicinal products

| *In your experience, what medicinal product are consumers more inclined to buy*? | Response (%) |
|---|---|
| Foreign pharmaceutical products | 81% |
| Nigerian pharmaceutical products | 19% |

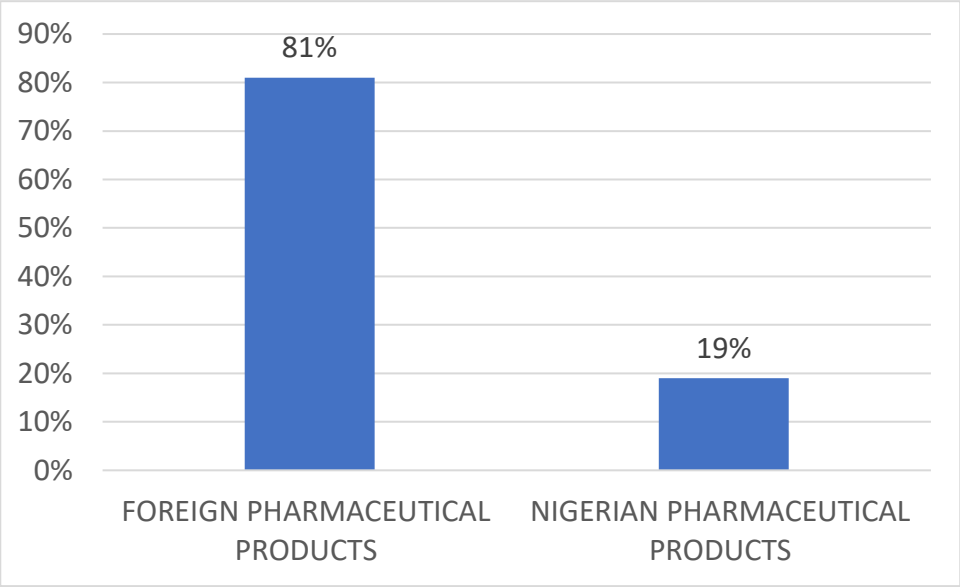


**Figure 4.8** bar chart representation of the response of the pharmacists about the preference of the consumers as regards choice of medicinal products

Table 4.8 and figure 4.8 shows that out of the 20 pharmacists that responded to the survey, 14(81%) stated that the consumers are more inclined to buying medicinal products from foreign pharmaceutical company while 6(19%) stated that the consumers are more inclined to buying their medicinal products from the Nigerian pharmaceutical company.

## 4.4 ANALYSIS OF OBJECTIVE THREE : To compare the quality and effectiveness of medicinal products by the Nigerian pharmaceutical companies that of the foreign pharmaceutical companies in Nigeria

**4.4.1** According to the question (*Do you agree or disagree with the statement, medicinal products by Nigerian pharmaceutical companies are more effective than those produced by the foreign pharmaceutical companies*)

This question was asked to determine the respondents knowledge about the effectiveness of the medicinal products manufactured in Nigeria based on their use and experience.

**Table 4.9** Showing the level of agreement to the statement medicinal products by Nigerian pharmaceutical companies are more effective than those produced by the foreign pharmaceutical companies

| | |
|---|---|
| Agree | 64% |
| Neutral | 32% |
| Disagree | 4% |

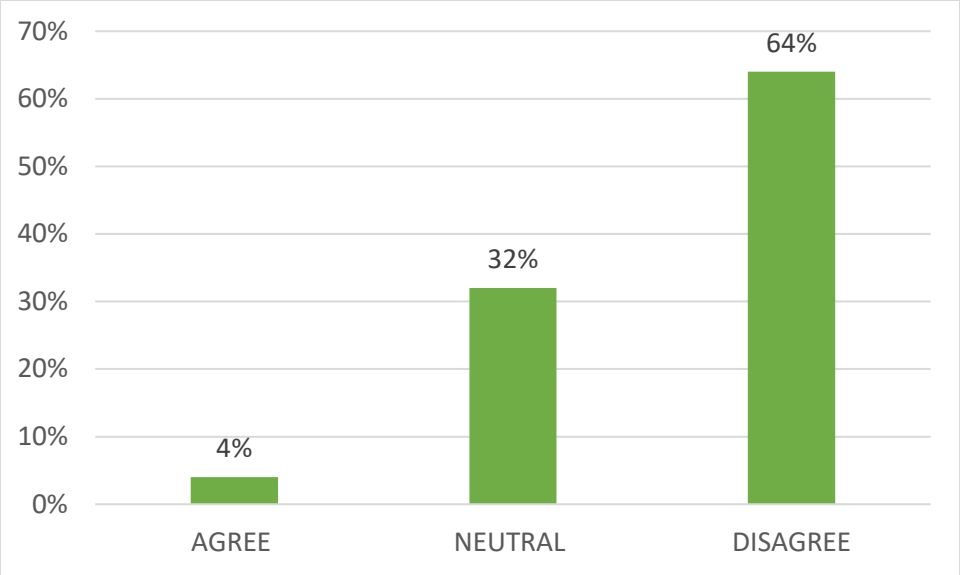


**Figure 4.9** Bar chart representation of the level of agreement to the statement "*medicinal products by Nigerian pharmaceutical companies are more effective than those produced by the foreign pharmaceutical companies*"

Table 4.9 and figure 4.9 shows that a large percentage of the respondents 32 (64%) disagreed to the statement that Nigerian products were more effective and only 2(4%) agreed with the statement. Others were neutral on the matter 16 (32%).

**4.4.2** According to the question *(Do you agree or disagree with the statement "Medicinal products by Foreign pharmaceutical companies are more effective than those produced by the local pharmaceutical companies*)

**Table 4.10** Showing the level of agreement to the statement Medicinal products by Foreign pharmaceutical companies are more effective than those produced by the local pharmaceutical companies

| | |
|---|---|
| Agree | 65% |
| Neutral | 33% |

| | |
|---|---|
| Disagree | 2% |

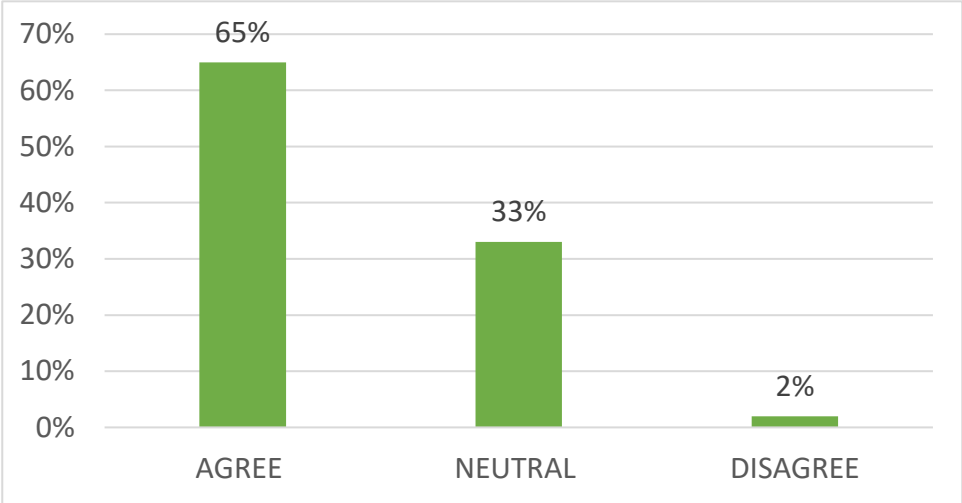


**Figure 4.10** Bar chart representation of the agreement to the statement Medicinal products by Foreign pharmaceutical companies are more effective than those produced by the local pharmaceutical companies

Table 4.10 and figure 4.10 shows an obvious contrast to the results of the previous question, a large number of the respondents 32 (65%) agreed with the statement that medicinal products by foreign pharmaceutical companies were more effective, only 1 (2% ) disagreed with the statement while the others were neutral on the matter 16 (33%).

