THE STUDY OF THE KEY CHALLENGES FACING PHARMACEUTICAL MANUFACTURING INDUSTRY IN LAGOS, NIGERIA WITH EMPHASIS ON COST AND ACCESS TO QUALITY RAW MATERIAL

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

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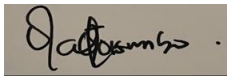
I certify that the dissertation entitled:

"The study of the key challenges facing Pharmaceutical Manufacturing Industry in Lagos, Nigeria with Emphasis on Cost and Access to quality raw Material" submitted for MSc in Pharmaceutical Business and Technology is the result of my own work and that where reference is made to the work of others, due acknowledgement is given.

Candidate signature: 

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Dedication

This dissertation is specially dedicated to my parents, who have sacrificed everything to make me who I am today. Their beliefs, strength and prayers have always given me the courage to strive for excellence.

Acknowledgements:

I am eternally grateful to God for the gift of life, Grace to come to Ireland to study and to complete this master's degree programme even at this strange time of Covid 19 where we had to receive lectures and do assessments online.

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ABSTRACT

The Nigerian pharmaceutical manufacturing industry is very important to the economy of Nigeria. From empirical research already done on the Nigerian pharmaceutical industry, it was gathered that several challenges drag the development of the sector. This gave good understanding about this work which aims to study the challenges facing the pharmaceutical manufacturing industry in Lagos, Nigeria with emphasis on cost and access to quality raw materials.

Considerably, 25% of the pharmaceutical products required by Nigerians are locally delivered by Nigeria's pharmaceutical industry. The excess 75% are imported from other developed nations like UK, India and China (WHO/PQT, 2014).

The Research Onion proposed by Saunders and his colleagues Lewis and Thornhill in 2009 forms the bases and provides the structure for the research process used in this study. Central in the context of this dissertation is the research philosophy of interpretivism. The research approach was deductive and aimed to collect data and build a theory based on the results (Saunders, Lewis and Thornhill, 2009). A case study strategy was used to properly understand the challenges especially in the area of cost and access to quality raw materials, facing the four pharmaceutical manufacturing firms employed in this study. A mono method research choice (only qualitative research strategy) was adopted for the collection of data. Then data were collected and analysed into themes which assisted in the overall research findings.

The results from this study on the accessibility of raw material reveal that all the pharmaceutical firms in Nigeria rely heavily on the importation of raw materials. On the affordability of quality raw materials, all data collected pointed to the fact that the prices of quality materials are becoming increasingly expensive and unaffordable. On the impact of accessibility to quality raw materials on the production capacity, this study revealed that accessibility to quality materials dramatically influences the production capability of pharmaceutical firms in Nigeria. Lastly, on the impact of cost of quality raw materials on the production capacity, this study revealed that the cost of the materials is prohibitive.

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LIST OF ABBREVIATIONS

PMI	PHARMACEUTICAL MANUFACTURING INDUSTRY
R & D	RESEARCH AND DEVELOPMENT
M & A	MERGER AND ACQUISATION
GMP	GOOD MANUFACTURING PRACTICE

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CHAPTER ONE

INTRODUCTION

1.1 Background Overview

Nigeria's pharmaceutical industry is very important to the economy of Nigeria. It was purely an import-based industry before independence. The whole of West African sub-region (which includes Nigeria) is home to nearly 115 registered pharmaceutical manufacturers involved in the production of high quality pharmaceutical products. Out of the nearly 115 registered pharmaceutical manufacturers, Nigeria accounts for about 60% of the entire drug manufacturing industries in the sub-region (Wakeel and Ekundayo, 2016). Before Nigeria's autonomy, local drug industries were described fundamentally through distribution of drugs by companies that addressed different foreign pharmaceutical companies in Nigeria (Ugbam and Okoro, 2017). Hence, pharmaceutical industries in Nigeria advanced into sectors prevailed by privately owned pharmaceutical producing firms under the umbrella of Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN) (WHO/PQT, 2014).

Considerably, 25% of the pharmaceutical products required by Nigerians are locally delivered by Nigeria's pharmaceutical industry. The excess 75% are imported from other developed nations like UK, India and China (WHO/PQT, 2014). It is imperative to state that the industry is yet to realise its true abilities as a result of the difficulties that has faced the sector. This large scale dependence on imports pharmaceuticals makes it difficult to achieve high "indigenous learning curve" among local manufacturers and consequently, limited growth within the Nigeria pharmaceutical sector (Ekeigwe, 2019).

Undoubtedly, the pharmaceutical industry in Nigeria is faced with numerous challenges, many of which is believed to be incredibly affected by political and economic changes (Marketa, 2013). Corruption and lack of vision in governance has had a huge negative impact on the political framework of Nigeria over the years. This effect has also been seen across all sectors

of the economy and has also undermined capacity utilization of the pharmaceutical industry. Out of the allocations budgeted for the manufacturing of pharmaceutical products, very little gets to be utilised for its intended purposes. The disbursement of funds intended to build storage and processing facilities as well as manufacturing facilities are diverted for personal use and the eventual implementation carried out are for the most part sub-standard. No doubt this has affected quality and quantity of pharmaceutical products grossly and has caused a significant setback in the development of the pharmaceutical manufacturing industry in Nigeria.

Pharmaceutical manufacturing industry have also had their fair share of the impact of Nigeria's economic recession. Nigeria's dependency on crude oil as its major income earner has been a major challenge to the country's economy. Dwindling oil price in the world oil market led Nigeria into economic recession for the second time in five years. This likewise adversely affected cost and access to quality raw material for this industry. Quite a large number (if not all) of raw materials required for production such as active pharmaceutical ingredients are imported from countries such as China and India. Exchange rate fluctuations, high import duties on imported raw materials, high taxation, poor funding and maintenance of infrastructure, are some of the impacts of the current economic recession which has contributed to the high cost of pharmaceutical productions and sales (Chukwu *et al*., 2015).

Sub-Sahara African countries populated largely by low and middle income earners, have over the years thrived to improve the production capacity of pharmaceutical manufacturing through importation of sophisticated machines and packaging of active pharmaceutical ingredients (APIs) from higher income countries. In any case, this was met with the current Coronavirus pandemic and presented a challenge of exporting pharmaceutical products such as Personal Protective Equipment (PPE) and quality raw materials such as API from higher income nations. Prohibitive actions are embraced by these nations to guarantee satisfactory and easy access to clinical items for their citizens before export considerations to other countries (Reichman, 2009).

Despite the several challenges the pharmaceutical industry in Nigeria is faced with, it is still a force to reckon with in Africa at large. It holds huge prospects in terms of size, diversity of products and potential to meet up with international quality compliance (WHO/PQT, 2014). The desire to improve the quality and also efficiency of production is of utmost priority to meet demands of the teeming population of Nigerians. Hence, this study aims to provide a comprehensive understanding on how the challenge of cost and access to quality raw material

affects the Nigerian pharmaceutical manufacturing industry and possible recommendations to tackle these challenges.

1.2 Research Purpose

Recently, Nigeria is increasing her interest in economic diversification, this is surreal a good move to stop over reliance on raw petroleum. It is recommended, that the assembling area is a feasible ground to take advantage of to resuscitate the country's economy with viable broadening. Therefore, revamping the native drug fabricating industry and empowering privately created drug items and crude materials to reduce the expense on importation will affect emphatically on the country's financial turn of events, since the utilization of the local drug producing industry in the nation is underneath 30% while about 70% of the medications are being imported (Okoli, 2000).

It is a reality that even with a high human resource (roughly 190 million individuals) and immense common assets, Nigeria is as yet confronted with significant degree of destitution, infections and unhealthiness (WHO, 2013). As indicated by report from the World Health Organization (WHO), Nigeria's health sector is ranked 187th out of 191 individuals (WHO, 2000). This low rating is to a great extent because of absence of standard hardware for nearby creation and capacity of drugs (Obohokwo *et al*., 2018); thus, increasing dependency in importation of pharmaceutical products.

There is no doubt, that this high dependency on importation of pharmaceutical products in Nigeria is largely attributed to several challenges facing the local pharmaceutical manufacturing sector; much of which can be related to cost and access to raw materials. It is therefore fundamental to recognize the elements restraining or that will facilitate cost effective pharmaceutical manufacturing and access to quality raw materials as an initial plans to rectifying the myriad of issues plaguing the Nigerian pharmaceutical industry.

1.3 Significance of the Study

The Nigerian pharmaceutical industry is generally accepted to be a sector with humming possibilities, but the industry has experienced a huge setback owing to the several challenges that has plagued it. Undoubtedly, Nigeria’s recent economic recession affected pharmaceutical manufacturing industries immensely in terms of cost and access to quality raw material; thereby, affecting local manufacturing power of indigenous pharmaceutical companies. The financial downturn liquefied on the nation is due to over reliance on crude oil as the significant income earner for the country, with the cost of crude oil getting too negative in the worldwide

oil market lately. Thus, there is no doubt that the current focus on industrialization and promotion of local manufacturing sector like the pharmaceutical industry in the country is a way forward to reduce crude oil dependency in the country. However, the Nigeria's pharmaceutical industry which has become a significant aspect of the local manufacturing sector has been underused to a good extent to satisfy the nation's pharmaceutical needs. This underuse can be accrued to some significant challenges facing the industry, especially in the areas of cost of production, cost of - and access to - quality raw materials, government policies and infrastructural decay.

Justification for the emphasis on cost and access to quality raw material in this study is necessary as several studies have been done in the Nigerian manufacturing sector which includes its sub-sector such as the pharmaceutical manufacturing sector. Many of these studies were conducted on factors that pose challenges to the growth of the pharmaceutical sector. However, none has been directly conducted on how cost and access to quality raw material has challenged this sector. Filling up this gap therefore became sacrosanct as it would provide in-depth understanding about the challenges facing the pharmaceutical industry in Nigeria especially in the area of cost and access to quality raw materials and suggest possible ways to tackle these challenges and contribute to meeting the national economic diversification goals. The cost and availability of raw materials of suitable quality and quantity is a basic factor in making decisions on the establishment of a production plants, regardless of the scale of production. So the justification for the choice of cost and access to quality raw materials as a case study was informed from the prevailing issues facing the Nigerian pharmaceutical manufacturing industry stated above. High import rate of quality raw material and stiff competition for quality raw materials with foreign firms which has been attributed to unfavourable government policies has led to the proliferation of illicit drugs and has posed a threat to the pharmaceutical industry's market returns, as well as a direct threat to people's lives and well-being (Ohuabunwa, 2002).

1.4 Study Aim and Objectives

The aim of this research work is to provide a comprehensive understanding on how the challenge of cost and access to quality raw material has affected the Nigerian pharmaceutical manufacturing industry and possible recommendations to tackle these challenges. In order to achieve this aim, the following research objectives and questions occur:

	Research Objectives	Research Questions
1.	Determine the accessibility of quality raw materials to the pharmaceutical manufacturing firms.	Are quality raw materials accessible to pharmaceutical manufacturing firms?
2.	Ascertain the affordability of quality materials by the pharmaceutical manufacturing firms.	Are quality raw materials affordable by pharmaceutical manufacturing firms?
3.	Determine the effect of accessibility to quality raw materials on the production capacity of pharmaceutical manufacturing firms.	How does the accessibility to quality raw materials affect the production capacity of pharmaceutical manufacturing firms?
4.	Ascertain the effect of cost of quality raw materials on the production capacity of pharmaceutical manufacturing firms.	To what extent does the affordability of quality raw materials affect the production capacity of pharmaceutical manufacturing firms
5.	Make recommendations for effective management of cost and access to quality raw material issues.	

Table 1.1 Showing the Research Objectives and the Research Questions

1.5 Methodology

This research study will be done to understand the key challenges facing the pharmaceutical manufacturing industries in Lagos, Nigeria with focus on the challenge of cost and access to quality raw materials that these pharmaceutical manufacturing companies use. From secondary research already done on the pharmaceutical industry in Nigeria, several challenges such as political and economic issues, high cost of importing raw materials, government policies, poor manufacturing facilities and others will help as a guide in setting out interview questions that will be used in the course of this dissertation.

The study will be done across 4 pharmaceutical manufacturing companies in Lagos, Nigeria using Qualitative Approach. All presiding protocols would be duly carried out to gain access to the pharmaceutical companies. Digital interview/ phone interview would be done with at least two senior pharmaceutical officers of each company; with each having good knowledge of how the company procures and the cost of the raw materials used for their manufacturing. The two pharmaceutical officers in each selected pharmaceutical company would be interviewed on some related topics that are tailored to address the study questions and aim and objectives. The interview records would be transcribed and the data worked upon and analyzed to get the results for the research study.

1.6 Structure of the study

There are five chapters or stages in this dissertation. The first chapter introduced the study, and gave credence to the purpose, significance, aim and objective of the study. In the second chapter, an extensive literature research will be conducted. The chapter will also shed light on the study's conceptual framework. Afterwards, the research design or methodology will be explained in details in chapter three. This includes description of the overall research strategy, primary data collection technique, and data analysis approach. In chapter four of the dissertation, the primary data collected will be presented, and the findings from the analysis will be discussed. The last chapter of the dissertation will give a final conclusion and reflection to the research question and shine more light on the research contribution, its limitations and recommendation for further studies.

CHAPTER TWO

LITERATURE REVIEW

2.1 OVERVIEW

This chapter is intended to provide an overview on the key topics around the Nigerian Pharmaceutical manufacturing industry. It will cover the pre- and post-independence Era of the Nigerian Pharmaceutical sector. In section 2.2, it will give a brief account of the emergence of pharmaceutical industries in developing countries and also digs into the categories of pharmaceutical manufacturers having manufacturing facilities in these developing countries. The general drug situation in Nigeria which will explain the various issues currently facing the Nigerian pharmaceutical manufacturing sector will be addressed in section 2.3. The sub topic 2.4 is about the general lifecycle and the economic impacts of pharmaceutical products around the world while the strategic challenges confronting pharmaceutical product lifecycle across the drug's supply chain I.e., from the development to the marketing and post marketing stage of a pharmaceutical product is discussed in section 2.5 and its sub sections.

The 2.6 sub topic expresses the various forms of production in the pharmaceutical sector while 2.7 states the rationale of cost and access to quality raw materials as a challenge facing the pharmaceutical manufacturing industry in Nigeria. It also includes the importance of understanding cost as an important factor in any business space while lack of good infrastructures such as poor transportation system, communication network, constant power supply as one of the major issues associated with access to quality raw materials for pharmaceutical productions in Nigeria. The theoretical framework which encompasses the theory of cost and accessed material efficiency are contained in the sub sections under 2.7.
Various secondary research carried out on the performance of the pharmaceutical industry in Nigeria which otherwise known as the Empirical Research makes up section 2.8. Section 2.9 will depict the conceptual framework that will be further applied throughout this dissertation. It will give insight into the relationships that exist between variables such as moderators, independent, dependent and intermediates. The concluding part of the literature review is contained in 2.10, it identifies the gap, support the research aim and objectives and provide compelling rationale for the research questions.

2.2 EMERGENCE OF PHARMACEUTICAL INDUSTRIES IN DEVELOPING COUNTRIES (NIGERIA)

Due to economies of scale and technical requirements for the manufacturing of medicines, a study from the World Bank in 1986 indicated that local drug development in developing countries such as Argentina, Brazil, China, Egypt, India, Mexico, and Thailand were impractical with broad local markets and sizes to yield Active Pharmaceutical Ingredients (APIs) (Pharmapproach, 2020). As a result of this research, local pharmaceutical manufacturing has been discouraged, and there has been a greater focus on quality management of imported pharmaceuticals, as well as the licensing of generic drugs produced by foreign affiliates. In comparison to the Western and Asia-Pacific areas, the Middle East and Africa have traditionally had weak economic and healthcare growth, which continues today (WHO, 2009), necessitating pharmaceutical globalization. Globalization of the pharmaceutical industry and the implementation of global public health funding schemes also culminated in a more open market for generic pharmaceuticals, resulting in a significant reduction in the cost of essential medicines (Pharmapproach, 2020). According to a World Bank report, there are many categories of pharmaceutical manufacturers operating manufacturing facilities in low- and middle-income countries, each with its own business model (World-bank, 2005). They are as follows:

1. A subsidiary of a major global corporation that produces marketed, patent-protected goods for local and regional markets.
2. Generic drug manufacturers with an emphasis on industrialized markets such as the United States and Europe, as well as large-middle-income markets like India and China.
3. Generic companies are those that are mostly national in nature and depend on local sales with sporadic exports to surrounding countries.
4. Local small-scale producers that make a limited range of goods, such as herbal drugs, to satisfy local or regional customers.

Furthermore, most hospitals repackage medications in smaller unit-dose packets and can formulate specialized products for their own patients and satellite clinics, such as creams with special formulas, for their own patients and satellite clinics. Secondary processing using current raw materials which are typically imported as well as packing or repackaging completed dosage types into smaller dispensing packs and course-of-therapy packages are examples of this variety of small-scale pharmaceutical production in a hospital pharmacy.

2.3 GENERAL DRUG SITUATIONS IN NIGERIA

Nigeria's drug crisis from manufacture to delivery and regulation is in a dire state. In Nigeria, there are over 130 pharmaceutical producers but only around 60 are actively producing. The pharmaceutical manufacturing industry in the country has a capability and usage rate of about 30%, while about 70% of pharmaceutical products are imported. (Okoli, 2000). This high import ratio is primarily attributed to the Nigerian government's lack of funding for the manufacturing sector and limited access to raw materials. While Nigeria is showing a strong interest in economic diversification in order to minimize overdependence on crude oil and increase industrialisation, there are reliable indicators that the manufacturing sector is a viable ground to tap into in order to revive the country's economy. As a result, revitalizing the domestic pharmaceutical manufacturing industry and promoting the use of locally manufactured pharmaceutical and raw materials to reduce import costs would benefit the country's economic growth.

Nigeria is also faced with the issue of fake and counterfeit drugs and this is one of the significant issues confronting the pharmaceutical production supply chain. Almost all sectors of the economy in the country has a false equivalent including computer parts, engine spare parts, chemicals and adulterated food. Faking and quackery, bogus medications, quack and inept medical personnel have all been a common place in Nigeria over the last few decades. This proliferation of illicit medications has posed a threat to the pharmaceutical industry's market returns, as well as a direct threat to people's lives and well-being (Ohuabunwa, 2002). The selling of counterfeit drugs has increased in recent years in low-income countries, especially Nigeria. The influx of bogus and generic products into the pharmaceutical industry has been easy. This is because the prices of medicines are decided by the vendor’s financial potential as against competency and regulatory licenced protection. This made researchers to conclude that there could be more fake than real drugs in circulation (Osibo, 1998). Holders of patent and patented drug vendor licenses should be able to sell patent medicines. Unregistered dealers on the other hand market any medicine based on their financial strength which makes for the distribution of more counterfeit drugs, based on the expertise of these dealers whose credentials are insufficient to distinguish between false and legitimate drug goods (Erhun and Adeola, 1995).