The contrasting response from both questions shows that the respondents have more faith in the effectiveness of medicinal products manufactured by foreign pharmaceutical companies.

**4.4.3** According to the question (*In your experience, What medicinal products do you think is more effective in treatment of disease conditions*?)

This question was asked strictly to health care professionals in order to determine what medicinal product in their practice has proven to be more effective in treatment of disease conditions.

**Table 4.11** Showing the healthcare professionals opinion regarding effectiveness of medicinal products

| *In your experience, what medicinal products do you think is more effective in treatment of disease conditions*? | Response (%) |
|---|---|
| Foreign pharmaceutical products | 100% |
| Nigerian pharmaceutical products | 0% |

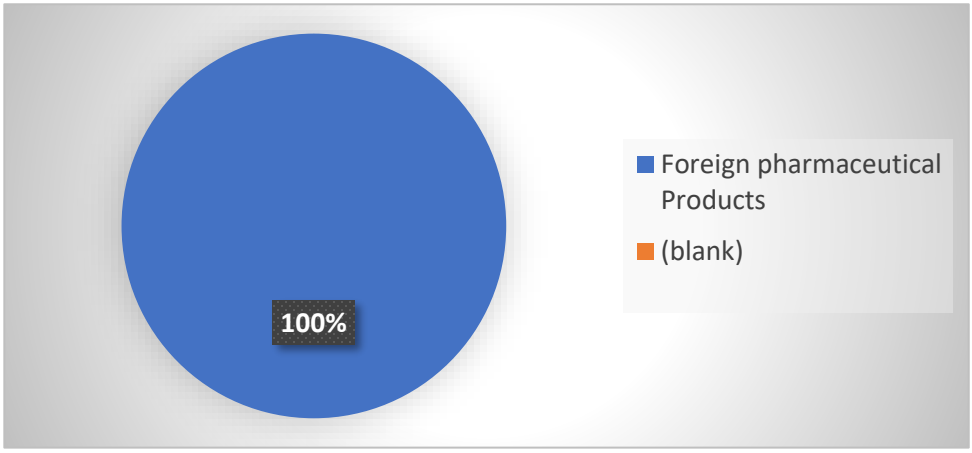


**Figure 4.11** pie chart representation of the healthcare professionals opinion regarding effectiveness of medicinal products

Table 4.11 and figure 4.11 shows that a 100% of the health care professional respondents chose the foreign pharmaceutical products were more effective in treatment of disease condition.

The results prove that according to the healthcare professionals, foreign pharmaceutical products are more effective in treatment of disease conditions.

**4.4.4** According to the question (*Have you had any experience where medicinal products that you purchased from a pharmacy had to be sent back to the pharmacy due to production errors such as incomplete drugs, bad/wrong packaging, inaccurate labelling, improper seal, smudges, scratches and ink splatter on the medicinal product leaflet or other issues*?)
This question was asked to determine the physical quality of the medicinal products sent out to the pharmacies and also to determine the source of faulty products distributed to the pharmacies.

Table 4.12 Showing the response of participants about medicinal products being sent back to the pharmacy

| *Have you had any experience where medicinal products that you purchased from a pharmacy had to be sent back to the pharmacy due to production errors* | Response (%) |
|---|---|
| Yes | 37% |
| No | 63% |

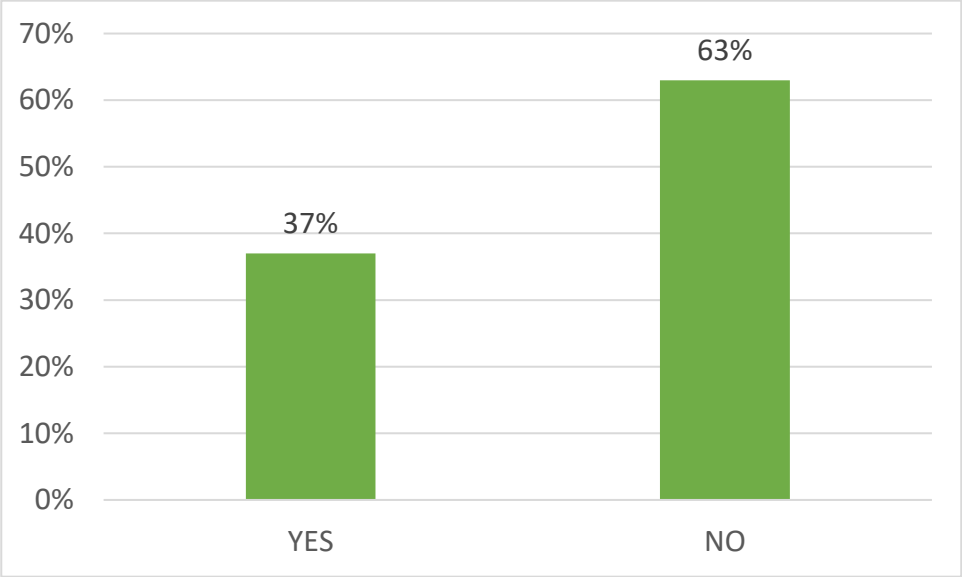


**Figure 4.12** Bar chart representation of the response of participants about medicinal products being sent back to the pharmacy

Table 4.12 and figure 4.12 shows that 18 (37%) of the respondents claimed to have had experiences were the medicinal products that was purchased from a pharmacy had to be sent back to the pharmacy due to production errors. However, 31(63%) of the respondents have not had this experience.

**4.4.5** According to the question (*What pharmaceutical company produced the faulty medicinal product*?)

This question was a follow up to the to the previous question so as to determine the company where the faulty products came from.

Table 4.13 Showing the source of the faulty medicinal product

| *What pharmaceutical company produced the faulty medicinal product*?) | Response (%) |
|---|---|
| Foreign pharmaceutical products | 2% |

| | |
|---|---|
| Nigerian pharmaceutical products | 98% |

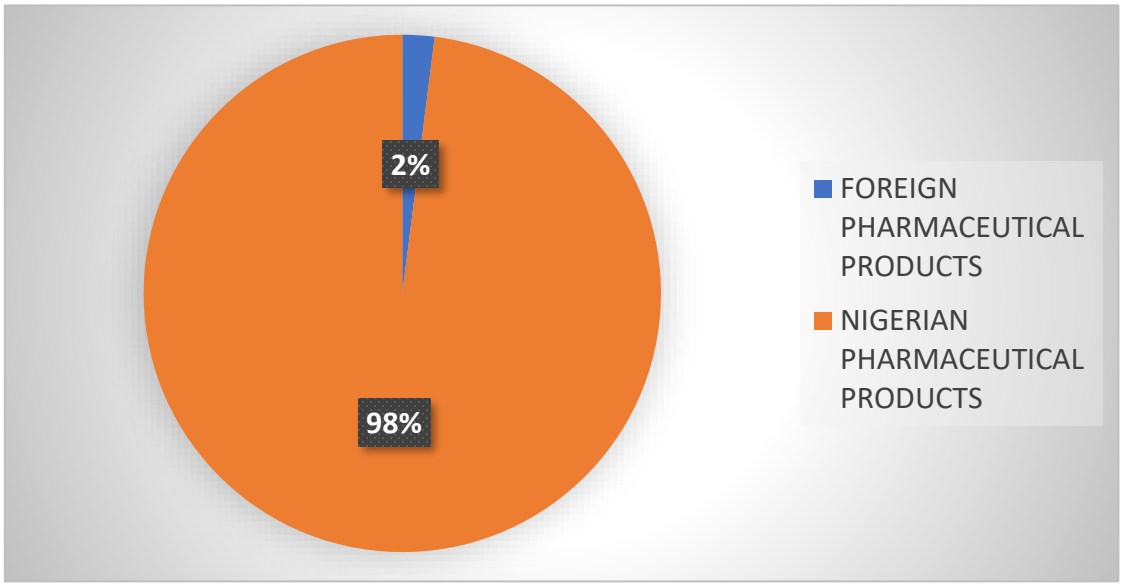


Figure 4.13 pie chart representation of the source of the faulty medicinal product

Table 4.13 and figure 4.13 show that out of the 18 (37%) person that claimed to have had experiences where they had to return a product due to production errors in different aspects, 17 (98%) stated that the medicinal products they had to return was from a Nigerian pharmaceutical company and only 1 (2%) person stated that the returned product was of a foreign pharmaceutical company.
The response implies that most of the medicinal products with errors came from the Nigerian pharmaceutical companies.

**4.4.6**According to the question (*How often do medicinal products from Nigerian pharmaceutical companies have production errors, such as incomplete drugs, bad/wrong packaging, inaccurate labelling, improper seal, smudges, scratches and ink splatter on the medicinal product leaflet or other issues*?)
This question was asked to ascertain the quality of the products from the Nigerian pharmaceutical company from the pharmacists. In a bid to compare it to that of

their foreign counterpart. 34% of the respondents said that it happened often while 13% stated that it happened very often. A majority of 44% was neutral on the matter and about 9% claimed that it has never happened.

Table 4.14 showing participants response to the frequency of return of medicinal products manufactured by the Nigerian pharmaceutical companies

| *How often do medicinal products from Nigerian pharmaceutical companies have production errors,* | Response (%) |
|---|---|
| Very often | 13% |
| Often | 34% |
| Neutral | 44% |
| Never | 9% |

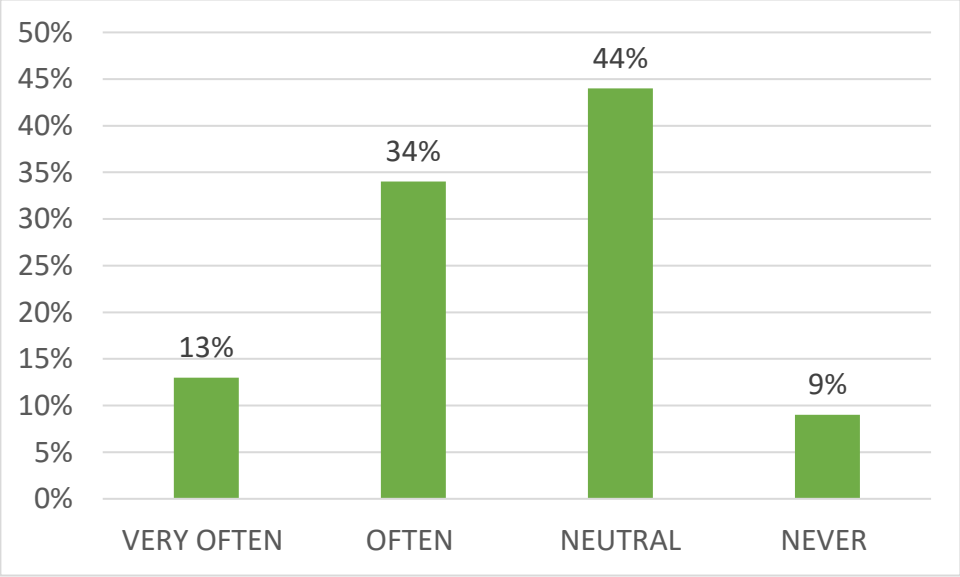


Figure 4.14 Bar chart representation of the participants response to the frequency of return of medicinal products manufactured by the Nigerian pharmaceutical companies

Table 4.14 and figure 4.14 shows that 11(34%) of the respondents said that it happened often while 4(13%) stated that it happened very often. A majority of 14(44%) was neutral on the matter and about 3(9%) claimed that it has never happened.

**4.4.7** According to the question (*How often do medicinal products from foreign pharmaceutical companies have production errors such as incomplete drugs, bad/wrong packaging, inaccurate labelling, improper seal, smudges, scratches and ink splatter on the medicinal product leaflet or other issues*?)

**Table 4.15** Showing the participants response to the frequency of return of medicinal products manufactured by the foreign pharmaceutical companies

| *How often do medicinal products from foreign pharmaceutical companies have production errors,* | Response (%) |
|---|---|
| Very often | 0% |
| Often | 0%% |
| Neutral | 67.74% |
| Never | 32.26% |

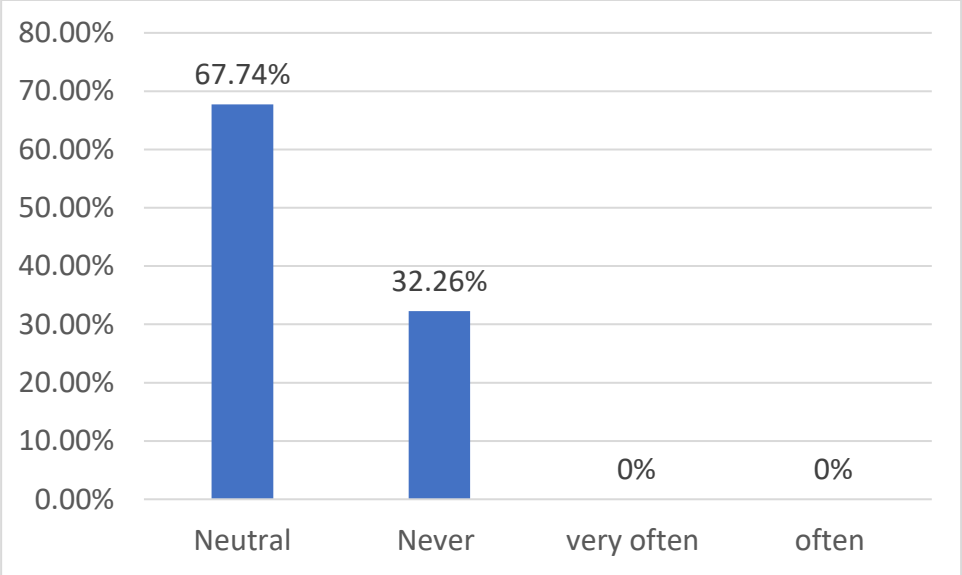


Figure 4.15 bar chart representation of the frequency of return of medicinal products manufactured by the foreign pharmaceutical companies.

In direct contrast to the response in the previous question, the response to this question showed that 21(68%) were neutral on the matter while a whole 10(32%) stated that the incidence has never happened. No one stated that the incidence happened often or very often.

The response for both questions indicate that the product that would most likely be delivered to the pharmacy with production errors from incomplete drugs to issues with the product leaflet is the Nigerian pharmaceutical product.

**4.4.8** According to the question **(***Do you have any experience where medicinal products had to be sent back (due to production errors) to the pharmaceutical company where it was manufactured*?)

These questions were asked specifically to the pharmacists to further establish the quality of the medicinal products manufactured in Nigeria.

Table 4.16 Showing the pharmacists response to medicinal products that are returned to the pharmaceutical company

| *Do you have any experience where medicinal products had to be sent back to the pharmaceutical company where it was manufactured*? | Response |
|---|---|
| Yes | 44% |
| No | 56% |

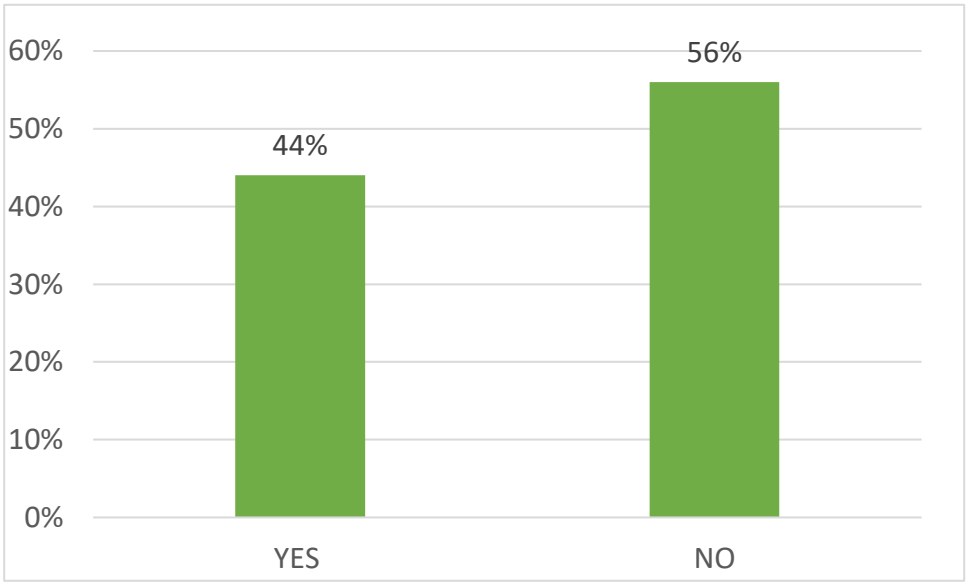


Figure 4.16 bar chart representation of the pharmacists response to medicinal products that are returned to the pharmaceutical company

Table 4.16 and figure 4.16 showed that 14(44%) of the respondents claimed to have had experiences were medicines had to be sent back to the pharmaceutical company due to production errors while 18(56%) claimed to have never had this experience.