Other factors that have primarily contributed to the lack of genuine pharmaceutical products in Nigeria include:

1. A scarcity of professionally qualified manufacturing pharmacy staff.

2. A shortage of primary factories capable of producing vast volumes of pharmaceutical-grade raw materials.
3. The import phenomenon, as well as a lack of faith in local opioid development and manufacturing.
4. Discouragement from multinational businesses whose parent companies set the price of raw materials and manufacturing plants, as well as the quality control of dosage forms in developing nations.
5. Taxation policies for overseas and domestic medicinal goods that are different. This has a major effect on manufacturing choices. If the aim of public policy is to have a level playing ground for producers to choose where and when to export, there should be little difference in the tax status of raw materials, both active and inactive additives, and finished products. The imposition of high taxes on packaging goods would stifle local economic growth and result in a shortage (Pharmapproach, 2020).

2.4 GENERAL LIFE CYCLE OF PHARMACEUTICAL MANUFACTURING INDUSTRY AND THE ECONOMIC IMPACTS IN DEVELOPED NATIONS

There is no doubt that the pharmaceutical industry contributes significantly to the economies of developed countries by supporting large high-tech manufacturing employers and indirectly creating three to four times more employment (EFPIA, 2016). The life cycle of a pharmaceutical product like that of other consumer goods starts with product development and manufacturing followed by market release of viable products and finally commercialization (supply chain and logistics) which involves a revenue growth phase, a maturity phase, and finally a decline phase (Marques *et al*., 2019).

Each of these phases in the pharmaceutical industry has some distinct characteristics that set it apart from other sectors, posing major and special management challenges (Marques *et al*., 2019).

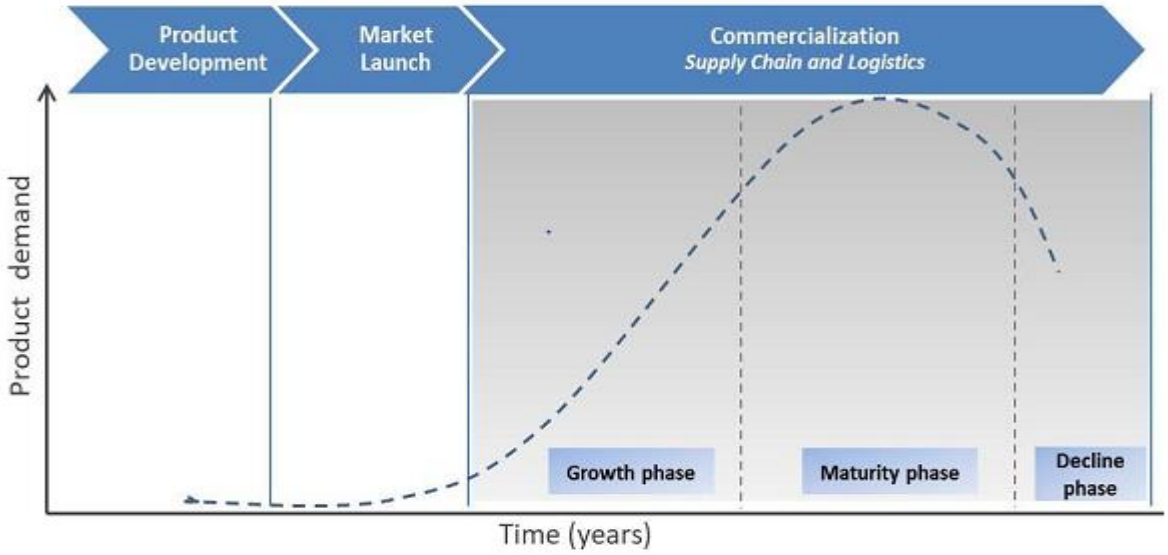

Figure 2.1: Pharmaceutical product life-cycle (Adapted from Laínez *et al.*, 2012)

The pharmaceutical market is highly globalized with 80 percent of sales coming from North America, Europe, and Japan (Azzaro-Pantel, 2018). According to estimates, North America accounted for 48.9% of worldwide opioid sales in 2018 while Europe accounted for 23.2 percent (EFPIA, 2019). In 2018, worldwide drug spending surpassed $1.2 trillion which is forecast to exceed $1.5 trillion by 2023 (IQVIA, 2019b).

Figure 2.2: Global medicine spending and growth 2009-2023 (Adapted from IQVIA, 2019b)

Without a question, the pharmaceutical sector plays a vital part in most countries' healthcare structures by providing drugs and vaccines that have a significant effect on people's quality of

life (Marques *et al*., 2019). In addition to the direct benefits to the public, medicines result in significant cost savings in total healthcare expenses by reducing the requirement for expensive surgery and/or long-term hospitalization (Pfizer, 2014).

As a result, the sector is critical to a country's economic sustainability because it is a key component in maintaining the country's economic stability in every healthcare system (Marques *et al*., 2019). The pharmaceutical industry is made up of large R&D multinationals, small businesses, generic manufacturers, contract development and manufacturing organizations (CDP/CMO without their own product portfolio) and biotechnology corporations that mostly concentrate on research and drug discovery (Sousa *et al*., 2011). Despite the fact that large R&D-based multinationals are by far the most economically powerful sub-sector in terms of creativity and sales, generic manufacturers produce the overwhelming majority of medicines prescribed worldwide (Marques *et al*., 2019). As a result, though the majority of stakeholders are similar their supply chains and drivers (particularly monetary) are significantly different (Association for Accessible Medicines, 2019).

The supply chains of generic drug companies are largely characterized by vast portfolios of completed drugs and distribution networks with little high-risk discovery testing and product creation activities. Despite the fact that R&D-based multinationals cover the entire pharmaceutical life cycle from discovery to market supply, they depend heavily on a precarious mix of off-patent medicines, patent medicines and the introduction of new drugs that are protected by patents (Marques *et al*., 2019). According to IQVIA (2019b), the global cost of exclusive product exclusivity losses between 2019 and 2023 is expected to be $121 billion. As a result, supply chains in this situation (R&D-based multinationals) are extremely complex and tough to manage making them more susceptible to risk and uncertainty (Marques *et al*., 2019).

2.5 STRATEGIC CHALLENGES AFFECTING THE PHARMACEUTICAL MANUFACTURING INDUSTRY PRODUCT LIFECYCLE

The pharmaceutical industry according to Azzaro-Pantel (2018) has two distinct supply chains: one for drug development and the other for successful drug marketing (including production and distribution). A more comprehensive understanding of the challenges confronting the pharmaceutical supply chain is skewed against new development and market launch prices, supply chain management, and decision-making difficulties.

2.5.1 Product development and market launch challenges in pharmaceutical industry

Due to well-known high prices, low production speeds and long development periods, the product development process in the pharmaceutical industry's innovative product market is particularly challenging (Marques *et al*., 2019). The four major activities in the New Product Development (NPD) process are research, pre-clinical tests, human clinical trials, acceptance, and product launch; afterward, there will be post-launch pharmacovigilance (Marques *et al*., 2019). The estimated time between discovery and commercial launch is 15 years (Lanez *et al*., 2012), with a total loss of $2.6 billion in 2013 dollars per approved new compound. Furthermore, according to a recent pharma forecast survey in 2017, overall pharmaceutical R&D investment is projected to hit US$181 billion in 2022 marking a 2.4 percent annual growth rate (Marques *et al*., 2019).

According to IQVIA (2019a), 15 biggest pharmaceutical firms announced total R&D investments of more than US$100 billion for the first time in 2018. Clinical trials alone account for more than half of all spending (EFPIA, 2016). Before a possible new molecule (Active Pharmaceutical Ingredient – API) is discovered, the pharmaceutical industry's discovery protocol involves testing thousands of chemical compounds (Marques *et al*., 2019). Before going on to human testing in the clinical trials stage, the new API is put through a series of studies (preclinical tests) in animals to determine its toxicity and safety thresholds (Azzaro-Pantel, 2018).

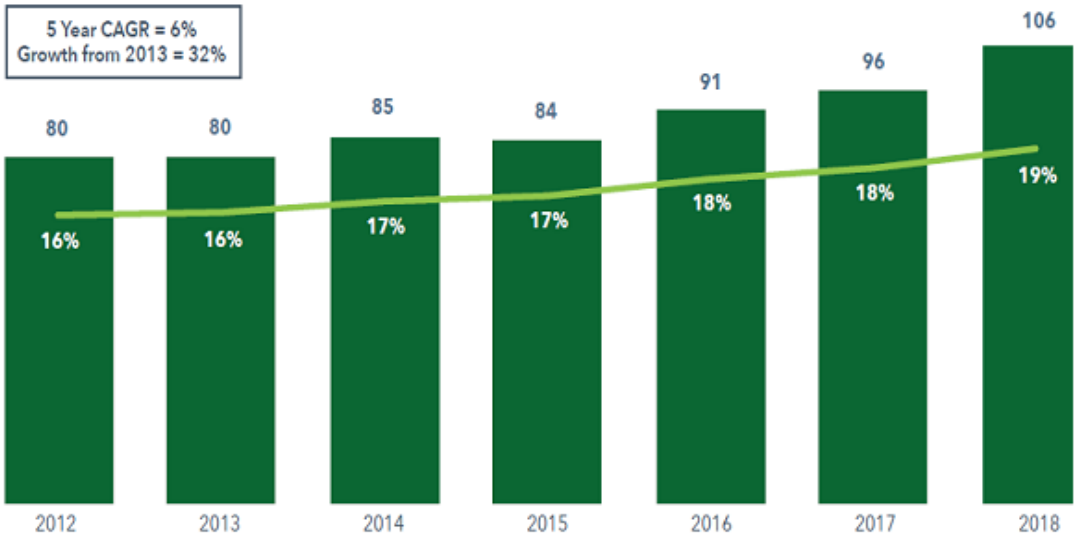

Figure 2.3: Large pharma. R&D spending and percentage of sales, US$BN (Adapted from IQVIA, 2019a)

In the past four years, non-orphan opioid drug trials in the United States have taken an average of 6.7 years (IQVIA, 2019a). Clinical trials are the most expensive and time-consuming activity in the product development process, taking more than 6 years to complete all three stages (I, II, and II) (Petrova, 2014). Both of these steps necessitate the availability of a larger quantity of the experimental medication in order to complete the enforcement agencies' stringent checks (Marques *et al*., 2019). In phase I, the new molecule is tested in humans, mostly for safety and dosage determination. In phase II, medium-scale efficacy trials are conducted in stable human patients, and in phase III, large-scale tests are conducted to compare the efficiency of the new therapeutic compound to that of other medications and to assess its long-term effects (Azzaro-Pantel, 2018).

When all of the clinical trial phases have been successfully completed, a New Drug Application (NDA) is often submitted for approval and commercialization (Marques *et al*., 2019). Overall, 11.83 percent of new medications entering clinical trials are recognized compared to 21.50 % in previous studies by the same authors (DiMasi *et al*., 2016). In 2018, the success rate of clinical research in the United States was 11.4 percent, according to IQVIA (2019a). As a result, not only is R&D investment increasing, but the success rate of drug trials is decreasing (Wang *et al*., 2015).

Once a new drug is commercially sold, sales increase cannot be assured. This may be due to a lack of differentiation or perceived therapeutic value by end-users and payers who are more concerned with the new drug's cost/benefit impact on their patient population than with existing medications.

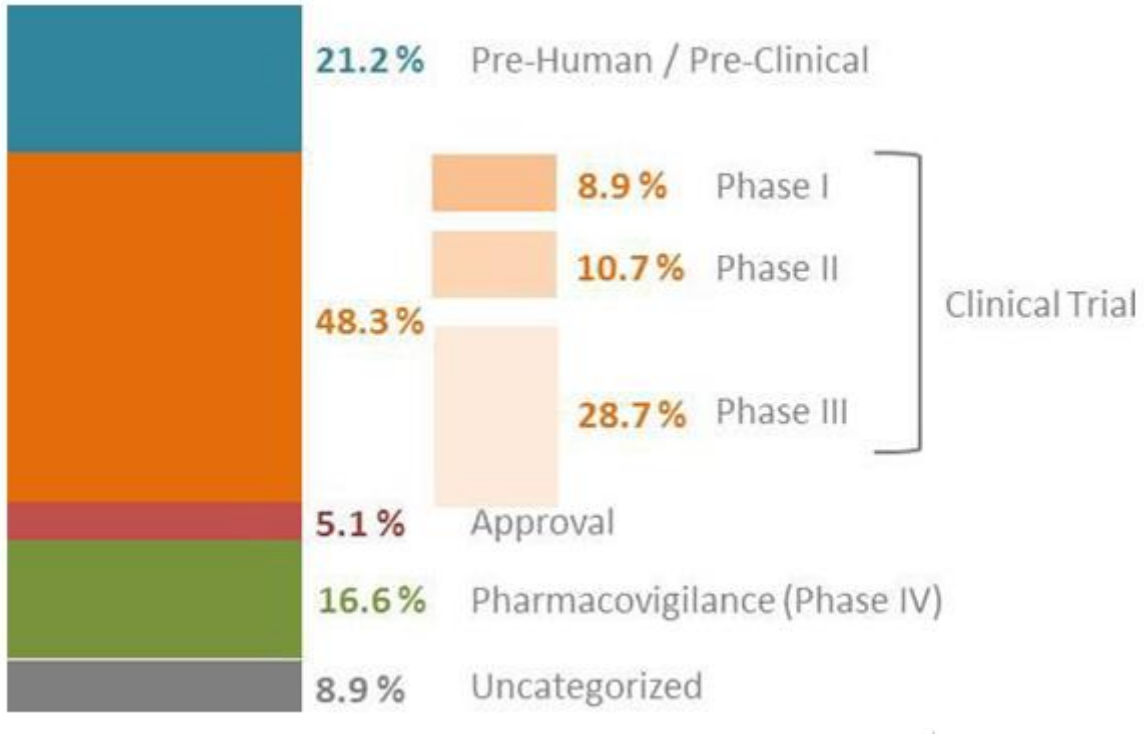

Figure 2.4: Allocation of R&D investment by main activity (EFPIA, 2016).

Many other activities related to the production process must be performed simultaneously with the above-mentioned product development and regulatory authorities must license both the product and the production process. Industrial scale manufacturing capabilities must be available as soon as the new drug is approved (Stonebraker, 2002).

Hansen and Grunow, (2015) suggested investing in new API production facilities about 5 years before commercialization, which is a long time before clinical trials are performed and FDA approval is determined. Despite their high risk, these decisions are important to prevent market launch delays and revenue losses as a result of the patent current life being reduced. Finally, after gaining regulatory approval for both the material and the treatment, a network of manufacturing and distribution agents works together in a coordinated supply chain to release the new medication into the market under patent protection (Marques *et al*., 2019). Overall, the pharmaceutical industry's product development process is sluggish and inefficient making it a capable future investment for change (Pammolli *et al*., 2011).

The three major obstacles that pharmaceutical companies face today can be divided into three categories:

1. Cut down on the time it takes to make a commodity (reduced time-to-market).
2. Boost the value of the commodity pipeline by maintaining a decent balance between the quantity of commodities in the pipeline and the technical quality of such products (safety, efficacy, and market differentiation).
3. Keep production costs to a minimum.

2.5.2 Pharmaceutical industry supply chain and logistics

Following market launch, companies enter a growth phase in which they want to gain and grow as much market share as they can. Of course, the pace of progression may be dictated by the therapy's relative effectiveness in relation to existing medications, as well as any possible side effects that could arise when the treatment is used and economic factors. As the product matures, the balance of these parameters will decide the product's demand level. Despite the fact that the maturity period is where the asset will produce the best returns, the innovator will find this stage particularly difficult for two reasons. For starters, a successful product will inspire competitors to market "me too" items, which may occur just a few years after the new product is released. These products would be able to capture a share of the market resulting in price competition.

Secondly, as a common drug approaches the end of its patent era, generic manufacturers will work to bring bioequivalent products to market. Typically, the first generic competitor would enter the market with a price as low as 25% of the brand-name price, but once more generic manufacturers flood the industry, the price will continue to collapse as they compete only on price and the products are supposedly bioequivalent (Petrova, 2014). This alters the supply chains of both innovators and generic drug manufacturers. If the first brand loses market share without a significant price drop, the drug price declines dramatically in the second case. The drug's overall amount on the other hand will rise. According to the exclusivity period after prescription, clearance accounts for nearly 74% of all new (brand) product sales in the United States. Businesses must take steps to ensure adequate performance and capacity management, as well as effective output and capacity management in order to remain versatile to retain the required service levels during this time frame (Petrova, 2014).

Since the pharmaceutical industry is inherently global, its supply chains are usually large and diverse encompassing a system of primary and secondary vendors, processing facilities, regional distribution centers (wholesalers) and final healthcare providers such as hospitals and pharmacies.

As a result of globalization Mergers and Acquisitions (M&A) approaches, many of these agencies (including food manufacturers) will be located in a variety of locations around the world forcing businesses to comply with a variety of competition rules, customs and tax regimes (Marques *et al.*, 2019). The supply chain is further complicated by raw material suppliers, vendors and third-party distribution providers necessitating close cooperation among all of these agents, regulatory agencies and regulators. Each of these officers on the other hand continues to operate independently following their own organizational efficiencies and objectives, often with a lack of accountability or exposure (Marques *et al*., 2019).

As a consequence, lack of accountability or exposure, networks become disconnected causing shortages and inefficiencies across the supply chain. Reduced production lead times and prices, more efficient utilization of processing capital, improved resources and energy use efficiency are all major issues addressed at the manufacturing level. Production stability and agility have increased, inventory levels have decreased, waste production has decreased, and output yields have improved (Srai *et al*., 2015).

The following are some of the supply chain's challenges: supply chain volatility reduction, supply chain resilience and responsiveness enhancement, sourcing and distribution cost reduction, end-to-end visibility across the supply chain, strategies for seamless convergence and synchronization across the network, inventory mitigation at every supply chain node and the incorporation of sustainability aspects (Marques *et al*., 2019).

2.5.3 Planning decision-making processes

Regardless of market segment, the decision-making processes involved with supply chains span many organizational and temporal stages. So, strategy models that support these decision processes must be consistent with the stage in question (Marques *et al*., 2019). The construction of a planning problem necessitates a precise understanding of the study's objective, as well as the framework and system limits, decision components, and a methodical approach to problem solving.

Decisions can be strategic or pragmatic, based on how they will affect the organization, how long they will take to implement and how much money they will cost. The ability to manage supply chain projects effectively necessitates a thorough knowledge of the decision-making processes (Marques *et al*., 2019). These decisions are usually divided into different categories or taxonomies, which are then contained in matrices and systems that help analysts and practitioners in framing decision problems accordingly due to the complexity of supply chains

(Marques *et al*., 2019). Supply chain preparation matrix stating that it is one of the commonly known models that has been established (Meyr *et al*., 2008). The architecture and structure of the supply chain was covered by long-term or strategic actions, which usually require substantial costs and long-term consequences (Marques *et al*., 2019). The operational or mid-term decisions are relevant to production preparation with the primary objective of achieving the strategic goals. Individual activities/operations and their timing are addressed directly in the short-term or organizational decisions in order to fulfill the development criteria specified at the tactical level. The ISA-S95 standard's hierarchical automation pyramid representation is often used as a reference to categorize the decisions involved in supply chain management issues (Marques *et al*., 2019).

2.6 FORMS OF PRODUCTION IN PHARMACEUTICAL MANUFACTURING INDUSTRIES

There are three main stages of development in the pharmaceutical processing industry: primary, secondary, and tertiary.

Primary production level

The processing of raw materials into Active Ingredients (AIs) as well as additives, excipients and ancillary substances for pharmaceutical formulation takes place in this stage of development. The final Active Ingredients which are the biologically active compound in the mixture that causes the medicinal benefit should meet all normal specifications. In primary manufacturing, chemical or biological methods may be used involving various types of processing facilities, technology, expertise and experience. The manufacturing of active ingredients is the costliest component of pharmaceutical production due to the need for capital equipment, process improvement and quality assurance systems. The greater the capability and expertise needed to build and manage manufacturing methods, the more advanced the goods (Pharmapproach, 2020).

Secondary production level

Secondary production is the large-scale processing of finished drug formulations such as tablets, capsules and injections from domestically or globally sourced raw materials or intermediate ingredients. Using any local, sterile and non-sterile preparations (such as injections, prescriptions, and intravenous fluids including oral solids, liquids and topical preparations) may be made with either locally produced or imported packaging materials. This

level although less technically demanding than primary processing must be completed to exacting standards. Modernization and achievement are needed particularly when adhering to international GMP standards. They can be thought of as legitimate factories that devise and produce a wide range of dosage forms. For medications and excipient raw materials supplies, primary factories are fully dependent on secondary industries. Similarly, tertiary industries such as engineering/tooling, paper, rubber, glass and metallic packaging unit industries cannot exist without primary and secondary industries (Pharmapproach, 2020).

Tertiary production level

This sourcing stage includes the packaging and marking of finished products from primary and secondary manufacturers into bulk packs, smaller dispensing packets, tubing, or course of therapy units for individual use. The original stability of the medicinal product, which was established in earlier phases of growth must be maintained in the tertiary step and the final and most critical step of upholding high-quality standards by stringent operating procedures is critical.

Based on average production, pharmaceutical manufacturing industries are grouped into three categories: small, medium and large. Small companies are owned by private individuals, while medium-scale industries are owned by a group of persons or owners. Multinational companies make up the so-called big scale industries, which are represented in foreign currency (Pharmapproach, 2020).

2.7 ACCESS TO COST AND QUALITY RAW MATERIAL RATIONALE AS A CHALLENGE FACING MANUFACTURING SECTOR

Access to cost and quality raw materials is one of the major constraints of production. Cost ceases the degree of freedom of a person to choose enterprise and work on that. Cost also forces manufacturing firms (such as pharmaceutical industries) or production companies to work according to their cost bearing ability. Cost is not so simple and straight forward. It has multiple attributes, can be clearly seen or hidden and may be incurred in short run or may appear in long run. So cost is very vast in itself and its effects are very serious. Hence to manage the problem of cost there should be proper knowledge on the cost, types, its attributes, its impact and idea presented by different theory on cost. A good micro-economist must have good information regarding the cost related to pharmaceutical industries that can be a key to plan sound projects and planning in a firm to achieve sustainable profit. Cost has multi-attributes; entrepreneur

needs to study various theories, types, nature of different costs, how the cost can be reduced, relation of a cost with other costs and many more. So the study regarding cost and access to raw materials is very crucial and worth studying to be successful in any enterprise and business.

Accessed material efficiency has been defined by various scholars, including Peck and Chipman (2007) and Worrell *et al*. (1997), and its semantic characteristics are similar to other sustainability concepts such as dematerialization, eco-efficiency and resource efficiency. While Rashid and Evans (2010) defined material efficiency as the ratio of output of products to input of raw materials; Allwood *et al*. (2013) defined it as "to continue to provide the services delivered by materials, with a reduction in total production of new material".
The concept of accessed material efficiency is broad and encompasses various terminologies. Both industrial waste and the depletion of virgin material pressure manufacturing companies to find new, viable strategies consistent with environmental, social, and economic sustainability. There are boundless multitudes of factors influencing the future development of accessed material efficiency in pharmaceutical manufacturing sector. However, a common factor is material availability; which is the key resource consumption (Mills, 2013; Teknikföretagen, 2013); scarcity of raw material (Schwenker and Raffel, 2012; Ribeiro *et al*., 2012; Teknikföretagen, 2013), global competition for resources (Ribeiro *et al*., 2012), higher prices for products and raw materials (Schmidt, 2012), the substitution of materials (Garetti and Taisch, 2011).

Lack of good Infrastructure such as transportation systems, communication networks and constant power supply (The African Union Commission 2012), is common challenge influencing lack of access to raw materials in pharmaceutical industries, (Ekigwe, 2019). It is imperative to state that the health care sector is highly dependent on drugs, vaccines, medical devices, and diagnostics externally developed and procured, especially from India and China, denying opportunity for indigenous learning curve (Ekigwe, 2019). Undoubtedly, raw materials and equipment needed for the production of medicines in West Africa are mostly imported (Ekigwe, 2019). There is only one small-scale manufacturer of active pharmaceutical ingredients located in Ghana (West African Health Organization 2018). There is very little capacity for the production of any of the raw materials or equipment (The African Union Commission 2012). Manufacturers in the region are finding it difficult to attain WHO (World

Health Organization) pre-qualification because of financial and technical constraints (United Nations Industrial Development Organization 2015).

Technical constraints include, but not limited to skilled personnel, required equipment, and reference materials. The financial constraints have two prongs – the resources (local capital formation) are scarce and foreign exchange rates are tipped against importation i.e., local currencies have very low equivalence rates to currencies accepted in international trade. Furthermore, it is important to state that exacerbation in physical insecurity in the rural areas resulting in fear of being kidnapped or killed, makes healthcare professionals and scientists to avoid areas accessible to raw materials, that are prone to terrorist or kidnapping groups; thereby, impeding access to pharmaceutical raw materials in those areas (Ekigwe, 2019). Importantly, pharmaceutical manufacturing sector do not only face challenge of material accessibility, but in relation to material efficiency. This is because, sometimes, accessed raw materials do have low industrial efficacy.

2.7.1 Theoretical framework

2.7.1.1 Theory of cost

The term cost refers to a sacrifice done in order to get something. Cost in business is the monetary estimation of all efforts, time, resources, materials and utilities consumed, risk incurred and opportunities forgone in the process of producing and delivering goods and services. To be more precise, the costs incurred by a firm in the process of producing a product attached to resources broadly categorized into explicit costs and implicit costs. It can then be said that "not all costs are expenses but all expenses are costs". Costs that are incurred in the process of acquiring income generating assets are therefore not regarded as expenses. There are two broad categories of theory of costs, the traditional and modern theory of cost.

Traditional theory of costs: This theory of costs examines the behavior of cost curves in the short-run and long-run. It then concludes that both the short-run and long-run cost curves are U-shaped but the long-run cost curves are flatter than short-run cost curves.

Short-run costs of the traditional theory: In the short run of the traditional theory of the firm, variable inputs and at least one fixed input are present. This tells us that short run costs are divided into fixed costs and variable costs. Here, three concepts of total cost in the short run are observed: Total fixed costs (TFC), total variable costs (TVC) and total costs (TC).

TC = TFC + TVC

Total fixed cost: This refers to costs of production that remain unchanged with the level of output. They are incurred whether the firm is producing or not and they do not depend on the level of output. It is the sum of all costs incurred by the firm for fixed inputs, and it is always the same at any level of output.

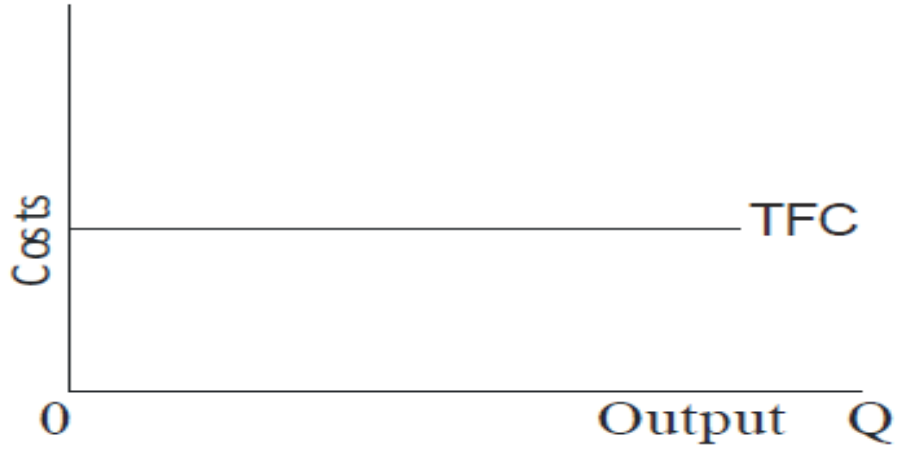

Figure 2.5: Total fixed cost (Adapted from Nwokoye and Ikechukwu, 2018)

Total variable cost: This refers to costs of production that changes directly with output level. There is a concomitant rise in cost of production when output increases and a fall in cost of production when output declines. They include the:

(a) raw materials

(b) cost of direct labour

(c) running expenses of fixed capital, such as fuel, ordinary repairs and routine maintenance.

It is the total cost incurred by the firm for variable inputs.

TVC = f (Q)

The total variable cost (TVC) in the traditional theory of the firm has an inverse-S-shape graphically shown below and it reflects the law of variable proportions (Nwokoye and Ikechukwu, 2018).

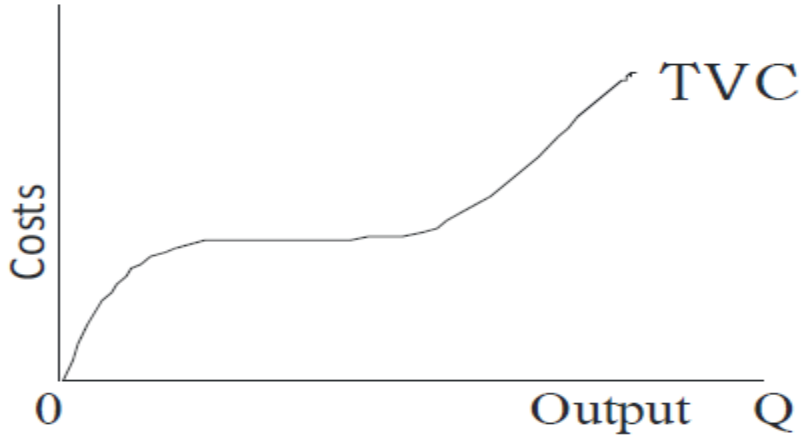

Figure 2.6: Total variable cost (Adapted from Nwokoye and Ikechukwu, (2018)

Total cost: The firm's short run total cost refers to the sum of the total fixed cost (TFC) and total variable cost (TVC) at any given level of output. Total cost also varies with the level of the firm's output.

TC = TFC + TVC ……..……1

TC = f(Q) ……..……...2

From Equation 1, it follows that:

TFC = TC - TVC ……3

Therefore,

TVC = TC - TFC ……4

The law of variable proportions accordingly states that at the initial stage of production with a given plant, as more of the variable factor(s) is employed; its productivity increases and the average variable cost fall. This continues until the optimal combination of the fixed and variable factors is reached (Nwokoye and Ikechukwu, 2018).

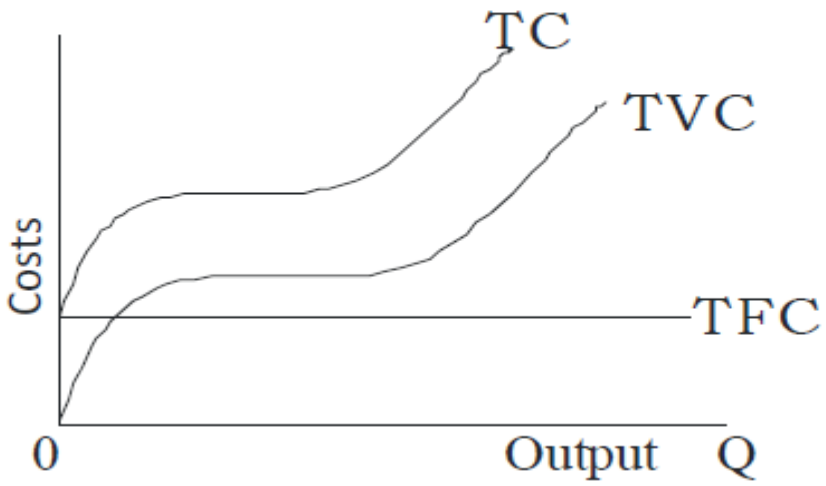

Figure 2.7: Total cost (Adapted from Nwokoye and Ikechukwu, 2018)

Modern theory of cost

The modern theory of cost differs from the traditional theory of costs with regards to the shapes of the cost curves. The U-shaped cost curves of the traditional theory have been questioned by various writers both on theoretical, a priori and on empirical grounds (Nwokoye and Ikechukwu, 2018).

As early as 1939, George Stigler suggested that the short-run average variable cost has a flat stretch over a range of output which reflects the fact that firms build plant with some flexibility in their productive capacity.

The shape of the long run cost curve has attracted greater attention in economic literature, due to the serious policy implication of the economies of large-scale production. Several reasons have been put forward to explain why the long-run cost curve is L-shaped rather than U-shaped. It has been argued that managerial diseconomies can be avoided by the improved methods of modern management science and when they appear (at a very large scale of output) they are insignificant relative to the technical (production) economies of large plants, so that the total costs per unit of output falls at least over the scales which have been operated in the real industrial world.

2.7.2 Theory of Accessed Material Efficiency

According to the definition of Rashid and Evans (2010) on material efficiency (the ratio of output to input), a suitable equation can be derived.

Material efficiency = Product output／Material input Eqn. (1)

= Product weight / Incoming material weight

However, industrial material input data are not always precise, which leads to equation 2.

Material efficiency = Product output / (Generated waste + Produced product) Eqn. (2)

= Product weight / (Waste weight + Product weight)

These criteria can also be indexed per unit produced, per production or per tonne of products. It is also possible to utilize cost equivalents or volume measures (Kurdve, 2008), as shown in equation 3.

Material efficiency = Product value / (Waste cost + Product value) Eqn. (3)

Moreover, material efficiency is related to economy, and economical efficiency is measured in terms of money. Thus, equations 4 and 5 can be written as suggested by Allwood *et al*. (2013).

Materials required/Service provided = Materials required / Money spent × Money spent / Service provided Eqn. (4)

Physical material efficiency = Economic material efficiency × Price of service Eqn. (5)

All of these measures consider total material efficiency, including product material. Because the focus of this thesis is on residual material, efforts were made to identify literature on material efficiency that addresses residual material. However, there is scant research on material efficiency in the manufacturing industry that addresses the segregation of residual material.

2.8 EMPIRICAL RESEARCH ON PERFORMANCE CAPABILITY OF PHARMACEUTICAL INDUSTRIES IN NIGERIA

The Nigerian pharmaceutical industry which is perceived to be diverse includes manufacturers, national regulators, wholesalers and retailers, government ministries and other stakeholders (Obohokwo *et al*., 2018). In order to truly appreciate the sector's potential, these stakeholders must make additional efforts to create an enabling environment. The Nigerian pharmaceutical industry according to the Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN) in terms of efficiency has the potential to be a regional leader in pharmaceutical production and distribution (PMG-MAN, 2010). In the pharmaceutical industry of developing economies, there are many reports on productivity and its determinants (Jiankang, 2014), but few studies occur in emerging countries like Nigeria.

While material availability refers to the rate at which essential raw materials are available for manufacturing purposes; Material efficacy is described as the ratio of output of products to input of raw materials, (Rashid and Evans, 2010). Pharmaceutical industries do not only face the challenge of raw materials accessibility, but mostly its efficiency. This is because, in most cases, accessed raw materials are sometimes not industrially efficient. Hence, there is need to understand the raw materials efficiencies in relation to material accessibility. In the production process, efficiency can be described as the difference between observed and optimal output and input values (Obohokwo *et al*., 2018). Several researches on the pharmaceutical industry's productivity have been conducted (Behname, 2012). However, there have been several reports on the performance of pharmaceutical companies in developed countries (Vyas, *et al*., 2012). Mishra and Vikas (2010) used a revised Structure Behavior and Performance (SCP) model to analyze 176 pharmaceutical firms and discovered a bi-lateral relationship between performance and conduct variables in the chosen firms. Furthermore, the outcomes of Mishra and Chandra's (2010) research, which used data from 52 Indian pharmaceutical companies to find a measure of efficacy showed that increasing selling measures like commercials, discounts and so on has a strong and important effect on a company's profit margin.

In Africa, Ogaji *et al*. (2014) reported that the Nigerian pharmaceutical industry's capacity utilization grew steadily but slightly from 1984 to 2014. Furthermore, in the Nigerian pharmaceutical business according to Ugbam and Okoro (2017), larger companies are extra aggressive implying that smaller companies will face heavy competition from rival firms and as a result will eventually collapse (Olugbenga, 2010). Another report conducted by Obukohwo

et al. (2018) on the evaluation of quality in the pharmaceutical industry revealed that inefficiency exists in the pharmaceutical sector. As a result, an appropriate combination of legislation and policy making is suggested in order to improve proficiency in the Nigerian pharmaceutical division by increased Research & Development (R&D).

2.9 CONCEPTUAL FRAMEWORK

This section of the dissertation will further explain the theoretical context of the variables of this study. In addition, it identifies hidden variables in works of literature that act as pointers to the research objectives, as well as, describing the inter-relationships between these variables. Also, it highlights how the research model will look like and how the proposed analysis will be conducted.

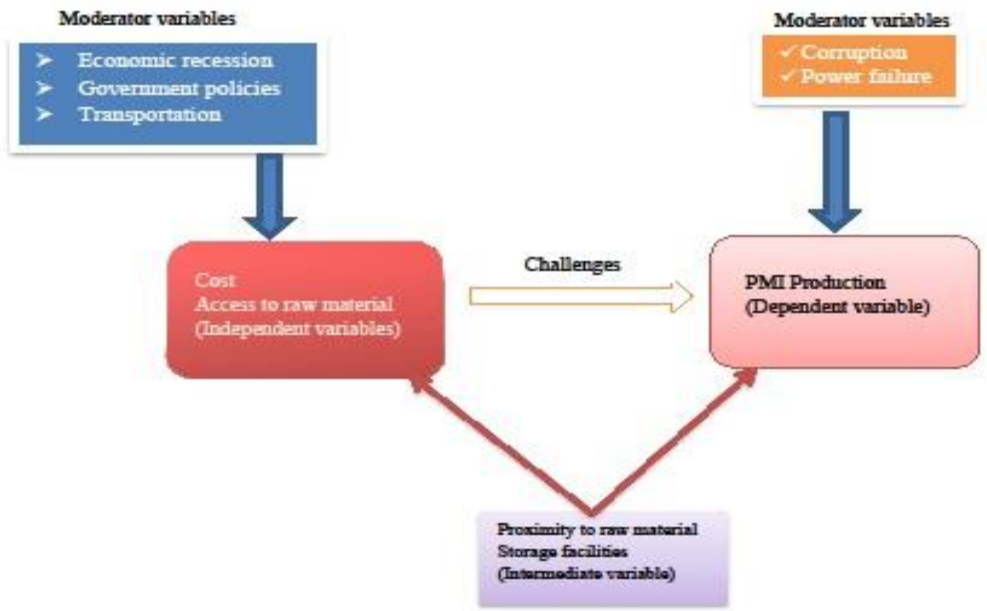

Figure 2.8: Schematic diagram of the challenges and associated variables affecting Pharmaceutical Manufacturing Industries (PMI) production

Taking a cue at critical analysis on the production performance for pharmaceutical manufacturing industries (PMI) in Lagos, Nigeria, several key areas have been highlighted as the bottleneck affecting PMI productive capacity. This research model differentiated variables into separated independent, mediating and intermediate variables militating against PMI production which is considered as the dependent variable in this study.