**4.4.9** According to the question (*What pharmaceutical company produced the faulty medicinal product*?)

Table 4.17 Showing the pharmacist response to the source of the faulty medicinal product

| *What pharmaceutical company produced the faulty medicinal product*? | Response (%) |
|---|---|
| Foreign pharmaceutical company | 7% |
| Nigerian pharmaceutical company | 93% |

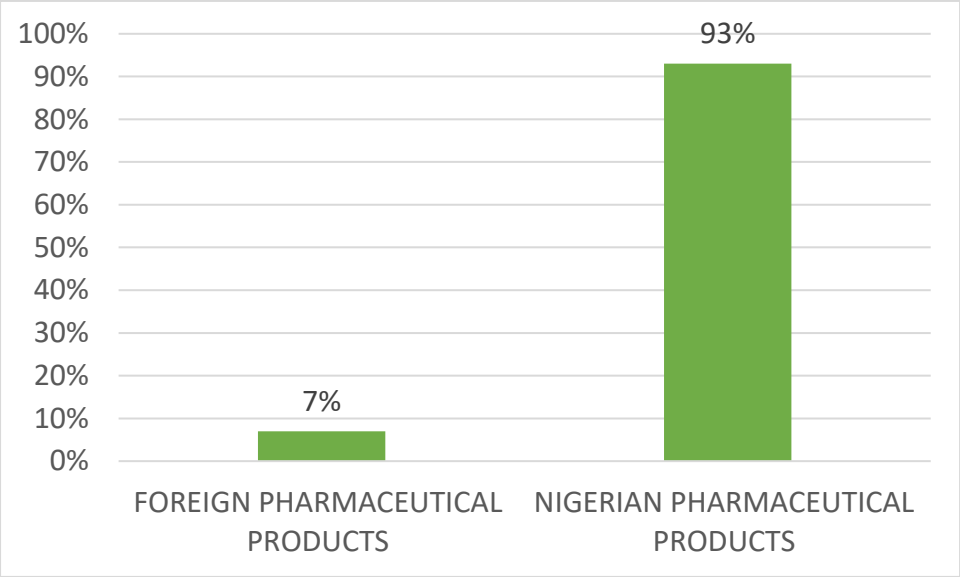


Figure 4.17 Bar chart representation of the pharmacist response to the source of the faulty medicinal product

According to table 4.17 and figure 4.17, when asked what pharmaceutical company was responsible for the faulty medicinal product, 13(93%) claimed the faulty medicinal product was from the Nigerian pharmaceutical company while

only 1(7%) stated that the medicinal product came from a foreign pharmaceutical company.

## 4.5 ANALYSIS OF OBJECTIVE FOUR: To identify the factors that affect the quality and availability of medicinal products in Nigeria?

4.5.1 According to the question (*Do you think these aspects can influence or impact on the quality and availability of the medicinal products in Nigeria"? the factors include*

*Government policies, Socio Economic status of the country, Inadequate laws or poor enforcement of the existing regulations/guidelines for manufacturing of good quality medicinal products, Inadequate funding/support for Nigerian pharmaceutical manufacturing companies, Demand exceeding supply and high cost of good quality medicinal product)*

This question was asked to determine the thoughts of the genal consumers about the factors that affect the quality and availability of medicinal products in Nigeria as a whole.

**Table 4.18** Showing the participants opinion about the selected factors that influencing the quality and availability of medicinal products in Nigeria

| FACTORS | Agree | Neutral | Disagree |
|---|---|---|---|
| ***High cost of good quality medicinal product.*** | 90% | 2.50% | 7.50% |

| | | | |
|---|---|---|---|
| ***Demand exceeding supply*** | 75.60% | 17.10% | 7.30% |
| ***Inadequate funding/support for Nigerian pharmaceutical manufacturing companies*** | 92.90% | 7.10% | 0% |
| ***Inadequate laws or poor enforcement of the existing regulations/guidelines for manufacturing of good quality medicinal products*** | 90.70% | 9.30% | 0% |
| ***Socio Economic status of the country*** | 97.60% | 2.40% | 0% |
| ***Government policies*** | 89.40% | 8.50% | 2.10% |

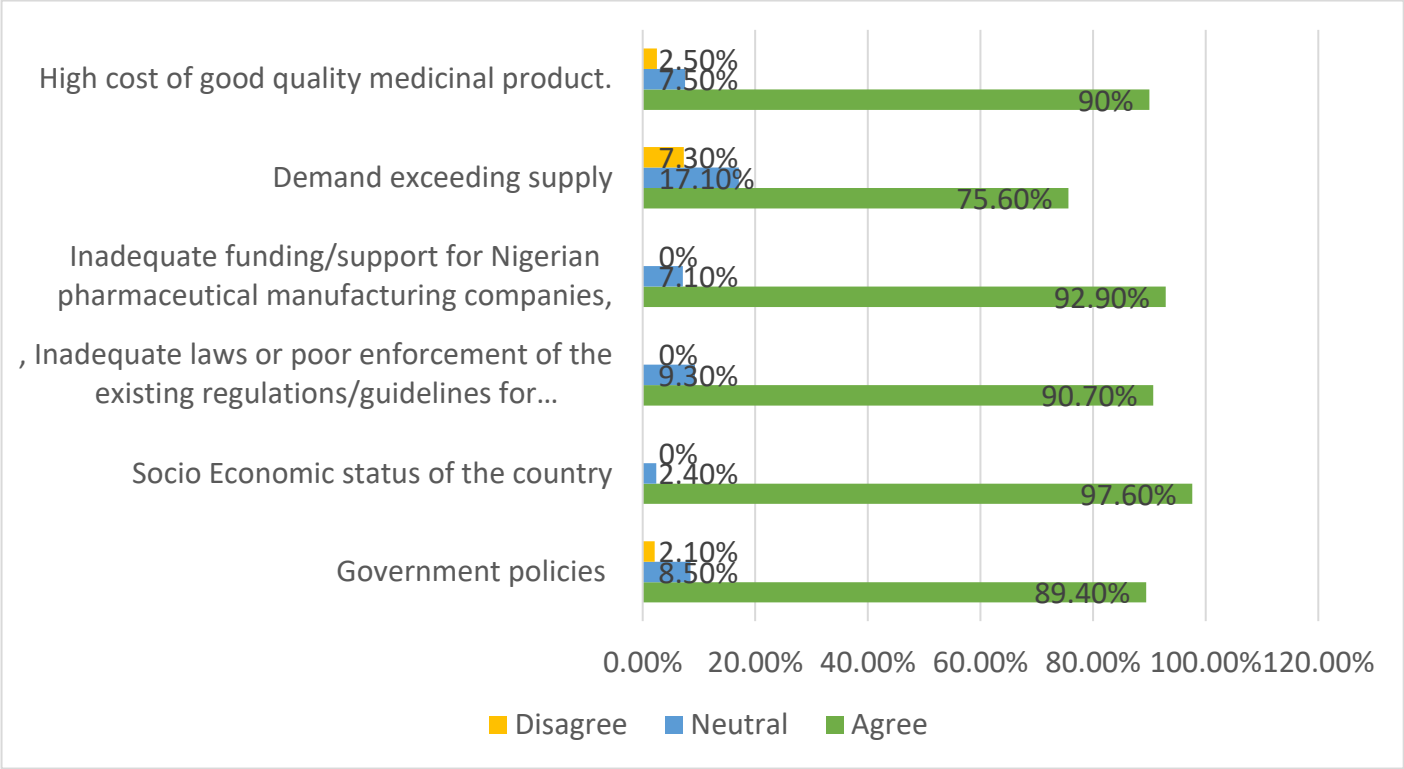


**Figure 4.18** bar chart representation of the participants opinion about the selected factors that influencing the quality and availability of medicinal products in Nigeria