In other to evaluate PMI production in Lagos, Nigeria, the dissertation will consider two key factors, which are viz-a-viz; cost and access to the raw materials needed for production. These factors have been proven over and again to be the fulcrum of PMIs existence. This is because

without essential materials (which act as inputs for production) as a result of the asking price and its accessibility, outputs will not be defined.

On the other hand, other research scholars have documented certain variables which are called moderator (in this dissertation), they are known to affect the core variables. Moderators determine and predict the potencies in the dynamism of the key variables. In this dissertation, activities of economic recession, government policies and transportation are moderating variable which dictates the cost and availability of quality raw materials to PMIs. Conversely, if moderator variables are tamed, PMI production will be increased. On other hand, Corruption (human factor) and power failure are moderating factors that act as a threat to PMI productive ability; however, these moderators can be controlled by effective man management and alternative power supply.

In addition, proximity to raw materials and storage facilities are intermediate variables, bridging the independent variable (cost and accessibility to quality raw material) and the productive ability of PMIs. This implies that proximity to raw materials and storage facilities have significant impacts on the cost and availability of quality raw materials. This in turn would have impact on the production among PMIs.

Furthermore, existing literature has documented these variables (moderators and intermediates) to be the bottleneck of pharmaceutical manufacturing industry's production. However, they neglected the fact that all these factors tailor their effect on the cost and accessibility to quality materials needed for production. Therefore, for the above-mentioned reason, the objective of this dissertation is to first determine the effect of cost and access to quality raw material on the production capacity of pharmaceutical manufacturing industry in Nigeria. Secondly, is to determine the accessibility of quality raw materials to PMI, relating accessing the raw materials to the production capacity of PMIs. Overall, the broad aim is to provide a comprehensive understanding of how cost and access to quality raw material acts as a challenge to PMI production in Lagos, Nigeria.

-

2.10 Conclusion:

The preceding pages within the literature review chapter present detailed reports on pharmaceutical industries. These reports described the evolution of pharmaceutical industries with an emphasis on Nigeria, highlighting various factor that affects the production pharmaceutical products. Also, the *modus operandi* of Pharmaceutical manufacturing industry in developed nations was well illustrated.

Furthermore, strategic challenges affecting the mode of operation in pharmaceutical industries were identified under three major heading as; the time taken for a pharmaceutical product to be developed and launched; supply chain and logistics, as well as, processes involved in decision making. Within these headings, several literatures reported various factors such as, global competition; infrastructural deficiencies, economic recessions and corruption as barriers to production for pharmaceutical industries. However, none have reported how cost and access to quality raw material has challenged this sector. Hence, there is need to fill the gap for knowledge and understanding about this major challenge facing Pharmaceutical manufacturing industry in Lagos, Nigeria. This will be achieved by studying and understanding the effect of accessibility and affordability of quality raw material to the pharmaceutical manufacturing companies in Lagos, Nigeria.

Conclusively, the dissertation concentrated on cost and access to quality raw material as the primary challenge posing a threat to PMI production. The subsequent chapter will illustrate the methodology and research design that would be applied to achieve the research objective as well as, provide answers for the research questions

CHAPTER THREE

METHODOLOGY AND RESEARCH DESIGN

3.1 OVERVIEW

This chapter describes the methodological and overall approach taken in conducting this research. Every study requires a research approach in order to achieve the goals and make logical conclusions from the study. A notable researcher Saunders and his colleagues Lewis and Thornhill in 2009, proposed the so-called Research Onion which is a research model that enables researchers to determine an appropriate research process by working from the outer layers to the centre of the model. This Research Onion therefore forms the base of this chapter and provides its structure. The concept will be introduced in this section and applied to the research context of this dissertation over sections 3.2 to 3.5.

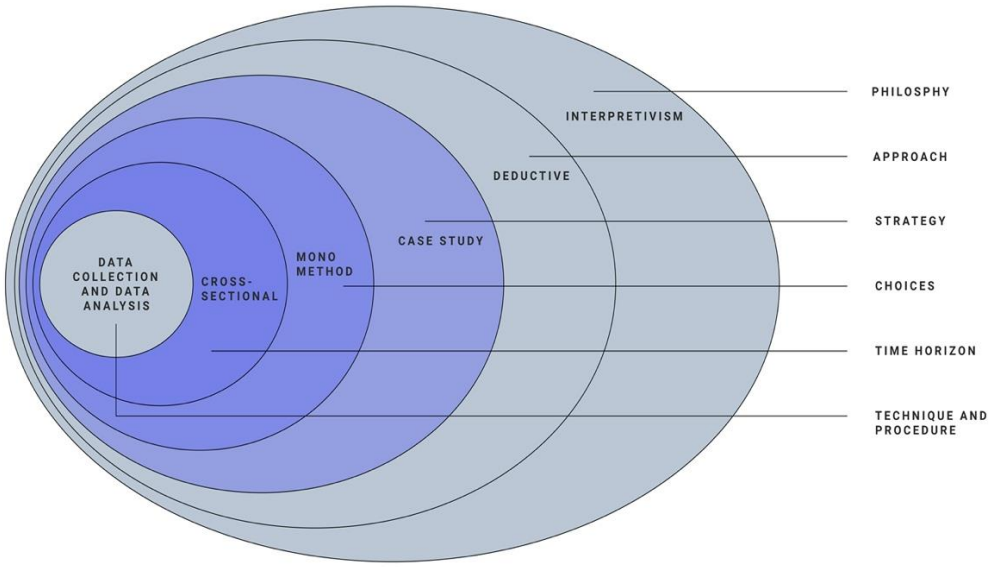

Figure 3.1: Research Onion used for this study adopted from that of Saunders, Lewis and Thornhill (2009: p. 138).

Figure 3.2 shows the Research Onion used for this study. Starting from the outer layer and working the way towards the centre, a researcher should first of all reflect on his or her research philosophy.

The research philosophy is a belief or an idea about the collection, interpretation and analysis of data collected (Levin, 1988). It contains important assumptions about a researcher's world view that influence the way in which a researcher thinks about the research process (Saunders, Lewis and Thornhill, 2009). Among the most significant research philosophies after Saunders, Lewis and Thornhill (2009) are positivism, realism, interpretivism and pragmatism. Central in the context of this dissertation is the research philosophy of interpretivism which will be further described in section 3.2

As for the second layer of the Research Onion, this is the Research Approach. The is the plan and procedure for the research. For this research, a qualitative study will be done and it would involve interviews used for data collection upon which to theories will be built to derive the results. This implies a deductive approach which aims to collect data and build a theory based on the results (Saunders, Lewis and Thornhill, 2009). The data is usually of qualitative nature (Sahay, 2016).

Furthermore, the next circle to the inside of the onion depicts the strategy for the research. The research strategy talks about the type of study conducted which could include a descriptive, an explanatory, an exploratory study and case study strategy (Saunders, Lewis and Thornhill, 2009). For this research project, a case study strategy to properly understand the challenges especially in the area of cost and access to quality raw materials, facing pharmaceutical manufacturing industry in Lagos, Nigeria will be performed.

Following the research strategy layer, is the research choices. This layer highlights the choices to be employed for collecting data. Three methods have been pinpointed as collection data techniques: mono method, multiple or mixed method. Mono- method depicts one method for collecting data, while either quantitative or qualitative technique employed various methods for collecting data. More so, the mixed-method data collection method refers the use of both quantitative and qualitative method for obtaining data. For example, the use of quantitative questionnaire combined with qualitative in-depth interviews) (Saunders, Lewis and Thornhill, 2009). For this research project, only qualitative research strategy i.e., mono method would be employed for the collection of data.

Finally, it has to be decided for concrete research techniques and procedures. This implies the choice of a data collection technique and related data analysis approach. Typical decisions include the questionnaire design or the choice of interview partners or sample groups (Saunders, Lewis and Thornhill, 2009). Based on all previous decisions, the final layer will help to condense knowledge from the data collection and answer the research questions.

Therefore, the research onion will be fully applied across all sections of this dissertation. This will further validate and elucidate the methodological research approach adopted for this research study.

3.2 RESEARCH PHILOSOPHY AND APPROACH

This research takes an interpretivist philosophical approach as I intend to analyze the key challenges the Pharmaceutical Manufacturing Industry in Lagos, Nigeria face with emphasis on cost and access to quality raw materials. This would assist to proffer solutions that will lead to efficient productivity and quality output of pharmaceutical products. The people that follow this concept have beliefs that are rather subjective as to denote collective studies among individuals to understand their perspectives about the world in general (Sharma, 2015). Social relations of people in terms of how they interact with the society are at the forefront of this research philosophy (Saunders and Thornhill, 2012).

Also, this study is hinged on an exploratory study; the overall approach for the study is an inductive approach. The inductive approach starts by collecting data, analyzing them into patterns and contributing to existing theories from inferences made on the data. The rationale for this is that, since the study is a case study research, as well as, subjective in nature, the approach presents an expert interpretation of the phenomenon in its natural setting. Furthermore, adopting an inductive approach is because I want to obtain a cogent finding of how cost and access to quality raw materials impedes productivity and outputs of the Pharmaceutical Manufacturing Industry in Lagos, Nigeria.

3.3 Research Strategy and Time Horizon

Saunders and Thornhill, (2012) identified various classes of research strategy; Ethnography, Experimental study, Archival Research, Action Research, Survey, Grounded theory, Case Study. This affords scholars the opportunity to choose which could suit their study

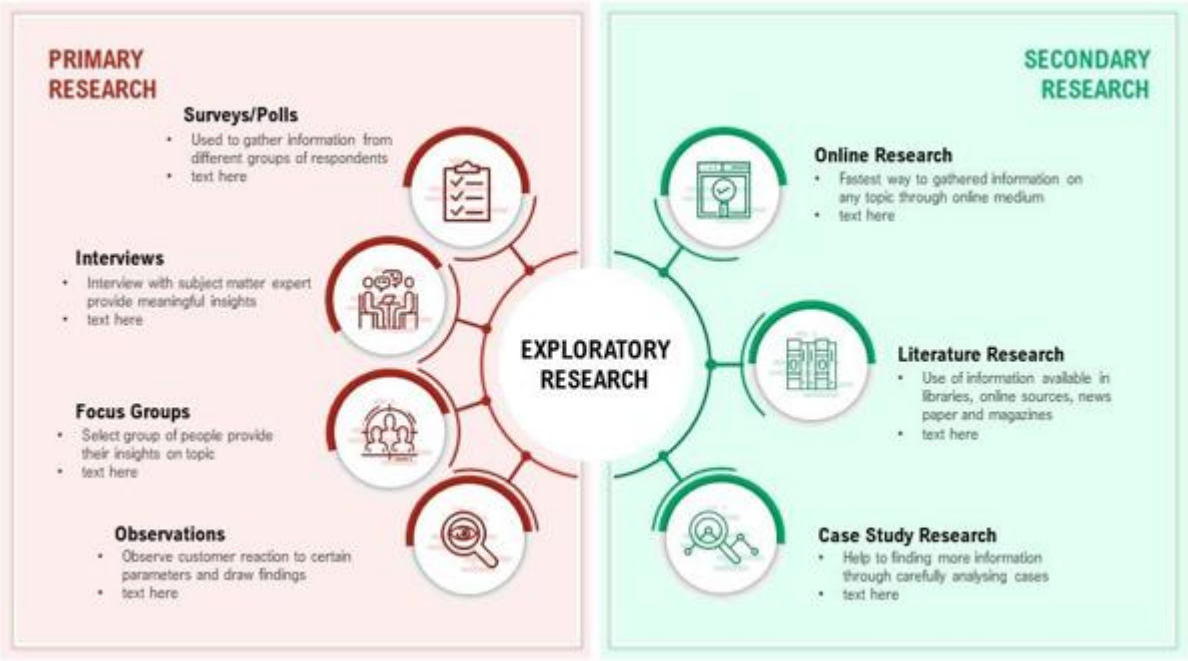

Fig. 3.2: Framework of Exploratory Research Methodology (Saunders and Thornhill, 2012).

This research will be carried out with qualitative research strategy through the use of structured interview on its participants from the production department of the Pharmaceutical Manufacturing Industry in Nigeria. The aim is to learn about the key challenges facing the Pharmaceutical Manufacturing Industry in Nigeria as it relates to cost and access to quality raw materials in order to proffer solutions that will lead to efficient productivity and quality output of pharmaceutical products. This study will determine the accessibility of quality raw materials to the pharmaceutical manufacturing firms and ascertain the affordability of these quality materials by the pharmaceutical manufacturing firms. The study will further determine the effect of accessibility to quality raw materials on the production capacity of pharmaceutical manufacturing firms, ascertain the effect of cost of quality raw materials on the production capacity of pharmaceutical manufacturing firms and make recommendations for effective management of cost and access to quality raw material issues.

Moreover, it is pertinent to consider the time frame during which data has to be collected. Saunders, Lewis and Thornhill (2009) opined either cross-sectional or longitudinal studies. Cross-sectional studies investigate a particular phenomenon at a given point in time. So, for this study, the cross- sectional horizon is adopted.

The case study strategy/ technique will be used for this research study. It is considered "a strategy for doing research which involves an empirical investigation of a particular contemporary phenomenon within its real-life context using multiple sources of evidence" (Robson, 2002: p. 178). In addition, Saunders, Lewis and Thornhill (2009: p. 146) state that "case study strategy has considerable ability to generate answers to the question 'why?' and 'what?' (…)" and thus, is most often used in explanatory and exploratory research. In addition, to its case study strategy, a mono method of research choice will be employed for this dissertation.

3.4. Collection of Primary Data

3.4.1 Sources

The method of data collection in any research methodology remains a prominent tool which encompasses the sources or domain which this research will undergo. Without stating the mode of collection of data or relevant sources that will be used in any research is like venturing into a vague or ambiguous research. The case study will be carried out using the experts (precisely, the production manager and quality control manager) interview method. This method opposes the document review of annual reports, company articles and bulletin, which would have offered multiple kinds of information. On the other hand, this may be weak, as it could indicate collection of historical data which would not reflect futuristic events.

For this dissertation, four pharmaceutical manufacturing companies such as Emzor Pharmaceutical Industries Limited, CHI pharmaceuticals limited, Nispo Pharmaceuticals limited (NAFDMU) and Miraflash will be used with two respondents each from three and one from the fourth company. Consequently, a total number of seven respondents will be involved in an expert semi structured one-on-one phone call interview and all audio recorded. The interview will last for about 10 to 15 minutes and the production and quality control officers will be involved as the respondents.

The choice for the respondents (production and quality control manager), is because these personnel officers understand excellently how the company procures its raw materials (inputs), as well as how they are utilized (output). Hence, the response from these personnel will validate the findings sought for the research.

Over the course of the interviews, respondents will be enlightened on the issues pertaining to data protection and privacy issues and how their data would be used specifically for research purpose.

3.4.2 Access and Ethical Issues

Case study research, in this context with expert interviews, comes with certain access and ethical issues. Saunders *et al.* (2009) highlighted the importance of access to good sources of primary and secondary data in the research strategy development is required to make necessary steps towards engaging the key stakeholders in the dissertation process on the reason and their interest to the research study to achieve a set objective (Bediako, 2017). Failure on the part of the researcher in obtaining the consents of or declaration from participants may result to a breach of privacy under the EU data protection regulation.

I intend contacting the participants through telephone calls as some of the respondents are readily accessible and since the research is taking a mono approach, the best method of getting all the necessary fact is by using telephone interviews to connect with the respondents. This process is limited by distance as there are travel restrictions which make it difficult for face-to-face interview and to draw a coherent research, it is only permissible to take this approach stating the rights of the individuals as participants such as rights of confidentiality, withdrawal, right to erasure and be forgotten.

Moreover, the confidentiality of respondents as well as the issues regarding the audio recordings planned have to be considered. Prior to the interview, the interviewer will have to assure to treat all information confidentially and ask for permission to make an audio recording.

A sample of the interview questions together with the sources from the literature is depicted in the table below:

Interview Question	**Literature Source**
1. What are the challenges your organization is facing in term of access to quality raw material?	Marketa, 2013
i. Are raw materials accessible? Yes or No	
ii. Are the raw materials local or imported material? In what percentage if Local or imported?	Okoli, 2000
iii. How easy has the organization been able to access raw material?	Ribeiro *et al.*, 2012

iv. What are the problems the organization face in term of access to quality raw material?	Ekigwe, 2019
2. What are the challenges undermining the capacity of production in your organization in term of (Policy, Financial, Access to Raw Material)?	Omotayo, 2020
3. Are quality raw materials expensive? Yes or No, where are the raw materials mostly imported from?	West African Health Organization (2018) and Ekigwe, 2019
4. How would you describe the affordability of raw materials in your organization?	Islam et al., 2019; Mill, 2013
i. Are quality raw materials affordable? Yes or No	
ii. Can your organization easily access them? Yes or No	
iii. What are the factors affecting affordability of quality raw materials? And how can it be solved?	
5. What are the effects of high cost of quality raw materials on production capacity? Has production capacity increase or decrease overtime?	Liu et al., 2017 and Marques *et al*., 2019
6. What is the measure in place to increase production capacity in your company?	Omotayo, (2019)
7. What will you proffer as solutions to the challenges faced by pharmaceutical manufacturing industry in term of access to quality and affordable raw material to improve production capacity in your organization?	

TABLE 3.1 TABLE SHOWING INTERVIEW QUESTIONS TO BE ANSWERED BY RESPONDENTS

3.5 Approach to Data Analysis

The two types of data analysis used in this study are Document analysis and Expert interview analysis.

The document analysis is a form of qualitative research in which documents are interpreted by the researcher to give voice and meaning around an assessment topic. It is an invaluable part of triangulation. The process of document analysis includes

1. Creating a list of texts to explore (e.g., population, samples, respondents, participants)
2. Consider how texts will be accessed with attention to linguistic and cultural barriers
3. Acknowledge and address biases
4. Develop appropriate skill for research in other to determine the authenticity of the document under review
5. Consider strategies to ensure credibility
6. Consider ethical issues (e.g., confidential documents)

There are many reasons why document analysis is an efficient data analysis approach.

1. It is an efficient and effective way of data gathering because documents are manageable and practical resources.
2. Documents are stable, non-reactive data sources, meaning that they can be read and reviewed multiple times and remain unchanged by the researcher's influence or research process
3. It can support and strengthen research in many different ways (e.g. as a primary research methodology or supplementary research methodology)
4. It can point to questions that need to be asked and it's a way to ensure research is critical comprehensive

The expert interviews will be analyzed according to the data analysis approach of Meuser and Nagel (2009). This analysis procedure is focused on identifying thematic units or passages with similar topics to ensure a greater comparability. Meuser and Nagel (2009: pp. 35-36) define the following six steps:

1. Transcription of thematically relevant passages are prerequisite for the analysis
2. Paraphrase or in other words sequence the transcription according to thematic units
3. Coding, meaning order the paraphrased passages thematically while adopting the terminology of the interviewee
4. Thematic comparison which follows the same logic as coding but now thematically comparable passages of all interviews are tied together
5. Sociological conceptualization provides a distant review of the texts and terminology used by the interviewees. The shared and differing features are determined.
6. Theoretical generalization thanks to the arrangement of categories according to their internal relations. A conclusion is drawn.

According to Meuser and Nagel (2009), it is crucial to go through all six steps of the data analysis in the described order and to avoid shortcuts. Moreover, it is important to always take into account in which context an expert statement was given (Bogner, Littig and Menz, 2009). This also implies double-checking on the adequacy of generalizations and potentially going back to an earlier stage.

3.6 Conclusion

The overall distinctions on the varying levels of research methodology have been largely considered in this chapter and it becomes important to signify at this point the investigative or detailed analysis of the approaches which has been succinctly explained above in line with showing the causal link/discussions which will be further dissected in the next chapter to properly arrive at the cogent point of this research. Generally, a whole lot of emphasis has been expressed pertaining to the research methodology in this context using structured interviews to get detailed data collection using the mono method. However, all the information as provided by the researcher will be further interpreted in a unique way in order to avoid complexities in reaching a conclusion for the entire research.

CHAPTER FOUR

PRESENTATION AND DISCUSSION OF THE FINDINGS

4.1 OVERVIEW

This chapter presents data analysis and interpretations of the empirical findings from the interviews conducted in some selected Nigerian pharmaceutical manufacturing industry with the possibility of providing a comprehensive understanding of how the challenges of cost and access to quality raw material can be addressed. This stemmed from the thematic analysis of data collected through the interviews.

4.2 Findings

4.2.1 Demographic Characteristics of the Participants.

It must be reported that seven (7) employees at the senior management levels were interviewed in four different pharmaceutical manufacturing firms in Lagos State, Nigeria. The demographic characteristic of the participants is depicted in Table 4.1.

Table 4.1: Demographic Characteristics of the Participants.

	Frequency	**Per cent**
	Gender	
Male	4	57.1
Female	3	42.9
Total	**7**	**100.0**
	Marital Status	
Single	1	14.3
Married	5	71.4
Others	1	14.3

Total	**7**	**100.0**
Age		
Less than 40 Years	1	14.3
41 - 50 Years	4	57.1
51 and Above	2	28.6
Total	**7**	**100.0**
Educational Qualification		
HND/B.SC	2	28.6
Postgraduate	5	71.4
Total	**7**	**100.0**
Work Experience in Pharmaceutical Firms		
Less than ten years	1	14.3
11-20 years	4	57.1
21 years and above	2	28.6
Total	**7**	**100.0**

Table 4.1 shows the demographic characteristics of the persons that participated in the interviews conducted on the challenges of cost and access to quality raw material in the four (4) selected pharmaceutical manufacturing industry in Nigeria. The gender distribution of the participants shows that out of seven persons interviewed, 4(57.1%) were male while 3(42.9%) were female. This suggests that both male and female were adequately represented in the interviews conducted for the purpose of gender inclusiveness. The marital status of the participants shows that 1(14.3%) was single, 5(71.4%) were married, while 1(14.3%) was either separated or divorced. The age bracket of the participants shows that only 1(14.3%) was less than 40 years, 4(57.1%) were between 41-50 years, while 2(28.6%) were 51 years and above. The table also depicts the data on the educational qualifications of the participants. Out of the seven participants, 2(28.6%) had first degree or equivalents, while 5(71.4%) has postgraduate degrees. This suggests that the information provided can be adjudged reliable. Similarly, the table also displays data relating to the work experiences of participants in pharmaceutical firms. The data shows that 1(14.3%) had less than ten years of work experience in pharmaceutical firms, 4(57.15) had 11-20 years of work experience in pharmaceutical firms,

while 2(28.6%) had 21 years and above in the industry. This implies that all the participants had requisite knowledge about the discussion.

4.2.2 Theme One: Accessibility of Quality Raw Materials

Accessibility of quality raw materials experienced by the pharmaceutical firms in Nigeria was critically described from similar but insightful perspectives. Most of the participants described accessibility of quality raw materials concerning easy access difficulties and increased production cost because of the unavailability of quality raw materials in Nigeria that necessitated relying on the raw materials from overseas mostly from India and China. The difficulties in accessing the quality raw materials both locally and the financial cost of importing and government policies have been highlighted as some of the challenges the pharmaceutical firms face in Nigeria. All the participant posited that over 90% of their raw materials are imported. This suggests that most of the raw material used are imported. It was noted by most of the participants that in order to ensure availability of the adequate and quality raw materials, they usually put in place strategic plans based on the number of materials used in the previous year.

Extracts from the statement of a participant are quoted as follows:

"Access to raw material is one of the major challenges we face in our organisation. Without adequate and quality raw materials, the production of our products becomes a serious challenge. Major APIs are not available in Nigeria, and you just must import. Only sugar and other minor things are available in Nigeria. The cost of importation is extremely high because of the high exchange range of our local currency to hard currencies. This is making our products more expensive, and the customers have been complaining while the sales too had dropped". **Participant 2**

"Most of the raw materials are not available locally, to purchase it we need foreign exchange, and currently there are deficiencies in the foreign exchange in the country this make it a challenge to access raw materials in the pharmaceutical industry" **Participant 7**

“I would like to say that the high cost of importation is one of the main challenges we have in our company; getting the materials down to Nigeria is expensive because we have to pay in cost per rate, custom fees, clearance fees, among others. All these make the materials not easily accessible" **Participant 3**

In ascertaining some of the challenges the capacity of production in Nigerian pharmaceutical manufacturing firms in the form of policy, financial and access to quality raw materials as part of the challenges faced by the pharmaceutical firms in Nigeria. Some of the participants have these to say:

“Well insufficient fund also could undermine the capacity of production because most times when you don’t have enough capital to purchase the raw materials, you tend to go for the fast-moving product, do you understand, you tend to focus on the fast-moving product and probably letting out the slow-moving one, of course, you have to put more capital, you have to invest more on the fast-moving product. I would also say government policies could as well affect the importation of some materials. Two years ago, we stopped manufacturing a particular product, emzorlin with codeine. Codeine was active for that product. Still, unfortunately for us, the Nigerian government banned its importation due to the misuse of the product” **Participant 1.**

As noted by one of the participants

“Of course, number one thing access to quality raw material, our factory producing several products, if the factory cannot get the raw materials needed for a particular product the, most time they will divert attention to other products, so getting raw material could be a challenge, sometimes you have to wait for materials to get into the country, and such waiting could bring loss and downtime to or firm, so we usually divert attention to other products” **Participant 5**

“the only thing that has been helping is planning. Usually, we plan ahead, like the previous year, we planned, of course, we know the number of batches we have been manufacturing over the years, its guides us into making preparations before the year begins" **Participant 5**

"I can tell you that there are many vendors that sell the raw materials that we need to carry out our production. They are easily accessible. However, the only challenge is that the prices had increased, possibly because of the cost of importation of those materials by the vendors. In addition to that, the logistics of moving the raw materials to the factory because of the traffic is another challenge. But in all, the materials are available" **Participant 6**

"lack of availability of raw material as at the time it is needed, it takes a lot of time when you have to bring in raw materials from another country" **Participant 7**

Table 4.2: Development of themes for Accessibility of Quality Raw Materials

Participants	Response Codes	Categorisation	Themes
P2 & 6	i. APIs are not available locally ii. Less than 10% of the raw materials are available locally	No accessibility of raw materials locally	Accessibility of Quality Raw Materials
P3&5	iii. Importation of raw materials are expensive. iv. High exchange rate	Total dependence on importation	
P7&1	v. Government policy	Unfriendly Government Policies	

Table 4.2 shows the development of the themes for the accessibility of quality raw materials by the selected pharmaceutical manufacturing firms in Nigeria. The formulation of themes for objective one required sifting and extracting important words in the form of concepts from each interviewee's excerpts. These key words are used to create response codes, which are used to highlight the most important points that interviewees want to express. This categorization process puts together multiple comparable response codes to provide the most often recurring concepts. Finally, the most often occurring concepts constitute the objective's themes.

4.2.3 Theme Two: Affordability of Quality Raw Materials

Affordability of the quality materials for different products manufactured by the pharmaceutical firms in Nigeria was considered in the interviews conducted. Most of the participants were of the view that the prices of quality materials are becoming increasingly expensive. The hike in the cost of products is a function of costly materials imported from other countries like China and India. Most of the participants opined that over 90% of their raw materials are imported from China and India. Extracts from the statement of some participants are quoted as follows:

"Even though most of the raw materials used for our products are imported, and the materials are expensive because of the high exchange rate and custom levies, we just have to make our products available because of the inevitability of our products to the citizenry. The materials are available, only that the cost of bringing them to Nigeria is extremely high. However, the cost of products is a function of the cost of the materials" **Participant 2**

"If we are to move forward in this country, Nigeria must be involved in the API productions; we do not have to import everything". **Participant 4**

This was also corroborated by another participant from other firms who noted that:

"The raw materials are costly because of the issues attached to the importation of these raw materials" **Participant 7**

Table 4.3: Development of themes for Affordability of Quality Raw Materials

Participants	Response Codes	Categorisation	Themes
P2 & 7	i. expensive raw materials ii. High exchange rate iii. High Importation duties	Costly raw materials High Importation Levies	Affordability of Quality Raw Materials

P4&5	iv. Local Production of API.	Local Production of Raw materials

Table 4.3 depicts the development of the themes for the affordability of quality raw materials by the pharmaceutical manufacturing firms in Nigeria. The formulation of themes for objective two, required sifting and extracting important words in the form of concepts from each interviewee's excerpts. These key words are used to create response codes, which are used to highlight the most important points that interviewer wants to express. This categorization process puts together multiple comparable response codes to provide the most often recurring concepts. Finally, the most often occurring concepts constitute the objective's themes.

4.2.4 Theme Three: Accessibility to Quality Raw Materials on the Production Capacity

Virtually all participants believed accessibility to quality materials greatly impacted the production capability of the pharmaceutical manufacturing firms in Nigeria. This implies that if the raw materials required for the production are readily available and accessible, it will increase the production capacity of the pharmaceutical firms. Some participants also reiterated that sometimes, they get the raw materials from other vendors that have imported the raw materials into the country. Some of the participants have these to say:

"Well, our firm is a multinational with branches in different countries of the world. We leverage on one another to easily access the quality of raw material needed in any part of the country where our companies are located" **Participants 4**

"let me say that the raw materials are available but importing them to Nigeria is on the high side" **Participants 3**

The participants also noted some of the factors affecting the affordability of quality raw materials. This includes but not limited to taxation, different levies on raw materials, high importation duties. One of the participants has this to say:

“Taxes collected, Levies on raw materials, high importation duties imposed by the Nigerian government on importing raw materials to me are some of the factors affecting the pharmaceutical firms in Nigeria. For example, if you put a 5% or 7% tax on raw materials and then zero importation tax on finished goods, how exactly are you encouraging local manufacturing? Everybody is just going to buy finished goods because it can be imported without levy”. **Participant 2**

"If my company is not able to access raw material, for example, sulfamethoxazole and trimethoprim are the active ingredients. If they are not available or accessed, the products will not be available in the market" **Participant 5**

“one of the significant problems we confront is the non-availability of raw materials in Nigeria. It is more necessary for the government to facilitate producing these raw materials for the pharmaceutical companies locally. This will reduce the cost of production and automatically reduce the cost of our products in the market. **Participant 7**

“Another factor that undermines the capacity of the pharmaceutical firms includes delay in the approval process by the regulatory body. This could be traced to the shortage of laboratory equipment needed to test and check the samples of the products before approval is given. Another thing that can affect production capacity is power. When there is no constant power, the firm has no choice but to use diesel. Some of the materials need be refrigerated; some machines must be permanently powered; the irregular power supply becomes a serious problem here" **Participant 6**

Table 4.4: Development of themes for Accessibility of Quality Raw Materials on the Production Capacity

Participants	Response Codes	Categorisation	Themes
P1 & 3	i. APIs accessed from Sisters Firms abroad ii. Materials are imported		

		Limited access to Raw Materials in Nigeria	Accessibility of Quality Raw Materials & Production Capacity
P2&5	iii. Production capacity Reduced		
	iv. Demand of products	Production Capacity	
P6&7	reduced	Reduced	
	v. Exchange rate and devaluation of Naira		

Table 4.4 shows the development of the themes for the accessibility of Quality Raw Materials and how it affects Production Capacity of the pharmaceutical manufacturing firms in Nigeria. For the objective three, sorting and extracting important words in the form of concepts from each interviewee's excerpts was necessary. These key words are used to produce response codes, which are utilised to emphasise the most critical information that interviewers want to communicate. Multiple comparable response codes are combined in this categorisation procedure to offer the most frequently recurring themes. Finally, the objective's themes are made up of the most commonly occurring.

4.2.5 Theme Four: Cost of Quality Raw Materials on the Production Capacity

Virtually all participants believed that the high cost of quality materials imported has a significant impact on the production capability of the pharmaceutical firms in Nigeria. The cost of the materials if nothing is done to address it, will affect the firms. If the products are expensive and people cannot afford them, it will force them to reduce the production capacity. It was also mentioned by some of the respondents that economic recession caused by the outbreak of COVID-19 pandemic that necessitated lockdown as one of the measures put in place by the government of different country contributed to the hike in the cost of materials. Some of the participants have these to say:

"Cost of quality raw materials is a significant determinant of any organisation's production capacity, including our firm. If the cost of material is high, then the affordability of the products

by the citizens could be affected thereby reducing the patronage of such products' **Participant 1**

“There are still talks with NAFDAC, PMG-MAN, and federal government of Nigeria on issues bordering on high taxation on APIs. These are some of the challenges we are facing with APIs. We hope it would be resolved soon so that we can focus on local manufacturing. Because we understand the needs of Nigerians, we are still financing and even buying at the same cost to ensure that the gap in the pharmaceutical industry is not left open. Still, at the same time, we are also hoping that the government can look into removing or reducing the tax. This could perhaps encourage more companies to import APIs and produce more drugs to meet the needs of Nigerians” **Participants 3**

“The economic recession has greatly impacted the cost of raw materials used to produce our different products. Since we usually imported raw materials, the cost of raw materials now is very high. This could be attributed to the devaluation of the naira. The exchange rate of naira to the dollar is extremely high" **Participant 6**

"We have noticed that if products are costly, people will not be willing to buy. Most of the time, only very few people can afford to buy expensive products” **Participant 2**

Efforts are put in place for proper and strategic planning and budgeting to increase the production capacity of the pharmaceutical firms in Nigeria. This becomes necessary to have the required number of quality and quantity raw materials needed to produce different products. One of the participants said:

“I would say that production planning and budgeting are some of the key strategies that we use in our firm. We know the numbers of products we make every year, planning ahead to source for the materials makes it easier for us to access the raw materials” **Participant 5**

Table 4.5: Development of themes for Cost of Quality Raw Materials on the production Capacity

Participants	Response Codes	Categorisation	Themes

P1 & 2	i high cost of quality materials ii. reduced the production capacity	High Cost of Production	Cost of Quality Raw Materials & Production Capacity
P6&7 **P2&5**	i. economic recession **i.** Demand and supply forces ii. Affordability of the products	Market forces	

Table 4.5 shows the development of the themes for the accessibility of cost of quality raw materials and how it affects production capacity of the pharmaceutical firms in Nigeria. Sorting and extracting relevant words in the form of concepts from each interviewer's excerpts was required for objective four. These key words are then used to create response codes, which are utilised to highlight the most important information that interviewer want to convey. In this categorisation technique, many similar response codes are combined to provide the most commonly reoccurring themes. Finally, the themes of th target are made up of the most frequently occurring issues.

4.2.6 Theme Five: Recommendations and Solutions

The fifth objective of the study focused on the recommendations suggested by the participants engaged in the interviews conducted. The aim was to provide solutions to these challenges facing pharmaceutical companies regarding quality access to raw materials to improve production capacity in the pharmaceutical firms in Nigeria. Virtually all the participants believed that government should provide enabling environment that will encourage business to thrive in Nigeria. It was discovered that most participants wanted the government to reduce the import duties and other levies charged to foster smooth importation of the raw materials. In addition to that, most of the participants also suggested that the government should ensure a regular supply of power and good transportation systems. These, according to them, will reduce the cost incurred on the raw materials. Some of the participants had these to say:

“Government should look into a way to help improve the capacity of production in Nigeria, reduction of duties or levy on imported raw materials, provision of stable electricity and incentives to manufacturers, it is essential, those are key solutions I think” **Participant 2**

“To encourage local production, the levies charged on importation of APIs should be reduced drastically. In addition to the provision of amenities like electricity, security, good transportation system and good road network. Currently, all these costs are incorporated into the cost of the drugs produced in the country. These are some of the things that government can do to help counter the challenges faced by pharmaceutical manufacturers in Nigeria” **Participant 1**

"The raw materials are imported; I believe that API (Active Pharmaceutical Ingredient) should also be locally synthesised in Nigeria, and government should support and create more infrastructure for industries. Efforts should also put in place to make grants available for the researchers to solve these problems” **Participant 3`**

“The regulatory body should speed up the approval process. In addition, the government should come up with policies that will encourage local manufactures to be actively involved” **Participant 5**

“Let raw materials be manufactured locally; let there be provision raw materials at an affordable rate, infrastructural development in the system; let there be political will from the government to support the pharmaceutical industries” **Participant 7**

4.3 Discussion

4.3.1 Accessibility of Quality Raw Materials

The first research question of this study focused on the accessibility of quality raw material by pharmaceutical manufacturing firms in Nigeria. The findings from the interviews conducted show that pharmaceutical firms cannot access raw materials locally. The result revealed that all the pharmaceutical firms in Nigeria rely heavily on the importation of raw materials. This implies that the continuous production of different products to meet the yearning needs of Nigeria depends largely on the ability of the various pharmaceutical firms in Nigeria to import

raw materials. This could be one reason why many pharmaceutical firms in Nigeria imported finished products to the country. This finding aligns with the similar finding of Okoli (2000). He found out that the

country's pharmaceutical manufacturing industry has about 30% capability and usage, while 70% of pharmaceutical products are imported. The high importation rate in Nigeria could be attributed to the lack of political will to create enabling environment that will foster local production of the raw materials needed by the manufacturing firms. It must also be noted that high taxation and import duties on the raw materials also contribute to some challenges of accessibility to raw materials. This could perhaps be one of the reasons why many pharmaceutical manufacturing firms produce sub-standard products.

As noted by Ohuabunwa (2002), the cost of importing raw materials is high; this gives room for some people to produce or import sub-standards and fake products to meet the people's purported needs. The sale of counterfeit medicine has expanded in recent years in low-income nations, particularly Nigeria. This proliferation of illicit medications has posed a challenge to the pharmaceutical industry's market returns and a direct hazard to people's lives and well-being. It has been relatively simple to get fraudulent and generic items into the pharmaceutical sector. It must also be noted that most pharmaceutical firms that usually have access to raw materials generally plan well ahead of them. Some even have branches in other countries. This allows production in other counties and brings the finished products to Nigeria to reduce cost. As suggested by Hansen and Grunow (2015), any country that invested in API production facilities may not have issues accessing such raw materials for a reasonable period.