Table 4.18 and figure 4.18 show the participants opinion about the selected factors that influencing the quality and availability of medicinal products in Nigeria. For government policies 89% agreed that it influences the quality and availability medicinal products while 2.1% disagreed and 8.5% were neutral on the matter. For socio economic status of the country, 97.6% agreed that it influenced the availability and quality of medicines in Nigeria. 2.4% were neutral on the matter and no one disagreed. For Inadequate laws or poor enforcement of the existing regulations/guidelines for manufacturing of good quality medicinal products, the polls came back that 90.7% agreed while 9.3% were neutral on the matter and no one disagreed. For inadequate funding/support for Nigerian pharmaceutical

manufacturing companies, the polls came back that 92.9% agreed that this factor influences on the availability and quality of medicinal products while 7.1% were neutral on the matter. No on disagreed. For demand exceeding supply, 75% of the respondents agreed that this factor affected the availability and quality of medicinal products while 17.1% were neutral on the matter and 7.3% disagreed. High cost of good quality medical products, 90% of the respondents agreed, 7.5% were neutral on the matter and 2.5% disagreed. The figures above are represented in the graph below

The bar chart above shows that most of the respondents agreed to the all the factors stated to have influence on the availability and quality of medicinal products. The chart shows that the respondents agreed the most with "socio Economic state of the county" as the factor with the most influence on the quality and availability of medicinal products. This was closely followed by inadequate funding/support for the Nigerian pharmaceutical manufacturing companies then the high cost of good quality medicinal products.

### 4.6 Sources and Availability of medicinal products

**4.6.1** According to the question *(Which of the medical products available in your region is more cost effective?*

Table 4.19 showing the participants response to the which medicinal product was more cost effective

| *Which of the medical products available in your region is more cost effective?* | Response (%) |
|---|---|
| Foreign pharmaceutical company | 32% |
| Nigerian pharmaceutical company | 68% |

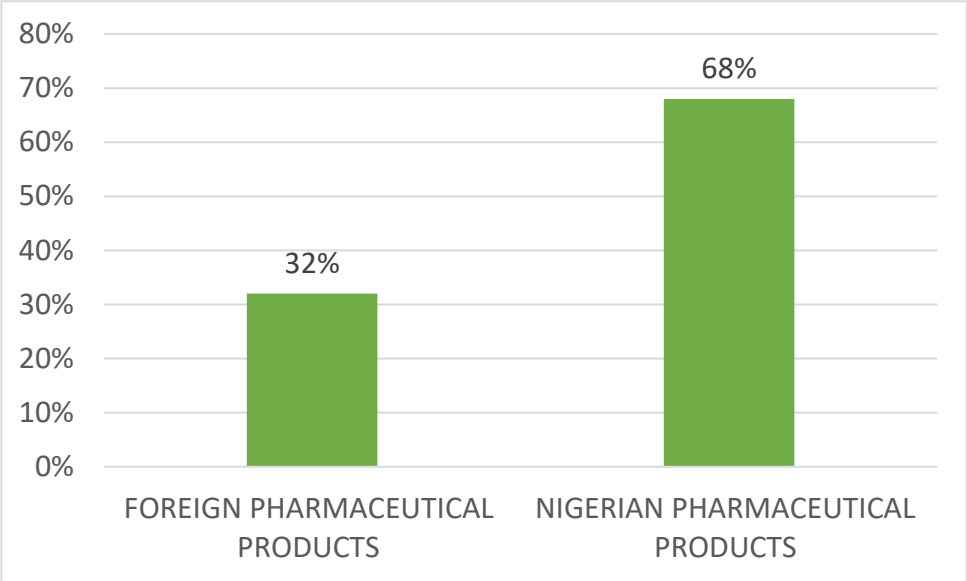


Figure 4.19 bar chart representation of the participants response to the which medicinal product was more cost effective

Table 4.19 and figure 4.19 showed that 34 (68% ) of the respondents chose the Nigerian pharmaceutical products to be more cost effective than that of the foreign pharmaceutical companies while only 16 (32%) said that the foreign pharmaceutical products where more effective.

The responses for this question shows that to a large extent, medicinal product from the Nigerian pharmaceutical companies are more affordable although in some areas, the foreign products may be affordable too.

4.6.2 (*In last few months, have you had any experience where the medicinal products you needed was not available in your local pharmacy*?)

**Table 4.20** Showing the participants response to the availability of medicinal products in their region

| *In last few months, have you had any experience where the medicinal products you needed was not available in your local pharmacy*?) | Response (%) |
|---|---|
| Yes | 94% |
| No | 6% |

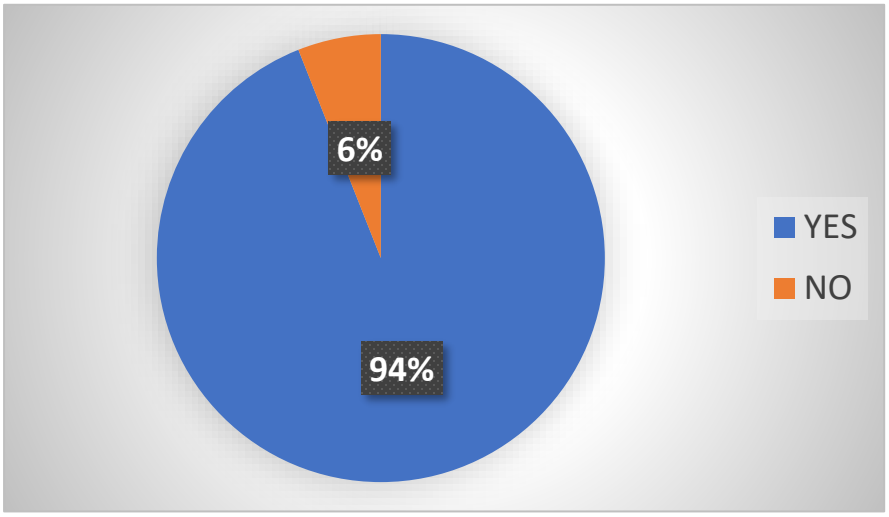


**Figure 4.20** Pie chart representation of the participants response to the availability of medicinal products in their region

Table 4.20 and figure 4.20 shows that 17(94%) of the respondents admitting to having this experience while only 3(6%) answered no, indicating that they had not had this experience.

4.6.3 According to the question (*Where do you get most of your medicinal products from*?)

This question was asked to determine the major source of the medicinal products that are available in the Nigerian pharmacies. The respondents in this case was only pharmacists.