4.3.2 Affordability of Quality Raw Materials

The second research question investigated the affordability of quality raw materials. All data collected pointed to the fact that the prices of quality materials are becoming increasingly expensive and unaffordable. This is because over 90% of the raw materials are imported from China and India. If the cost of the raw material is high, the prices of the products too will be increased in line with the realities of the market forces. This finding validates the similar finding of Schwenker and Raffel, (2012), Teknikföretagen, (2013) and Ekigwe, (2019). They posited that, Undoubtedly, raw materials and equipment needed to produce medicines in West Africa are mostly imported. This implies that the masses are at the mercy of the manufacturers outside the country, particularly during economic challenges.

The exchange rate of naira to the dollar is extremely high. The implication is that the products might be available but might not be affordable for a great number of persons in Nigeria. If Nigeria is to move forward, it is imperative for them to invest in how to produce these raw materials locally. One of the things that can be done is to give a research grant to the researcher to find alternative raw materials that can be used to produce locally. Ekigwe (2019) noted that some of the raw materials available locally could not be accessed due to increased physical insecurity in rural areas, resulting in fear of being kidnapped. This causes healthcare professionals and scientists to avoid areas accessible to raw materials prone to terrorist or kidnapping groups, thereby impeding access to pharmaceutical raw materials in those areas. This is also a scarcity of goods and foreign exchange rates skewed against imports, i.e., local currencies have meagre equivalent rates to international trade currencies.

4.3.3 Accessibility to Quality Raw Materials on the Production Capacity

The third research question focused on investigating the accessibility of pharmaceutical firms to quality raw materials as it affects the production capability of the pharmaceutical firms in Nigeria. The finding revealed that accessibility to quality materials dramatically influences the production capability of pharmaceutical firms in Nigeria. This finding implies that if the raw materials required for the production are readily available and accessible, it will increase the production capacity of the pharmaceutical firms. On the other hand, if the quality of materials is not easily accessible by the firms, its production capability of the firms will be affected. Most multination pharmaceutical firms quickly access raw material because they can easily get the materials from other countries where their firms are situated. The pharmaceutical industry faces challenges not only in terms of material availability but also in terms of material efficiency. This is because readily available raw materials might often be of low industrial efficacy/ quality. This was in line with the submission of Garetti and Taisch (2011). Similarly, it has been established in the interviews conducted that importation duties, taxes, and levies imposed by the government on the importation of raw materials also affect the easy accessibility of the materials. This indicates that if the government could review the import duties downward, it could reduce the difficulties in accessing the raw materials.

4.3.4 Cost of Quality Raw Materials on the Production Capacity

The fourth research question, which stemmed from the fourth objective of the study, examined the effect cost of quality raw materials on the production capacity of the pharmaceutical firms in Nigeria. The findings revealed that the cost of the materials is prohibitive, particularly when

they need to import those raw materials overseas. This implies that if the cost of importing raw materials is expensive and there are no local alternatives to such raw materials, the price of the products from such material will also be costly. The implication is that most people might not be able to afford the products. This will invariably affect the production capacity of such pharmaceutical firms. The reason is that a product's production capability is a function of the rate of demand for such a product. The production capacity will be reduced if there is a low rate of the order. In other words, the cost of quality raw materials is a significant determinant of the production capacity of any organisation. If the material price is high, then the citizens' affordability could be affected, thereby reducing the patronage of such products. This finding agrees with the submission of Ohuabunwa (2002). He noted that high importation rates of quality raw materials and stiff competition for quality raw materials with foreign firms are reasons for the challenges. These challenges have been blamed on unfavourable government policies, have significantly contributed to the cost of raw materials and the production capacity of pharmaceutical firms in Nigeria. Similarly, the finding also corroborates the submission of (Marketa, 2013) who posited that the pharmaceutical industry in Nigeria is faced with numerous challenges, many of which are believed to be incredibly affected by political and economic changes.

4.3.5 Suggestions and Recommendations Made by Participants

The fifth objectives of the study focused on the suggestions and recommendations made by the participants engaged in the interviews conducted. The aim was to provide solutions to these challenges facing pharmaceutical companies regarding quality access to raw materials to improve production capacity in the pharmaceutical firms in Nigeria. It was discovered that government has a critical role in providing lasting solutions to some of the challenges of cost and access to quality raw material by the pharmaceutical firms in Nigeria. If the government removes or reduces levies on the importation of raw materials, it will address some of the issues. The government can also have a bilateral agreement with some vendors across the globe to have their plants in Nigeria. This will bring the raw material closer to the firms that require such materials.

It was also discovered that importing raw materials is a challenge; transporting the raw materials within the country is another challenge. It is suggested that the government should provide a good transportation system like railways and a good road network to facilitate smooth transportation of the raw materials within the country.

Similarly, the government can also provide research grant to the researchers to find alternatives locally to the raw materials needed by the pharmaceutical firms in Nigeria rather than depending heavily on the importation of raw materials.

4.4 Conclusion

In conclusion, the study investigated the challenges of cost and access to quality raw material in the pharmaceutical firms in Nigeria. Participants were drawn from the high performing pharmaceutical firms in Lagos, Nigeria. The study concluded that over 90% of the raw materials used in pharmaceutical firms are imported. Though accessible, the cost of importation, particularly during this time that the exchange rate of naira to the dollar is high, makes it more challenging for the firms. Since the cost of importation of the raw material is high, affordability and accessibility of the raw materials are also threatened by the market forces. This end, the production capacity of the firms affected.

CHAPTER FIVE
Conclusion and Recommendations

5.1 Overview

This chapter presents the theoretical contribution of the study in line with the specific objectives of the study, the managerial implications, limitations of the research and direction for future studies.

5.2 Contributions

5.2.1. Accessibility to Quality Raw Materials

This study has contributed significantly to the subject of accessibility of quality raw materials by the pharmaceutical manufacturing firms in Lagos, Nigeria. The literature has established that pharmaceutical firms in Nigeria rely heavily on the importation of raw materials for their finished products. This study shows that over 90% of the raw materials used are imported from China and India. Hansen and Grunow (2015) saw the need for the government to invest in API to be sourced locally. This could be attributed to the heavy competition among nations of the world (Olugbenga, 2010). In addition, the current study also paid attention to the inefficiency of the pharmaceutical industry, as noted by Obukohwo *et al*. (2018). This study highlights some of the challenges to the quality of raw materials by the pharmaceutical firms in Nigeria. Some of the challenges include heavy reliance on the importation of the raw materials, reducing the number of products produced locally because of the cost of importation of the raw materials into Nigeria. Because of this, some firms that have their sisters' company in other countries where they can quickly get the raw materials usually produce their goods in that country and bring the finished products to Nigeria.

Policymakers should ensure that policies and measures are implemented to facilitate easy access to quality raw materials both locally and through easy importation arrangement. It will help in solving the challenges of access to quality raw material faced by the pharmaceutical firms in Nigeria. Moreover, the complementary role of various vendors to import the raw materials for the use of the pharmaceutical firms in Nigeria should be strengthened. This is because if the vendors can import the materials seamlessly without incurring additional charges in terms of high import duties, cost of transportation within the country, and regular electricity supply. Access to raw material will become more accessible to pharmaceutical firms. To this end, this study contributes significantly by filling a research gap in identifying some of the challenges of accessibility to raw materials by the pharmaceutical firms in Nigeria. The

empirical studies on the challenges of accessibility of quality materials have not been sufficiently researched, particularly within Nigerian pharmaceutical firms.

5.2.2 Affordability to Quality Raw Materials

The empirical studies on the challenges of affordability of quality materials have not been sufficiently researched, particularly within the context of Nigerian pharmaceutical firms. This study has made scientific contributions to the subject matter within the Nigerian Pharmaceutical firms. There is no doubt that the existing literature paid more attention to infrastructural deficiencies (Rashid and Evans, 2010), the influence of economic recessions (Ogaji *et al*. 2014), substandard products and corruptions in the pharmaceutical industry (Ugbam and Okoro, 2017), productivity (Behname, 2012) among other. This study has contributed more to the body of knowledge by highlighting some of the challenges associated with the affordability of raw materials and products in the market based on the interviews conducted. It was established during the interviews that the heavy reliance on importation contributes significantly to the affordability of raw materials. This will also affect the demands and supply forces of the market. Heavy importation of finished products was also attributed to the cost and affordability of the raw materials. This also makes Nigeria to be prone to the importation of sub-standard products.

5.2.3 Accessibility to Quality Raw Materials on the Production Capacity

This study provides some of the challenges of accessibility of the pharmaceutical firms to the quality raw material. The existing literature shows some of the issues that contributed to the easy access to quality materials. Some of the problems include but not limited to raw materials deficiency (Vyas *et al*., 2012) and inefficient bi-literal relationship (Mishra and Vikas, 2010). This current study has not only been able to contribute significantly to identifying some of the challenges of accessibility to quality materials but also looked at its impacts on the production capacity of the pharmaceutical firms in Nigeria. If the raw materials to work with are easily accessible and the prices of products are affordable, the firms' production capacity will be increased. Okoli (2020) posited that the Nigerian pharmaceutical manufacturing industry has about 30% capability and usage, while 70% of pharmaceutical products are imported.

5.2.4 Cost of Quality Raw Materials on the Production Capacity

Existing literature focused on knowledge, performance, infrastructure, competitive intelligence, among others. Still, it scarcely examined the cost of quality raw materials critical to the pharmaceutical firms' production capacity. Therefore, through the interviews conducted, the present study explains some of the challenges of the cost of raw materials and its implications on the production capacity of the pharmaceutical firms in Nigeria. This study noted that the cost of raw materials is prohibitive, particularly when they have to import those raw materials from overseas. The implication is that if the cost of raw material is high, it will automatically affect the cost of products. The level of demand of a product determines the quantity of production. If the prices are becoming unaffordable, the demand for such products will be reduced, which will invariably affect the production capacity. All these, in addition to the high cost of raw materials, make it possible for many pharmaceutical firms in Nigeria to get enough raw materials for their different products. As noted by some of the participants, many pharmaceutical firms in Nigeria have reduced the number of their products produced locally and leverage the importation of finished products to meet the customers need.

5.3 Managerial Implications

The accessibility of quality raw materials has been one of the challenges faced by pharmaceutical firms in Nigeria. Although, the materials are available in international markets such as China and India. More than 90% of the raw materials used by Nigerian pharmaceutical firms are imported. However, the cost of importation is becoming unbearable. It is suggested that the Nigerian government should reduce or subsidize the importation cost to facilitates smooth and seamless importation of these materials either by various interested vendors or directly by the pharmaceutical firms. It is also recommended that the government provide research grants to researchers to find alternative raw materials locally. This will engender easy access to raw materials and also provide job opportunities for people.

The affordability of the raw materials by the pharmaceutical firms is also very critical for the effectiveness of the firms in Nigeria. The prices of these materials are on the high side. This is because the materials cannot be sourced locally. It is recommended that the levies charged on importation of Active Pharmaceutical Ingredient (APIs) should be reduced drastically. At the same time, the Nigerian government is advised that they should endeavour to have an uninterrupted power supply, security, and a good transportation system. All these are some of the additional expenses incurred by the firms. This is also added to the cost of production, thereby making some of the products expensive. In addition, Active Pharmaceutical Ingredient

(API) should also be locally synthesized in Nigeria, and government should support and create more infrastructure to support this.

The accessibility of quality raw materials for improved production capacity cannot be overemphasized. Both the government, the management and other stakeholders have roles to play. It is suggested that the government create an enabling environment where the raw materials can be easily accessed locally or through importation. However, the vendors that are licenced to import the materials should not add to the burden of the firms. It is also recommended that the Nigerian government have an operational and effective bi-lateral agreement with some countries that produce the raw materials. Part of the agreement could be to have some plants where they produce such materials in some major cities in Nigeria. This will bring the raw material closer to the firms that require such materials. By so doing, the demand for the products might increase because the cost of production will be reduced while the products will become more affordable for the citizens.

The cost of quality raw materials also has a significant effect on the production capacity of pharmaceutical firms in Nigeria. To this end, it is suggested that efforts should be intensified to provide alternatives. In addition to that, the government should provide a good transportation system like railways and a good road network to facilitate smooth transportation of the raw materials within the country, while other social amenities should also be provided by the government. It must also be noted that because of the high cost of products, some persons take advantage of that to produce or import substandard products to Nigeria; NAFDAC should continue to fish them out and prosecute them appropriately.

5.4 Limitations

Only four pharmaceutical firms in Lagos, Nigeria, were selected for this study. In addition, only seven (7) employees at the management level cadre were interviewed in the four selected pharmaceutical firms out of so many pharmaceutical firms located in Nigeria. This implies that the scope of the study is limited. To this end, future study should broaden the scope of the study to include more pharmaceutical firms in Lagos and other major cities in Nigeria. This will perhaps make the findings to be generalized.

The study used only interviews to solicit for the data collected. Only a limited number of persons were interviewed. This implies that the wide range of opinion of diverse people working in different pharmaceutical companies in Lagos State could not be captured. Future study may consider the use of a mixed-method approach. This will perhaps provide opportunities for additional information that could aid adequate decision-making as part of an effort in providing lasting solutions to the challenges of cost and access to quality raw material.

Another limitation was the unwillingness of the selected firms and the difficulties in getting the attention of the senior management staff that can provide accurate answers to the interview questions. The researchers were able to address this through persuasion and assurance of allowing them to discontinue the interviews if feel uncomfortable. However, seven (7) persons participated in the interview section and the quality of response gotten attest to the fact that they have adequate knowledge on the subject of discussion.

5.5 Directions for future research

This study focused on the descriptive analysis; future study can look at the influence of the cost and access to quality raw material on the performance of pharmaceutical firms. Also, an intervening variable (moderating or mediating variable) can be introduced to see the extent they can contribute or reinforce the relationship between the independent and dependent variables.

In a related development, interviews were used as a qualitative data collection for the analysis. However, future research should use the mixed-method approach. The mixed-method approach will include the use of questionnaire and in-depth interviews. This could help get additional information that can help the firms in terms of addressing the issues relating to cost and access to quality raw materials.

The future study can offer a model that can be tested empirically in both developing and developed economy.

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APPENDIX

Emzor 1

Interviewer: Good afternoon, my name is Ojo Nathaniel Olatokunbo, am a master's student of Griffith College Dublin, Ireland, am doing this interview as part of the fulfilment for the award of master's degree in pharmaceutical business and technology.

These questions are both open and close ended, they are simple and directly structure to address the study aims and objective.

So there are seven questions here, each of them have some other sub questions, am going to be putting them to you but before we start, could you please tell me a brief about you, your years in service, your educational level and the company you work with please?

Response: Okay, I work for Emzor pharmaceutical industry limited and have been in service for over 27years and we produce well over 50 products……, am a micro biologist.

Interviewer: Okay that's good and which sector do you work, I think the production sector

Response: Yes, production and am actually the production supervisor

Interviewer: Thank you very much, so the first question is, what are the challenges your organization is facing in terms of access to quality raw materials. So under that we have the first question, the first question says that are raw materials accessible to your organization?

Response: Well, raw materials are not easily accessible

Interviewer: if you are going to say yes or no, can you say they are yes or no like in terms of their accessibility. Are they accessible?

Response: No

Interviewer: They are not accessible, thank you very much.

Are the raw materials local or imported?

Response: Our raw materials are imported; we source them outside the country

Interviewer: Thank you very much. In what percentage are they imported?

Response: 100%

Interviewer: Thank you very much. How easy has the organization been able to access raw materials?

Response: It's really not been easy, the only thing that has been helping is planning, usually we plan ahead, like the previous year, we planned, of course we know the number of batches we have been manufacturing over the years so that's like a guide, its guides us into making preparations before the year starts.

Interviewer: Okay that's perfect. So what are the problems the organization face in terms of access to quality raw materials?

Response: Okay, I would say the first is high cost of importation, getting the materials down to Nigeria is expensive considering the fact that we have to pay in cost per rate, custom fees, clearance fees and all that so all those makes the materials not easily accessible.

Interviewer: Okay, Question two

What are the challenges undermining the production in your organization in terms of policy, financial and access to quality raw materials? What am trying to say is what are the challenges that affects your company in like exercising their strength in production under some basic heading of policy, financial and access to quality raw materials. I think you have spoken about the access so you can simply talk about the financial and the policy.

Response: Okay, well insufficient fund also could undermine the capacity of production because most times when you don't have enough capital to purchase the raw materials, you tend to go for the fast moving product, do you understand, you tend to focus on the fast moving product and probably letting out the slow moving one, of course you have to put more capital, you have to invest more on the fast moving product.

Also I would also say government policies as well could affect importation due to bank list of some of the import of materials. I could remember two years ago, we stopped manufacturing a particular product, emzorlin with codeine, codeine was been active, government actually banned us from making that product due to the misuse of the product, so government policy as well is a major part affecting capacity of production.

Interviewer: Thank you very much. In your own opinion, are quality raw materials expensive?

Response: Of course, quality raw materials are very expensive because we don't go for the ones that are not good, most of our materials are USP(United States Pharmacopoeia), we go for quality materials.

Interviewer: That's perfect. Where are the raw materials mostly imported from

Response: Okay, India, Germany and China

Interviewer: How would you describe the affordability of raw materials in your organization ?

Are quality raw materials affordable?

Response: No, they are not affordable

Interviewer: Can your organization easily access them?

Response: Well, yeah I will say we can easily access them because due to proper planning that has really helped a lot.

Interviewer: Thank you very much. What are the factors affecting affordability of quality raw materials and how can it be solved.

Response: Okay, like I said earlier, finance can affect the availability of raw materials, when you don't have enough sufficient funds to buy the raw materials in bulk, you tend to get them in bits and that won't help at all so I think the solution is for government to support pharmaceutical industries, they should try to give out grants and loans to support them, that would really go a long way to help.

Interviewer: Thank you very much. What are the effects of high cost of quality raw materials on production capacity in your organization, has production capacity increased or decreased over time?

Response: Okay, if my company is not able to access raw material for example sulfamethoxazole, trimethoprim been the active ingredients, you won't have the product in the market, people won't be able to access the products since you don't have product in the market anymore due to the unavailability of the raw materials.

Interviewer: In your own opinion, do you think the high cost of these raw materials has affected in terms of decrease or has it increased the production capacity in your organization

Response: It has reduced production capacity.

Interviewer: Thank you very much. What is the measure in place to increase production capacity in your organization?

Response: First I would say production planning and budgeting, because over the years we know the numbers of product we make every year, when you plan ahead you source for the materials even before the year starts so that way the materials are available in the warehouses, you can easily access them that way but when you plan ahead and you have an order to make a certain number of batches of paracetamol, you have source for materials and due to high cost of importation, it might take 2 to 3 months before the raw materials gets to you that means you might really not meet up the deadline of the production of the product.

Interviewer: Thank you, and lastly what will you proffer as solutions to the challenges facing pharmaceutical manufacturing industries in terms of access to quality and affordable raw materials?

Response: First thing, raw materials are imported so I believe that API (Active Pharmaceutical Ingredient), should also be locally synthesize in Nigeria and government should support and create more infrastructure for industries, they should also support with loans and grants, they should bring more research facilities and all. Encouraging young researchers also is a way to solve all these problems.

Interviewer: Thank you very much, we have come to the end of the interview.