Table 4.21 Showing the pharmacist response to the source of majority of their medicinal products

| *Where do you get most of your medicinal products from*?) | Response (%) |
|---|---|
| Foreign pharmaceutical company | 56% |
| Nigerian pharmaceutical company | 44% |

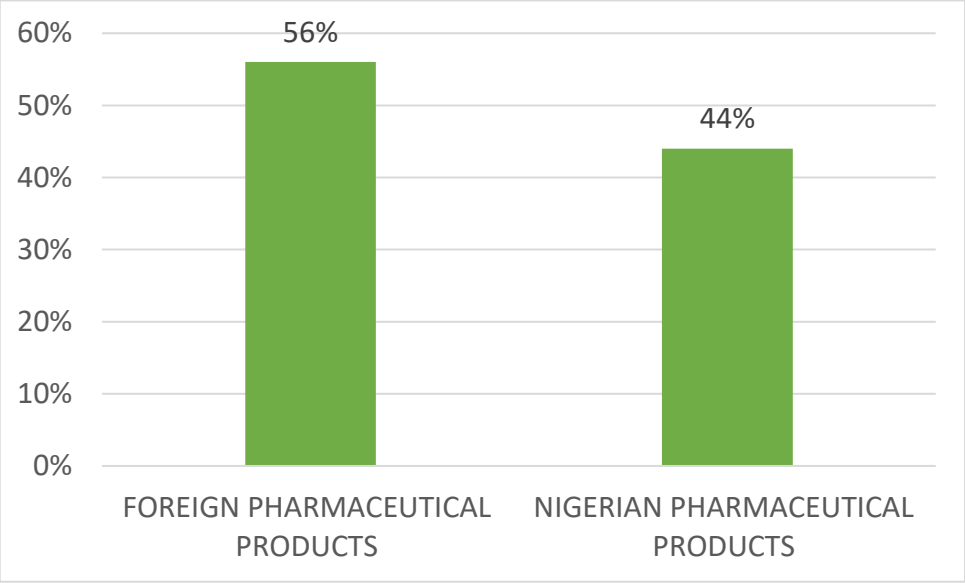


Figure 4.21 Bar chart representation of the pharmacist response to the source of majority of their medicinal products

The response from both questions further establishes that most of the medical products that a marketed and sold with production errors are most likely to have come from the Nigeria pharmaceutical company.

## 4.3 RESULTS

A complete analysis of all the data collected shows that the general opinion of the medicinal products manufactured by the Nigerian pharmaceutical company is significantly low in quality when compared to that of their foreign counterparts. According to the analysis, the consumers prefer to utilized medicinal products from the foreign pharmaceutical companies because according to their experience, the foreign medicinal products almost never come with production errors and over the years have proven to be more effective in treatment of their disease conditions as opposed to the medicinal products from the Nigerian pharmaceutical companies. From the analysis, it is also evident that the products from the foreign pharmaceutical companies is not cost effective. The evaluation shows that the medicinal product from the foreign company is significantly more expensive than that of their Nigerian counterpart. Even so, according to the pharmacists, the consumers are more inclined to buying the products of the foreign pharmaceutical company. Leaving the Nigerian medicinal products to be bought by the low income earners but only because that is the only one they can afford.

According the pharmacists, a majority of the medicinal products are delivered by the foreign pharmaceutical companies while a lower percentage of their products was delivered by Nigerian pharmaceutical companies. However, the products from the foreign pharmaceutical companies almost never have any physical productions errors like incomplete drugs, bad/wrong packaging, inaccurate labelling, improper seal, smudges, scratches and ink splatter on the medicinal product leaflet but on the other hand, the medicinal products from the Nigerian pharmaceutical companies often time came the above stated physical errors of production. These errors are the factors that reduce the faith of consumers in the product. These errors resulted in

the product being sent back to the production company that was always the Nigerian manufacturing company.

According the doctors, they were more inclined to prescribe medicinal products from the foreign pharmaceutical companies to their patient. This is because, in their experience, the medicines from the foreign companies have proven to be more effective for the treatment of their patients even though the Nigerian medicinal products more cost effective.

Further interpretation of the responses from the survey showed that all participants of the survey were in agreement of the stated factors that affect the quality and availability of medicinal products in Nigeria. The suggested factors include: Government policies, Socio Economic status of the country, Inadequate laws or poor enforcement of the existing regulations/guidelines for manufacturing of good quality medicinal products, Inadequate funding/support for Nigerian pharmaceutical manufacturing companies, Demand exceeding supply. For all the factors, there was a more than 90% agree rate with less than 20% being neutral on the matter and less than 10% disagreeing with the factors. And so inevitably the above stated factors affect the availability and quality of medicinal products manufactured in Nigeria.

# CHAPTER 5

# CONCLUSION AND RECOMMENDATIONS

## 5.1 CONCLUSION

Two of the top pharmaceutical manufacturing companies in Nigeria were chosen as a case study. GlaxoSmithKline plc a multinational UK based pharmaceutical company that established a subsidiary in Lagos Nigeria in the year 1971 and stated production of over the counter medications (OTC). It is regulated by the MHRA and utilizes the GMP guidelines and other guidelines of the ICH. Also, Emzor pharmaceutical industry limited was chosen. A Nigerian pharmaceutical company situated at Ikoyi, Lagos state. They produce different groups of medication including OCP, antibiotics, anti-malaria, anti-histamines, antitussives and others. Emzor is regulated by NAFDAC and utilizes the NAFDAC GMP guidelines for manufacture of medicinal products for human use.

Upon through examination of the quality systems at utilized in these companies as made available on their company websites, there was an obvious difference in the systems in play. The quality system of Emzor pharmaceutical limited represented on the company website was seen to be very weak, insubstantial and grossly inadequate. The information provided was not at all comprehensive and some important issues were neither mention or addressed. When compared to the quality system of the GSK company, their system was full proof covering all crucial aspects in detail. This fact the quality system in the Nigerian company was not comprehensive can creates loop holes in their quality assurance scheme and this would negatively affects the medicinal products they manufacture. Pharmaceutical manufacturing regulations have been set up to detect these issues and prevent the distribution of products that have failed the quality assurance check but the

regulators in charge and the regulatory system is plagued by corruption and so it is not effective. And so incomprehensive quality system In the Nigerian company will inevitably lead to poor quality medicinal products whereas, the comprehensive quality systems detailed by the foreign pharmaceutical company would lead to the manufacture of top quality medicinal products.

Furthermore, the Emzor website provide no information about audits (internal and external) or inspections carried out in the manufacturing site. It also had no information about product quality issues in the past even 20 years. Further research also showed that this information was also not available on the NAFDAC website as they were deemed to not be public records. This fact makes the whole pharmaceutical sector questionable as the regards the level of implementation of set regulations

The pharmaceutical sector is also seen to be very opaque with their activities. A lot of products are seen to be registered on the NAFDAC website but little to no information is made available about the products and due to this fact it is almost impossible to ascertain the impact of the company quality systems on the products they manufacture

According to the evidence provided by the questionnaire survey, up to 95% of the respondent medical doctors stated that they preferred to prescribe foreign medicinal products for their patients. The reason for this was made evident in another survey question. When asked what product was more effective for treatment of disease conditions a 100% of the health care professional respondents stated that the foreign pharmaceutical products were more effective in treatment of disease conditions even though the Nigerian pharmaceutical products were more cost effective and readily available. Furthermore, the consumers were asked

numerous question to ascertain their opinion about the medicinal products manufactured in Nigeria. A greater portion of the respondents stated that they believed that the medical products from the foreign pharmaceutical companies were of better quality than that of the Nigerian pharmaceutical companies. A greater portion of the respondents also stated that they believed that the medicinal products from the foreign pharmaceutical companies were also more effective for treatment than that of the Nigerian companies and the pharmacists stated that the consumers are more inclined to buying medicinal products that were manufactured by the foreign pharmaceutical as opposed to that of the Nigerian companies. These facts also provide information and insight about the quality systems at play in the Nigerian pharmaceutical company. Ineffective quality systems leads to manufacture of low quality products.

This research was also able to identify the other factors that affect the quality and availability of medicinal products in Nigeria. the factors as evidenced by the survey includes: High cost of good quality medicinal product because most of them are produced by the foreign pharmaceutical companies or imported from other countries and also because Nigeria is a low to medium income earning county with a large part of its population made up of poor people. Another factor is th*e* Demand of medicinal product exceeding supply due to the state of the country and the fact that Nigeria is a highly populated and tropical third world country, there is a lot of tropical illness and so individuals are constantly being treated. Due to these factors sometimes the medicine demand can be seen to exceed the supply as only 30% of the medicines used in Nigeria are manufactured in Nigeria. Inadequate funding/support for Nigerian pharmaceutical manufacturing companies, is another major factor. This is because Nigeria is a low to medium income country and the required fund is not readily available. In cases where the

funds are available, high level of corruption becomes an issue with people in power embezzling and diverting the funds. Inadequate laws or poor enforcement of the existing regulations/guidelines for manufacturing of good quality medicinal products is an important factor that the respondents agreed to. some regulations have been set up by NAFDAC although they are not adequate and the GMP is not as strong as that of ICH the major issue is the implementation of these regulation. The socio-economic state of the country as well as the underpayment of the regulators makes them more susceptible to bribery and corruption in exchange for turning a blind eye to quality issues.

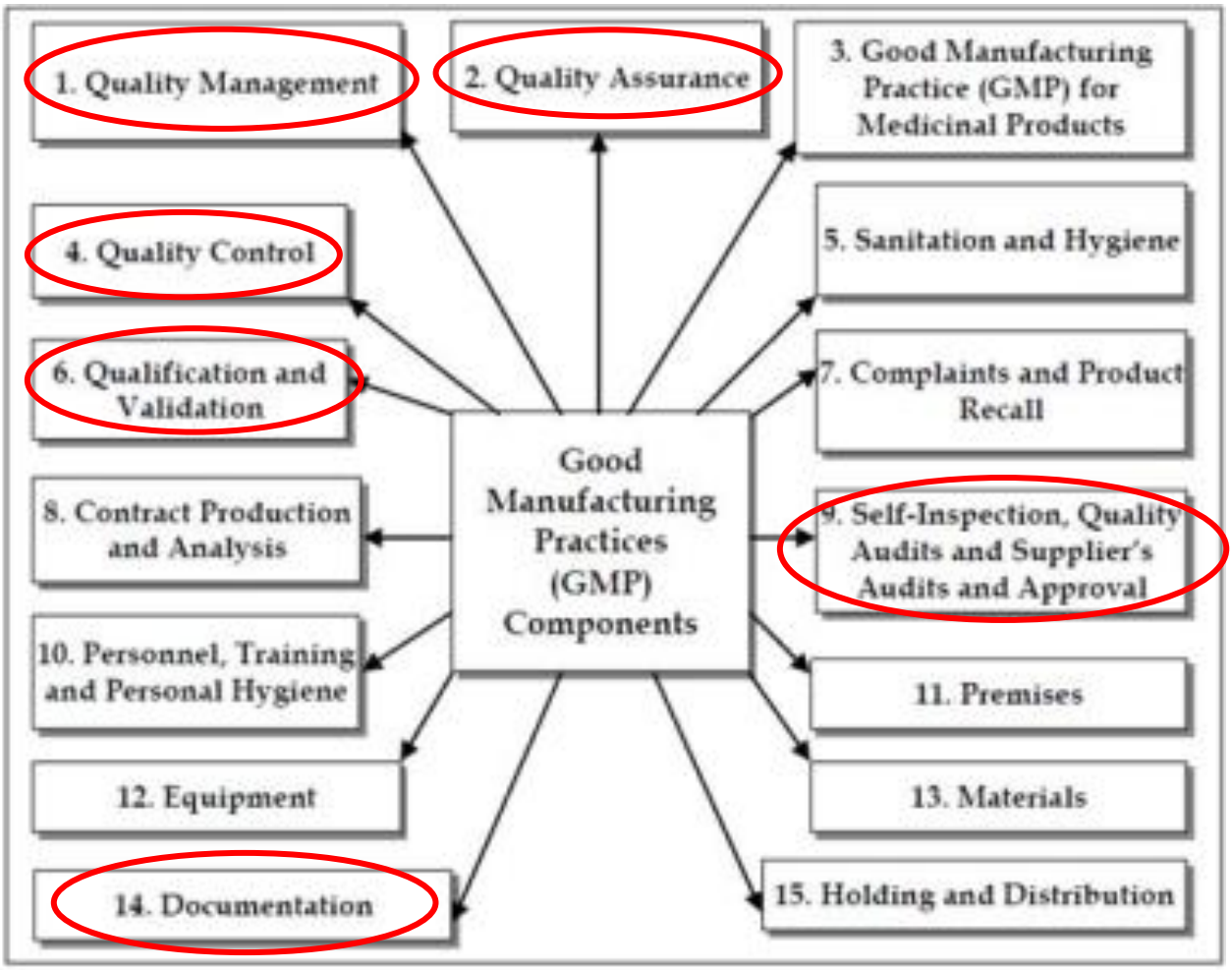


Figure 5.1 showing the components of good manufacturing practices

Figure 5.1 Shows the main components of GMP according to ICH. The pharmaceutical company "GlaxoSmithKline plc" utilizes the ICH guidelines for good manufacturing practices and so they ensure that all aspects of the GMP are functional in their manufacturing process. This however does not imply that all products manufactured are without error but that because of this functional system, the errors are easily identified and dealt with. An example can be seen in the GSK consumer healthcare recall of two lots of "children's Robiussin Honey cough and Chest Congestion DM" and "one lot of children's Dimetapp cough and cold". This was a voluntary recall by the company due to incorrect dosing cups in the children's medication. The company consumer healthcare department was concerned about possible overdose due to the incorrect calibration on the drug delivery cup. The company also put out notifications about the possible symptoms of overdose and other side effects in any case where the product couldn't be gotten back. This report was made in February of 2020 and as of June 2020, there had been no reports about adverse events. (GSK, 2020). This shows transparency in the system.

The Nigerian company however, claim that all the above components are included in the NAFDAC GMP and are utilized in the company. However, there is no proof even on the NAFDAC website that the aspects highlighted are implemented. The NAFDAC website had Inadequate product information and no information at all about NAFDAC inspection of production sites. There was also no accessible information about quality management, quality control or quality assurance in the Nigerian manufacturing companies. Most of these important information if available was not made public by NAFDAC or the company. This makes the Nigeria pharmaceutical system untrustworthy and unreliable.

## 5.2 RECOMMENDATIONS:

A recommendation that is considered a high priority recommendation is for NAFDAC to establish a conflict of interest (COI) guideline that is modelled after already existing and functional COI like that of the Canadian agency for Drugs and Technologies in Health. Establishment of this guideline will help in reducing the vulnerability of the Nigerian sector. Furthermore, in order to ensure effective implantation of these guidelines, there should be establishment of penalties in form of cash fines or even jail time for failing to adhere to the set guidelines as this would bolster effective implantation of the guidelines

A second high priority recommendation is that NAFDAC makes all audits (both internal and external) carried out in the pharmaceutical companies by the NAFDAC regulators and inspectors available to the public. This is recommended because the scrutiny that comes from the public can become an incentive to the regulators to do better work in ensuring compliance in the manufacturing companies and an incentive to the company to create a better quality system to avoid bad reviews getting to the general public. Also, there should be a rotation of inspectors so that one inspector does not have to inspect a particular site more than once. In this case there is no chance to familiarise and establish partnerships with companies. It is tantamount that all registered medicines on the NAFDAC website is accompanied with adequate information about the product and its features. This will restore confidence in the medicinal products manufactured the Nigeria pharmaceutical company.

A third recommendation is proper funding of the Nigerian pharmaceutical sector. Especially for NAFDAC. Provision of all required equipment and facilities need to properly enforce the law. Adequate salaries and benefits package to the regulators

so they don’t fall prey to bribe. Installation of CCTV cameras in storage sites and body cameras for the NAFDAC regulators in order to capture all ongoing activities during inspection of manufacturing sites. It is also very important to ensure that are regulators are authorised and have the required skill and training to carry out a good job.

Fourthly, as one of the NAFDAC mandate is to promote confidence in the products manufacture by the Nigerian companies. This mandate can be achieved by way of creating incentives that favour the Nigerian manufacturers. These incentives can encourage the manufacturers to produce more high quality medication in order to get the incentives.