Emzor 2

Interviewer: Good afternoon, my name is Ojo Nathaniel Olatokunbo, am a master's student of Griffith College Dublin, Ireland, am doing this interview as part of the fulfilment for the award of master's degree in pharmaceutical business and technology.

The question am going to be asking the participant are seven in number, each of them they have sub other sub questions but before I start, could you please tell me your grade level, your years in service your educational level.

Response: Thank you very much. I graduated from Obafemi Awolowo university where I obtained a bachelor's degree in micro biology with a second-class upper division, so currently have been working with emzor pharmaceuticals as micro biologist for over two years now, I actually resumed service there January 2019 so have been there for over two years now.

Interviewer: Okay, thank you very much. So, the first question is what are the challenges your organization is facing in terms of access to quality raw materials? So under that we have four other questions. The first one is, are raw materials accessible to your organization?

Response: Yes

Interviewer: Okay, thank you. Are the raw materials local or imported raw materials?

Response: Local and imported

Interviewer: Okay both. Son in what percentage can you say they are both?

Response: I would say local 20, imported 80.

Interviewer: Okay thank you. SO how easy has the organization been able to access these raw materials?

Response: For local its quite easy, very easy. For imported its less easy but its also easy but I will say for local its easier than imported.

Interviewer: Okay good. So what are the problems the organization face in terms of access to this raw materials? So you are going to talk about the problems they face locally and internationally the imported ones.

Response: Yeah so for local resourced raw materials, the first problem we have is sub-standard raw materials you know, a lot of local suppliers don't really stick to appropriate pump measures, so in a bid to try and meet the market demands they sometimes sells sub-standard raw materials, so as for locally sourced raw materials the problem of sub-standard or counterfeit raw materials are quiet paramount. Then apart from that is also the aspect of let's say politics in terms of you trying to bribe or trying to get stuffs done and things like that.

Interviewer: Okay, corruption

Reponse: I will say corruption

Interviewer: Okay so thank you very much. So the second question is what are the challenges

Response: For the imported right

Interviewer: Okay yeah, you are yet to talk about that

Response: So for the imported is basically on logistics

Interviewer: Okay

Response: Is basically on logistics, sometimes you get the raw materials to the border and trying them to your factory becomes a whole lot of problem, so for imported logistics.

Interviewer: Okay, So number two

Response: Yeah

Interviewer: What are the challenges undermining the capacity of production, capacity of production in your organization in terms of policy, financial and access to raw materials?

Response: For the financial aspect of it raw materials are really expensive coupled with fact that we have to import a whole of them it adds more to the expenses and overall cost of production, so the cost of raw materials especially the imported ones are all expensive and going by the fact that most of the raw materials are levied on high import is import of raw materials of lets say 2naira and you get to pay 8naira on it

Interviewer: Okay thank you very much

Response: Then apart from that is the logistics aspect that I mentioned

Interviewer: earlier okay thank you very much

Response: Yeah

Interviewer: So are quality raw materials expensive like a closed ended question like are quality raw materials expensive so yes or no

Response: Quality raw materials are they expensive yes

Interviewer: So where are these raw materials mostly imported from?

Response: Hmmm two countries basically, China and India

Interviewer: Thank you very much. How would you describe the affordability of raw materials in your organization? Are quality raw materials affordable to your organization?

Response: Are quality raw materials afford, can you take that again

Interviewer: I mean how would you describe the affordability of raw materials in your organization? So under that the first question is Are quality raw materials affordable?

Response: Yes quality raw materials are actually affordable

Interviewer: Okay

Response: You take for example in India there are over 150 industries

Interviewer: Okay

Response: Like many over 600 industries

Interviewer: Okay

Response: So you can get many industries that can give you affordable materials but the main problem is trying to clear it off the port

Interviewer: Okay

Response: Which is really killing in terms of bribing

Interviewer: Thank you very much

Response: You get levy done in terms of import duties

Interviewer: Thank you very much. So can your organization easily access these quality raw materials?

Response: Yes, we can Emzor is a big brand and we have been for over 32years so we have gotten better overtime and we can always find our way around stuffs.

Interviewer: Thank you very much. What are the factors affecting the availability of quality raw materials and how would you how can you suggest solutions to them?

Response: Two things basically in terms of do you mean imported raw materials or locally sourced raw materials

Interviewer: Anyone

Response: Okay, for imported raw materials it has to wait for the import, sometimes we get the raw materials for cheap but import duty we have to have are quite enormous so I think they have to be a balance in terms of the import duties levied on some certain raw materials, maybe they might need to do it in terms of quantities okay if you want to take this so so so quantities you have to pay these and if you want to take this so so so quantities you have to pay these and try to like find a balance such that companies don't have to like get quality raw materials for cheap and then end up paying high amount of money to just clear them off the port.

Interviewer: Okay

Response: Most especially when some of these raw materials are even legal like its not as if you are importing drugs or some contraband

Interviewer: Okay

Response: So I think they have to be a kind of balance in terms of import duties then raw materials can be quite affordable. You can always get them for cheap wherever you want to import them from but the real problem is the import duties you get to pay on them.

Interviewer: And in getting raw materials I think there should be a standard that you source for like a quality, some qualities or a kind of quality that you source for from your organization.

Response: Yes that's correct

Interviewer: So how do they impact how do they impact the production capacity of Emzor?

Response: Yes so errm most raw materials not only once all raw materials comes with what we call certificate of analysis, we have our specifications our in house specifications that these raw materials must conform with so if after we have received the raw materials, before we even receive the raw materials from any industries we have what we call pre buy samples, you send pre buy samples to us more like what they are going to bring eventually then we test it then we are sure it's okay with what we have as in house specifications then if we are fine with it we tell them to bring them, then we also test some samples of the whole container that they bring so we have in house specifications that these raw materials must conform with like in house quality that these raw materials must conform with, with that we can now proceed to use the raw materials

Interviewer: Okay that's good. So what are the effect of high cost of quality raw materials on production capacity? As production capacity increased or decreased overtime in your organization?

Response: Number one, the effect of high cost of what's it called quality raw materials

Interviewer: quality raw materials yes

Response: Yeah the most obvious thing is number one it automatically kills down production that's number one then number two, it sort of allows you not to take enough risk, lets say for example you are formulating a product you are doing what we call product formulation, formulation development, you want to try and make some research and try and know which proper combination will give you the best output of product along the line there will be lot of wastages there will be lots of trials and errors and the rest of them you wont want to take a lot of risk because you have brought in those raw materials on a high side and eventually you cannot get the best that you could have gotten if the raw materials were sourced at low price.

Interviewer: Okay

Response: Tthen number one you have to review if you don't want to take risk then number two is the most obvious ones, it automatically kills down your production capacity because if you are getting raw materials at high charges then you have to get the amount of raw materials that your money can actually cover.

Interviewer: Okay thank you very much

Response: So it automatically kills down production then it also reduces the risk you have to take in terms of formulating a given product.

Interviewer: Okay thank you. What is the measure in place to increase production capacity in your company?

Response: Yeah basically just like Emzor is a big brand, even though we source for these raw materials at cheap prices we can because we have been in the business for a long time, overtime we have gotten the experience on how to you know do our proper planning and how to ship in most of these things and also how to get our ways around import duties but some of these procedures also come with let's say with what do I call it now, with let's say you are supposed to clear today and you are not clearing today they are clearing tomorrow, what is it called? Is it banned or what is it called like a levy

Interviewer: Demurrage, maybe they entered demurrage

Response: Exactly

Interviewer: I guess demurrage, then you have to pay a certain amount for demurrage

Response: Exactly a certain amount of money, so we have gotten there over time, it doesn't really enter demurrage before we get those raw materials.

Interviewer: So that's good

Response1; so that way we have cut those cost of you know that high cost then apart from tat one other thing you can do is to make sure you actually get the cheapest but quality raw materials so let's say you can get a raw material for let's say 10 dollars and you actually see who can offer for 2dollars that 8dollars that you have saved will be used to clear your raw materials.

Interviewer: Okay

Response: So you get the cheapest but most reliable and quality raw materials that can be available

Interviewer: Thank you very much

Response: You also have to map out your country and stuffs like that you don't just import from any country, there are what we call vendor qualification, you don't just import from anywhere at any point in time you also have to go there to inspect there facility and make sure that they are doing the right thing you can have reasonable assurance that what they are doing is actually in conform with whatever you want them to supply to you

Interviewer: That's very good and lastly what will you proffer as solution to the challenges fancied by these pharmaceutical manufacturing industries in terms of access to quality and affordable raw materials? So these last question is like suggesting what can you proffer, what are the solutions you can proffer to the challenges the pharmaceutical manufacturing industries facing in terms of access to quality and affordable raw materials to improve their production capacity?

Response: Most of the challenges we have mentioned are high import levy that's for the imported raw materials then for local we have to identify the challenges before I can be able to proffer a solution so I want us to like recap on some of the challenges mentioned then which we can talk about the solutions.

So for imported raw materials we mentioned high levies on some of these raw materials then locally raw materials we mentioned that they are been sub-standard so let's start from the locally first

Interviewer: You also talked about the logistics for the imported raw materials

Response: Okay for the imported raw materials we mentioned the aspect of demurrage if you did not allow your raw material to be on the port for a long time so you don't have to pay demurrage so if your logistics what's it called, your supply chain is very effective then you don't have to pay some certain cost, one thing is to have your proper supply chain inspected as your raw materials are been sent to the port you are clearing them at once then you are paying the normal levy. Then also another thing you can properly do is write the government you know some of these companies are actually indigenous if production capacity is killed down you know some people will lose their jobs and the production will tell on the overall economy so you can also write the government about some of your grievances, the materials we are getting at these price look at the levy is there something you can do you know there should be considerations for that too, apart from that there is nothing much you can really do

Interviewer: Then lastly, do you consider power a major challenge facing the pharmaceutical manufacturing industry in Nigeria?

Response: Yes

Interviewer: And if Yes, how do you think power

CHI 1

Good afternoon ma, my name is Ojo Nathaniel olatokunbo and we will be having a short interview for my research project and the topic of the research project and the topic research project is study of the key challenges facing pharmaceutical manufacturing industries in Lagos Nigeria with emphasis on cost and access to quality raw materials. So, the questions is going to be. Both open and close ended, before we start ma, I will like to know little about you, your educational level and your years of service, and the company you work with.

RESP: I work f or chi pharmaceutical, I started working since 2004, that make it 16 years in service, we are into sales and marketing but manufacturing is the bases

INT 1a. What are the challenges your organization is facing in terms access to quality materials. 1b are they accessible to your company?

RESP: yes, we do have challenges concerning raw materials, no. Chalk as per sourcing 1c are the raw materials locally produced or imported

RESP: 1f imported in what percentage?

RESP; most of the API are imported in large quantities about 90%

2. How easy has your organization been able to access the raw materials, how can you describe how easy it is for your company to access them.
RESP: It is easy to access for manufacturing or import of API directly depending on how much you want to buy it. I will say it is easy

3. What are the problem your organization is faces in terms of access to quality raw materials
RESP: the only challenges is there are different types of purity level so the one that are expensive would definitely increase your cost of production, that makes it difficult for you to compete in the market. And also Accessing this raw material is not a not a challenge but accessing quality raw materials makes it difficult to compete with your competitors in term of pricing of the product. Your scale is production also determines how you able to negotiate with the raw materials. If your production car capital is large it favours you better than the other way. It's also impact on the final product and price in the in the market, so this are the challenges we face, in having to decide which API one have to use, but unfortunately If the price high you start speaking English and the consumer don't understand what processes it take to produce it.they will say why is your own costly. This happens because the raw materials come at a high cost so you need to be careful that your product price are not too high compared to your competitors.

4. What are the challenges undermining the capacity production in your organization in form of policy financial and access to quality raw materials?
RESP: it basically the same thing like I said earlier In CHI we go for quality according to our mission statement to provide affordable and quality products So at the end we go out for quality

materials and unfortunately that impacts on the cost price and this is not favourable to the consumer because of high price and some consumers are left out. Because all this raw materials are not readily available and the prices are not affordable and they are subject to custom duty and exchange rate this causes increase in price of raw materials

5. I believe all organizations have budgets for the raw material they want to purchase what happens if the price of the raw materials are more than the budgets, do you leave it or go for lesser ones as to meet budgets

RESP: generally, there is a budget for all organization, what we do is to is that we Refix the budget although we would have done some level of pricing before fixing a budget but in case of changes because we don't want to reduce the quality of our product a reapproval and justification is provided to the management to get approval to purchase.

6. Are quality materials expensive?

RESP: yes they are expensive because they are mostly imported and are subject to exchange rate and custom levies.

7. Which countries do your raw materials come from?

RESP; China and India, but majorly China

8. How would you describe the affordability of raw materials to your organization, are they readily affordable?

RESP: yes, it is affordable, but I will say in relative time affordability is not a problem to the organization. You have a client base and customer, is it affordable to them. Ask those questions, it is affordable to the company but you have to cut off some of. Your patient's if it not affordable to them.

9. Can your Organization easily access this raw material?

RESP:yes

10. What are the factors affecting availability of raw materials and how do you suggest they can be solved?

RESP: like I said majority of the raw materials are imported, and are subject to foreign exchange and customs levies, so Nigeria needs to be involved in the API productions, we don't have to import everything

11. What are the effects of higher cost of quality raw materials on production capacity, Will production capacity increase or decrease?

RESP: it could affect the company in a long term because at the end of the day your price in the market is what gives you inflows and ensure that your Kraft is sustainable.

12. Is Nigerian economic recession a major challenge To the pharmaceutical industry, how as it impacted the organization?

.RESP: it is but not a major challenge, it been difficult due to expensive nature of these raw materials and affordability it has a negative impact on product.

13. What are the other challenges asides cost of and access to quality raw materials?

RESP: machine used in the pharmaceutical company are not produced locally so it entails high cost of purchase, and also ina production processes it is important to have stable electricity, that we don't have we have to operate on other sources and all th is have impact on the production cost.

14. Lastly what would you prefer as solution to this challenges facing pharmaceutical companies in terms of quality access to raw materials to improve production capacity in the organization?

RESP. Government should look into way to help improve capacity of production in Nigeria, reduction of duties or levy on imported raw materials, provision of stable electricity and incentives to manufacturers, it is very important, those are key solutions, I think.

INTERVIEWER: we have come to the end of the interview.

CHI 2

Interviewer: Thank you very much ma. My name is Ojo Nathaniel Olatokunbo, I'm a Master's student. I'm doing this interview for the fulfilment of the award of Master's degree in Pharmaceutical Business and Technology, here in Dublin Ireland. The main purpose of this study is to examine the challenges facing pharmaceutical manufacturing industries in Lagos Nigeria, with emphasis on cost and access to quality raw materials. I have here a total of 7 questions, each with sub questions and they are as direct as possible. Before the questions, please tell me about yourself, your years in service, the company you work with and your educational level.

Response: Okay, educational level, MSc Pharmacology. Years in service, 6 years and I'm the head of marketing, company I work with is, Chi Pharmaceuticals.

I: Thank you very much ma.

R: No problem.

I: The first question is: What are the challenges your organization is facing in terms of access to quality raw materials? Under that, the 1st question is: Are raw materials accessible to your organization?

R: No. No, they're not.

I: Okay, thank you. Are the raw materials local or imported materials?

R: Both but if we're talking percentage, let's say 95% imported and 5% local.

I: Thank you very much. How easily has the organization been able to access raw materials?

R: Not easy at all.

I: Thank you very much. What are the problems the organization face in terms of access to quality raw materials?

R: Well, I mean cost definitely. First off, accessibility because number 1, the major places you import from are either India and China and you have over 115 or more pharmaceutical companies in Nigeria going to these same places to import these same manufacturing pharmaceutical APIs so really you have issues of stock out, issues of hiked prices because these guys understand that they have multiple people bidding for these same APIs. So, I think the major problem is number 1, accessibility in terms of being accessible in Nigeria and number 2 is the price and number 3 obviously is also tax because for whatever reason, APIs are being taxed in Nigeria, they have a levy while finished products don't, which kind of doesn't make sense because that doesn't encourage local manufacturing so yeah.

I: Okay, thank you very much ma. So, question 2, what are the challenges undermining the capacity of manufacturing in your organization in terms of your policies, financial and access to these raw materials?

R: Access to raw material is the major challenge because you can't produce without raw materials. What are the raw materials you have in Nigeria? So I don't maybe sugar or little things. So for major APIs, you can't find them in Nigeria, you have to import them so accessibility to raw materials is still the major challenge for production.

I: Okay.

R: If we're unable to access these raw materials, then production can't happen.

I: So, talking about the financial part, does it really have huge impact on the capacity of production of your organization?

R: Of course. Because if the cost of APIs is very high, the number of….. so let's say for example if we're supposed to have 10,000 tablets, and that same 10,000 tables you bid with say 2 APIs worth $2 for example in the last year and this year the dollar price has increased, a lot of things has happened and you're unable to buy that same quantity of APIs with that amount of money, obviously the number of drugs is going to reduce. But then, the financial still isn't the major problem because the company understands the profits they're going to get from these products so they can always work around it but then having the product itself is still the major challenge, that's the raw materials.

I: Okay, thank you very much. So to the next one: Are quality raw materials expensive generally speaking?

R: Yes, very expensive.

I: Where are the raw materials mostly imported from?

R: 2 countries. India and China.

I: Thank you very much. How would you describe affordability of raw materials in your organization? Are quality raw materials affordable?

R: It's expensive so I'd say no, I don't think they're affordable.

I: Can your organization easily access them?

R: Well, to be fair because Chi Pharma is under a group called Chi GI and Chi GI is a multinational because we have companies in different countries in the world, it is somewhat easier for us compared to other companies because we can leverage on our size against other companies to help us import them. So I won't use the word 'easily', but yeah we can access them.

I: Thank you very much. What are the factors affecting affordability of quality raw materials, and how can they be solved?

R: Tax. Levying raw materials, to me, by the Nigerian government I don't think that's right. I think I'd mentioned that earlier, if you put a 5% or 7% tax on raw materials and then zero importation tax on finished goods, how exactly are you encouraging local manufacturing? Everybody is just going to just going to buy finished goods because well, you can just import it without levy so yeah.

I: Yeah. Thank you. So what are the effects of high cost of quality raw materials on production capacity? Has production capacity increased over time?

R: Well, it has decreased over time.

I: Okay.

R: So the effect of the high cost of raw materials just means that, yes production capacity has decreased over time.

I: Thank you very much. So what is the measure in place to increase production capacity in your company?

R: So there are still talks with NAFDAC, with PMG-MAN, the federal government still bordering on this tax on APIs and these are the challenges that we're facing with APIs and these are the issues that we hope would be resolved soon so that we can actually focus on local manufacturing. So right now, because we understand the needs of Nigerians, obviously we are still financing and even buying at the same cost to ensure that the gap in the pharmaceutical industry isn't left open but at the same time we're also hoping that the government can look into removing that tax so that we have more companies import APIs and produce more drugs to meet the needs of Nigerians.

I: Yeah, thank you very much. Now to the last one, what will you proffer as solution to the challenges of pharmaceutical industry in terms of access to quality and affordable raw materials to improve production capacity in your organization? What are the solutions you can proffer to the challenges?