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APPENDIX: SURVEY QUESTIONNAIRE


Dear Participants

My name is Dr Chioma Awele Anyiam. I am carrying out this study as part of my dissertation in the final semester of my master's program in pharmaceutical business and technology in Griffith College, Dublin.

The purpose of this research is to examine and compare different pharmaceutical manufacturing companies in Nigeria. There will be a proper examination of regulatory systems and their impact on the quality and availability of medicinal products in Nigeria.

Anonymity as well as confidentiality will be maintained for all participants. There is no risk in participation of the survey because your responses will be confidential as identifying information such as your name or email address will not be collected. To help protect your confidentiality, the questionnaire will not contain information that will personally identify you. The results of this study will be used for scholarly purposes only.

QUESTIONNAIRE

Section A

Tick ✓ against the appropriate answer

1. Gender ___ ☐ Male ☐ Female ☐ prefer not to say

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

   ☐30-39yrs ☐40-50yrs ☐50+yrs

3. What is your level of work experience?

   ☐<1year

   ☐1-2 years

   ☐3-4years

   ☐5+ years

4. What is your profession?

   ☐ Medical Doctor
   ☐ Pharmacists
   ☐ Others

SECTION B

MEDICAL PROFESSIONALS.

Please tick the appropriate box:

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

☐Poor
☐Neutral
☐Good

a. Do you agree or disagree with the statement that medicinal products produced by local pharmaceutical companies in Nigeria are of better quality than medicinal products produced by foreign pharmaceutical companies?

☐Disagree
☐Neutral
☐Agree

b. Do you agree or disagree with the statement that medicinal products manufactured by foreign pharmaceutical companies are of better quality than medicinal products manufactured by local pharmaceutical companies?

☐Disagree
☐Neutral
☐Agree

2. As a Healthcare professional what medicinal products would you prefer to prescribe for your patients

☐ Foreign pharmaceutical products
☐ Local pharmaceutical products

3. Do you think these aspects can influence or impact on the quality and availability of the medicinal products in Nigeria?

*Please tick the appropriate box:*

i. Government policies

☐ Disagree
☐ Neutral
☐ Agree

ii. Social economic status of the country

☐ Disagree
☐ Neutral
☐Agree

iii. Inadequate laws or poor enforcement of the existing regulations/guidelines for manufacturing of good quality medicinal products

☐ Disagree
☐ Neutral
☐ Agree

iv. Inadequate funding/support for local pharmaceutical manufacturing companies

☐ Disagree
☐ Neutral
☐Agree

v. Demand exceeding supply

☐Disagree
☐Neutral
☐Agree

vi. High cost of good quality medical products

☐Disagree
☐Neutral
☐Agree

4. Do you agree or disagree with the statement, medicinal products by Nigerian pharmaceutical companies are more effective than those produced by the foreign pharmaceutical companies?

☐Disagree

☐Neutral

☐Agree

5. Do you agree or disagree with the statement, medicinal products by foreign pharmaceutical companies are more effective than those produced by the Nigerian pharmaceutical companies?

☐Disagree
☐Neutral
☐Agree

## SECTION C
## PHARMACISTS

Please tick the appropriate box:

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

☐Poor
☐Neutral
☐Good

a. Do you agree or disagree with the statement that medicinal products produced by local pharmaceutical companies in Nigeria are of better quality than medicinal products produced by foreign pharmaceutical companies?

☐Disagree
☐Neutral
☐Agree

b. Do you agree or disagree with the statement that medicinal products manufactured by foreign pharmaceutical companies are of better quality than medicinal products manufactured by local pharmaceutical companies?

☐Disagree
☐Neutral
☐Agree

2. Do you think these aspects can influence or impact on the quality and availability of the medicinal products in Nigeria?

*Please tick the appropriate box:*

i. Government policies

☐ Disagree
☐ Neutral
☐ Agree

ii. Socio Economic status of the country

☐ Disagree
☐ Neutral
☐Agree

iii. Inadequate laws or poor enforcement of the existing regulations/guidelines for manufacturing of good quality medicinal products

☐ Disagree
☐ Neutral
☐Agree

iv. Demand exceeding supply

☐Disagree
☐Neutral
☐Agree

v. High cost of good quality drugs

☐Disagree
☐Neutral
☐Agree

3. Where do you get most of your medicinal products from?

☐ Foreign Pharmaceutical companies
☐ Nigerian pharmaceutical companies

*4.* How often do medicinal products from Nigerian pharmaceutical companies have production errors, such as incomplete drugs, bad/wrong packaging, inaccurate labelling, improper seal, smudges, scratches and ink splatter on the medicinal product leaflet or other issues.

☐Very Often
☐ Often

☐ Neutral
☐ Never

5. How often do medicinal products from foreign pharmaceutical companies have production errors such as incomplete drugs, bad/wrong packaging, inaccurate labelling, improper seal, smudges, scratches and ink splatter on the medicinal product leaflet or other issues.
   ☐Very Often
   ☐ Often
   ☐ Neutral
   ☐ Never

6. Do you have any experience where medicinal products had to be sent back (due to production errors) to the pharmaceutical company where it was manufactured?
   ☐Yes
   ☐No

7. (ONLY ANSWER THIS QUESTION IF YOUR ANSWER TO QUESTION 7 IS YES)
   - What pharmaceutical company produced the faulty medicinal product
     *Please tick the appropriate box:*
     ☐ Medicine produced by Foreign pharmaceutical company
     ☐ Medicine produced by Local pharmaceutical company

8. In your experience, what medicinal product are consumers more inclined to buy?
   ☐ Foreign pharmaceutical products
   ☐ Local pharmaceutical products

9. Which of the medicinal products available in your pharmacy are more cost effective:
   ☐ Foreign pharmaceutical products
   ☐ Local pharmaceutical products

SECTION D

CONSUMERS

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

☐Poor
☐Neutral
☐Good

a. Do you agree or disagree with the statement that medicinal products produced by local pharmaceutical companies in Nigeria are of better quality than medicinal products produced by foreign pharmaceutical companies?

☐Disagree
☐Neutral
☐Agree

b. Do you agree or disagree with the statement that medicinal products manufactured by foreign pharmaceutical companies are of better quality than medicinal products manufactured by local pharmaceutical companies?

☐Disagree
☐Neutral
☐Agree

*2.* Do you think these aspects can influence or impact on the quality and availability of the medicinal products in Nigeria?

i. Government policies

☐ Disagree
☐ Neutral
☐ Agree

ii. Socio Economic status of the country

☐ Disagree
☐ Neutral
☐Agree

iii. Inadequate laws or poor enforcement of the existing regulations/guidelines for manufacturing of good quality medicinal products

☐ Disagree
☐ Neutral
☐ Agree

iv. Demand exceeding supply

☐ Disagree
☐ Neutral
☐ Agree

v. High cost of good quality drugs

☐ Disagree
☐ Neutral
☐ Agree

3. As a consumer what medicinal products would you prefer to use or buy

☐ Foreign pharmaceutical products
☐ Local pharmaceutical products

4. Which of the medicinal products available in your region ae more cost effective?

☐ Foreign pharmaceutical products
☐ Local pharmaceutical products

5. Did you have any experience where medicinal products that you purchased from pharmacy had to be sent back to the pharmacy due to production errors such as incomplete drugs, bad/wrong packaging, inaccurate labelling, improper seal, smudges, scratches and ink splatter on the medicinal product leaflet or other issues.

☐ yes
☐ No

6. (ONLY ANSWER THIS IF YOUR ANSWER TO QUESTION 7 IS YES)

- What pharmaceutical company produced the faulty medicinal product?
  - Medicine produced by Foreign pharmaceutical company
  - Medicine produced by Local pharmaceutical company

7. In last few months have you had any experience where the medicinal products you needed was not available in your local pharmacy
   - ☐ yes
   - ☐ No

The questions were prepared in form of a questionnaire but were sent out as an online survey due to the current lockdown in the COVID-19 pandemic.