R: I think my answer is in 6 already covers this but I'll just reiterate. Number 1 would be that levy because to encourage local production, you can't have people paying more for importation of APIs remembering the cost of even manufacturing in Nigeria so we have infrastructure like light, you're running gen, all these costs also have to be incorporated into the cost of the drugs. What I mean, for example is, if I am producing Paracetamol in Nigeria and somebody imports Paracetamol for let's say #100. I am producing Paracetamol, my API is already coming high, my cost of running my plant is already coming really high, I can tell you for free that my

Paracetamol is not going to be #100. Its most likely going to be more expensive and people will say ‘but you’re producing in Nigeria’ but remember that everything I’m using, I’m importing. So 1 would be removing that importation tax, number 2 also the government should help in terms of our infrastructure, let’s have better light, better water, roads, basic things, transportation, to transport even the goods from one place to another. So these are things that the government can do to help counter the challenges faced by pharmaceutical manufacturers in Nigeria. In terms of access to quality and affordable raw materials, these products are there but for them to be accessible, we need the relevant authorities or the federal government to ensure that number 1, the levies or taxes are off and then number 2, infrastructures are better. So these are 2 key areas that if addressed, things would take a very very different turn for good.
I: okay, thank you very much ma. We’ve come to the end of the interview.

NISPO 1

Interviewer: So good afternoon, sir. Um, um, we are having this interview solely for my research and project. So, and the project topic is the study of the key challenges facing pharmaceutical manufacturing, industry Lagos, Nigeria with emphasis on cost and access to quality raw materials. So please sir, can you please tell me about you, your grade and rank?

Response:
I've been practicing since 2013 and I work in various pharmaceutical industries.
Interviewer: Okay, that very good
Response: One of the industries is this NPS in Lagos and Nigeria Airforce Drug manufacturing company
Interviewer: Okay, Thank you very much sir. So, um, please, what is your educational level?

Response:
I have Bachelor's degree in pharmacy Bfam from Obafemi Awolowo University

Interviewer:
That's very good, sir. So, the purpose of this study, the main purpose of this study is to examine the challenges facing pharmaceutical manufacturing industry in Lagos, Nigeria, with the emphasis on cost and access to quality materials. The questions I'm going to put, I'm going to be asking you are both going to be open and close ended. That means one you're going to explain the other one you're just going to give a yes or no answer. They are also going to be

simple and directly structured to address the study hymns and aim and objectives. So here are the questions. Number one. What is the advantage? What are the challenges your organization is facing in terms of access to quality materials? So the first question under that is are raw materials are accessible to your organization. But before I start that sir, you are going to tell me the company you work with, sir. So what company do you work with?
Response:
Nigeria Airforce Drug manufacturing company in Lagos, Ikeja, Lagos

Interviewer:
That's very good, sir. So straight to the question, I raw materials, the quality raw materials that you use for your manufacturing in your company. Are they, are they accessible?
Response:
Yes.

Interviewer:
Okay. Thank you. The second one is, are the raw materials local or imported?
Response: Imported
Interviewer: Okay. In what percentage, if imported or if they're imported, like in what percentage can you say is imported
Response:
In general majority of the raw materials are imported, like

Interviewer:
Like if we are to base on 100%, like in what percentage can you say is imported
Response:
More than 90%

Interviewer:
More than 90% , thank you very much sir. So, how easy as your organization being able to access these raw materials, how easy have they been able to access the raw materials?

Response:
It has been easy through majorly use of importance we are buying directly from manufacturers and importing to the country, so majority of the materials we get it from importer

Interviewer:
Okay. Sir are you saying most of these raw materials you import, you don't get to import them directly from the manufacturers but you have like an intermediary that you talk to, like liaise with them so that they can help you in importing them to your organization. Is that what you're saying, sir?

Response:
Yes, we buy from those that have already imported into the country
Interviewer:
Okay, thank you very much sir. So in what, like, how is that? How is that like difficult for your organization? Is there any impact of having an intermediary between the manufacturer and the company importing the raw materials?
Response: I can't get you.
Interviewer: Like, are there any hindrances or are there problems you, your organization face because of the intermediary between the major manufacturer and the people liaising between you, your company and the people manufacturing, the raw materials, are there problems, what problems do you face?

Response:
Since, uh, importing directly from the manufacturers is somehow hard to buy in large quantities, and some of the materials we need only in minor quantities, so you cannot back you buy, you buying from the manufacturers, but buying from those that have imported into the country can choose the amount that we need and we can but from them.

Interviewer:
Okay, thank you very much sir. So, the fourth question under question one, what are the problems that your organization face in terms of the access to the due to these quality raw materials? Like what are the challenges you face?

Response:

Um, one of the challenges is since we are relying on the, on the, materials that have already been imported into the country, If these, uh, this dealers, uh, this importers are out of it, our reliance on them will be a problem. Second the materials they are supplying, we have to be sure that they are supplying us quality raw material and sometimes they default on this, when we take the materials to our own company and do our findings we do find out sometimes that the materials do not pass the quality test, it means we have to return it back to them.

Interviewer: okay.

Response: Since you cannot get it direct from the raw material we do face one of these problems

Interviewer:

Okay. Thank you very much sir. So, to the second question, what are the challenges under mining the capacity of production in your organization in terms of the policy, the financial access to the quality of materials, like what are the challenges that is undermining that is affecting the utilization of the strength of your company in producing in terms of their policy the financial and the access to these quality of materials,

Response:

Of course, number one thing access to quality raw material, our factory producing several products, if the factory cannot get the raw materials needed for a particular product the, most time they will divert attention to other product, so getting raw material could be a challenge, sometimes you have to wait foe materials to get into the country, so and such wait could bring to loss and downtime in the factory, so you divert attention to other product. So, second thing that affects is like I mentioned the issue of financial too, since the factory have um, an amount of capital they are working with just like like, as we said earlier, there is no as it there is unlimited money, uh uh, so the amount of capital the factory have, they have to see how they can optimize is used in making , making the best in available capital to produce the product needed and so if materials is not found in the market, they have to divert funds to production for other product.

Interviewer: Okay.

Response: And talking about the policy, that one affects too in product that are been close monitored by the government, for example the production of some drug like codeine containing products, there are policy controlling all these drug that there is even a particular quota that each factory must produce.

Interviewer:

Thank you very much sir. So, the, so the next question are quality raw materials expensive to

your organization, to your company rather, are they expensive, can you say they are expensive.

Response:
Yes, since quality of, any material that is to be used in production have to pass the quality tests, just like the sources of the materials you import, is just a particular country have more quality than a particular, on another country. So they are more expensive than each other, the manufacturers what they do that they find a particular raw materials that have has passed the quality test and at least can still be affordable for their use.

Interviewer:
Okay. Thank you very much sir. So, which comp, which country does your company imports most of these raw materials from?

Response:
Like I said earlier, the raw materials that they import directly from themselves, most of these materials, there sources come from China, India, some experience come from Indonesia and some from US.

Interviewer:
Okay. Thank you very much sir. So, to the fourth question, how would you describe the affordability of raw materials in your organization? So under that we have three questions. The first one is are quality raw materials affordable.
Response: Yes, yeah, they are Affordable.
Interviewer: Okay. Thank you very much. Are your, can your organization, organization easily access them?
Response: Yes, it can be accessed
Interviewer: Okay Thank you very much. What are the factors affecting affordability of quality raw materials? What can you say are the factors affecting the affordability of the raw materials and how can they be solved?

Response:
Um, the, uh, factors affecting them, number one is, the, sourcing of fund, sourcing of forex this thing for it, maybe there's change in the country lets say probably it will affect the eventual cost by which the material will be coming with

Interviewer: Okay

Response: That's the number one issue, second factor affecting affordability is the markets competition of the final product after production, if the competitive market, materials gets more costly, some cost cannot be added to the final product based on the competition, that's another problem.

Interviewer: Okay.

Response: Um, another problem is, uh, if someone cannot get it from the usual source, let's say a particular country you have to source from another country, some products comes from, some materials comes from Australia too, some of these countries, their own might be more expensive than the one that, former sources.

Interviewer:

Okay, Thank you very much, sir. Then how do you think we, these problems can be solved. How can they be tackled?

Response:

Um, about which it can be tackled are uh, first if they are establish manufacturers of local materials in the country, it will solve majority of this problems to a large extent.

Interviewer:

Okay. Thank you very much sir. So, what can you say is the major factor affecting, um, establishment of a local manufacturer in Nigeria? Generally? What, what can you say is the major factor that is affecting, establishing a pharmaceutical, um, plant that can produce all these raw materials in the country?

Response:

The number one thing is to, uh, the technical know-how, like raw materials must be of high standard, since it's the, they have to be of high standard, that one requires a lot of certifications from international certification before that can be achieved, some have been taking step in establishing something like that or I feel like there are still some things they are battling with as regard, how to maintain the level of standard been required to establish, um, such factory. Another thing could be the processing involved, the actual, some processing involves synthesis sometimes thr=e raw materials involve are the raw materials from these sources and maybe in the country, the machine involve and like I said technical know-how, having a professional that can handle the, those raw materials

Interviewer:

Thank you very much sir. So, to the fifth question, what are the effect of high cost of quality raw materials on production capability, capacity rather as production capacity increased or decreased over time? Like, what are the effect of high cost of quality or materials on production capacity?

Response:

Uh , actually affecting production capacity, in that's, uh, while the raw materials, while raw materials have been able to produce a particular product, while the raw material are getting expensive, the manufacturers finds it difficult to produce such product, um, that's why some manufacturers are dropping production of some particular products because of the eventual price, they compare the cost of production and the eventual price by which they can sell the products, so if they feel like production is too cost, and that's that many product are been produced in the country before are now being imported, let's say from China, that's finished product.

Interviewer: Okay.

Response: So, that's where the problem is

Interviewer:

Okay. Thank you very much. And as production capacity increased or decreased over time?

Response:

Uh, well, you somehow can judge it in terms of, uh, uh, quantity and in terms of, uh, someone can judge in terms of layers of product and in terms of number of batches been produced of course, the larger productions, larger populations demand, has demanded for production of larger quantity of medications in the country, but at the same time there have been variance in the number of product been produce before and the one been produce presently, while this, actually in summary, several production manufacturing industries have sprung up in the country and I can see it's kind of a larger number of products in the country.

Interviewer:

Okay, so the next one is what is the measures in place to increase production capacity?

Response:
The measures in place by the government or who?

Interviewer:
Just, just generally, what are the measures in place to increase production capacity in your organization, in your company?

Response:
Um, measures in place to improve capacity, um, actually, there are some of these, have been trying to harness some of the, uh, some of the easiness or let me say some of the provisions bee made by the government and, which has been made by in other to join groups in Nigeria, to see how they can, uh, improve capacity, and there programs seminars been made as regards getting more materials for production of pharmaceutical industry, there is a program that happens yearly, they call it Copac West Africa, like, um, Indians, Chinese, all of them came around and other manufacturers in west Africa, to see how they can, it's like a meeting between the manufacturers of raw materials, especially in packaging area and the local manufacturers in Nigeria.
Interviewer: Okay
Response: To try and discuss how they can increase capacity production in the country

Interviewer:
Okay. Thank you very much sir. Then also, what can you say is the, or are the measures in place by the government of Nigeria to increase production capacity or the pharmaceutical industry or sector?

Response:
Uh, the government capacity be like, there was a time they advocate for a deduction of taxes been levied on this manufacturers, the time they, uh, discussion about providing them, um, forex, mentioned getting dollars or foreign exchange to procure some foreign material is a

challenge, but there is a time there was a question about providing them forex to import the raw material.

Interviewer:

Okay, thank you Very much sir. So then what can you say is the major impact of economic recession we have in the country currently on manufacturing industries in Nigeria pharmaceutical manufacturing industry in Nigeria?

Response: What are the major?

Interviewer: What can you say are the major, um, what, uh, what can you say are the major factors that we can say as that has come out, that we can say has affected the pharmaceutical industry, in terms of the economic recession we currently have in Nigeria, like, what can you say is the effect of economic recession we have in Nigeria on pharmaceutical manufacturing industry?

Response:

The response about the, it has impacted it because the raw materials getting, they are costly more than what they are before, since the dollar to naira rate have, um, the situation has impacted, since you are a trying to get ypur product outside the country, the siruation have actually cause things to get more costly and that one have affected getting this raw materials easily.

Interviewer:

Thank you very much. And to the last question, what will you proffer as the solution faced by the pharmaceutical industry, in terms of the assets to quality and affordable raw materials to improve production capacity in your organization? Like, what can you say? What can you say is the solution, what solution can you proffer to the pharmaceutical industry in terms of the challenges they face in terms of access to quality and affordable raw materials, what solution can you proffer?

Response:

Uh, the solution which I can proffer is, uh, reaching out, uh, to, instead of relying on some of these, um, local, on some of these, um, dealers on raw materials, like two or three companies can come together and buy directly from the, um, the international manufacturers of this raw material, another solution is that if Nigeria pharmaceutical can come together, they can see a

way where they can talk to government for one or two local manufacturer of raw materials can spring up. There was a time they are talking about common starch that it's not, no manufacturers of starch in the country, that since its common to most of the, how they can see they can start the production of this raw material in the country.

Interviewer:
Okay. So that's, that's makes us come to the end of the interview. Thank you very much for you for your time and for your insight

NISPO 2
Interviewer:
So good afternoon, sir. My name is Ojo Nathaniel Olatokunbo, i am carrying out this research interview. Sole for the fulfilment as part of the requirement for the fulfilment of the award of master's degree, uh, in Dublin, in Griffith College, Dublin Ireland. So, um, I have seven questions here and each of them they have so models some, um, some other questions. So I'll be asking you then you'll be responding some of the questions, they are open ended while others are closed. So please sir, no, you can, you can start by telling me your years in service, your educational level, then your grade sir and the name of your organization.

Response:
Okay. Uh, I work with Nigeria Airforce Drug manufacturing industry, air force base her in Ikeja in Lagos, I am the manager, I read microbiology and am a BSc holder and have been working or the past three years.

Interviewer:
Thank You very much sir. So, straight to the question, what are the challenges your organization is facing in terms of access to quality raw materials? So the first question is, are the raw materials accessible to your organization?

Response:
The raw material is very much accessible.

Interviewer:

Thank you, Are the raw materials locally, locally made or imported and if yes, if they are locally made, in what percentage?

Response:

The raw materials are all imported, they are not locally made.

Interviewer:

Okay, so, you are saying they are a hundred percent imported.

Response: Yes

Interviewer: Thank you very much, sir. So how easy has your organization been able to assess these raw materials?

Response:

Its easily accessible, yeah, there are a lot of vendors that sells raw materials in Nigeria, they are easily accessible

Interviewer:

Okay. Thank you very much. So, so what are the problems your organization is facing in terms of access to quality raw materials?

Response

Key problems we are facing in accessing quality raw material is cooperation in when you want to buy it and the second challenge is logistics problem, moving it from one point to the other location, how traffic and the rest are in Lagos, to be to cushion the details, you can't easily access raw materials.

Interviewer:

Okay, thank you very much, sir. So what are the challenges undermining the capacity of

production in your organization in terms of policy financial and access to qua and access to these or materials?

Response:
Um, If we can access the raw materials

Interviewer:
yes, like the challenges undermining affecting the capacity of production in your organization. Um, in terms of the policy, maybe government policy, Um, financial, the financial cost aspect of your production and in your access to raw materials, you need to talk about does the policy and financial, because you've talked about the access to raw materials.

Response:
When the regulatory body try to approve, accessing and producing anything, me I believe it can be effective and give approval on time because there is a lot of laboratory testing and checking of the and the inspection, these are the things that can delay or undermine the capacity to give approval, even the quantity of what you produced must be approved based on capacity of your outlet and machine, long permission of approval can affect your output. Another thing that can affect production capacity is power here, when you don't have , um, a constant power generating, uh ,uh, body that giving power and you keep on using diesel, there are some machine that generator cannot power, there are some machines you need to keep them on, they need constant power supply, because they have to, there are other things that affects production, experience manpower is another factor, that's how we can equip at local challenge, when you don't have experienced manpower, it affects your output
Interviewer:
Thank you very much sir. So, the next one is our quality raw materials in your own opinion are they expensive.
Response:
Yes they are
Interviewer:
Okay, and where are the raw materials mostly imported from
Response: China and India

Interviewer: Thank you very much. How would you describe the affordability of raw materials in your organization? Are quality raw materials are affordable to your organization.

Response:

Um, based on market demand, these raw materials are starkly used with us, because we knows every raw materials is in our company because of the use so we can go for averagely affordable.

Interviewer:

Thank you very much sir, So can your organization easily assess them these raw materials? Can you access them easily? Yes or no, or maybe fairly

Response: Yes we can access them

Interviewer:

Thank you very much sir. So what are the factors affecting affordability of quality raw materials and how can these factors be, be solved? What are the factors affecting the affordability of quality raw materials and how can they be solved?

Response:

The factors affecting affordability is the demand from the people, if your brand is produces quality material yesterday which is expensive and if the people cannot afford it, you can't be producing what people cannot buy, so what affects the quality too is the demand, the demand from the people, because if the price of the things is high because of the quality is there the price will also be high and if the price is high the people cannot afford it, many people cannot afford to buy it in Nigeria, trying to say is that not many people can buy it there by making it high expensive taste.

Interviewer:

Thank you very much. So, um, and um, okay. What is the effect of high cost of quality raw materials on production capacity? What are the effects of high cost of quality raw materials on production capacity and how has the production capacity increased or decreased over time because of these effects?

Response:

Yes, quality raw material will make you to produce less, quality raw material will make you

to produce less because you cannot buy quality and produce large quantity because many people will not buy it, so most times when you buy quality, you are targeting a very few aspect of the population, and before you produce another one, the one you produced will be finished.

Interviewer:
Thank you very much. So, what are the measures in place to increase production capacity in your company? What are the measures in place to increase production capacity in your company?

Response:
In other to increase production capacity is apply more machines and employing more labors, these are things of production that could change in increasing capacity, you know the raw materials, they are constant, when you keep increasing your machine and manpower

Interviewer:)
Okay, Thank you very much, sir. So what, the last question? What will you proffer as solutions to the challenges facing the pharmaceutical manufacturing industry? Like what will you proffer as the solution or as a solution to the challenges facing the pharmaceutical manufacturing industry in Nigeria or in Lagos Nigeria

Response:
Number one, regulatory body should make it easier to get approval and lighter traffic in approval, you just make sure that you keep inspections and approval because those things can affect the time you take to, and getting all those should become one family and lets people be more interested in production and manufacturing, should be highly minimize for indigenous protection and government should create policies that will enhance local manufacturing, local content should be encouraged with, policies that , uh, enabling environment for them to thrive, enabling environment for conducive power supply, um, um, these are the things that can help production in Nigeria and also security that one too.
Interviewer:
Okay. Thank you very much sir

Miraflash

Good morning, my name is Ojo Nathaniel olatokunbo, I am carrying it this research interview as part of the r fulfilment for the award of master's degree program in Dublin, Griffith college Dublin in Ireland. The research topic is the study of the key challenges facing pharmaceutical manufacturing industries in Lagos Nigeria with emphasis on cost and access to quality raw materials, the interview consists of seven questions each of which carries sub questions, so I will be starting by you some questions sir. But before we proceed, I will like to know little about you, your educational level and your years of service, and the company you work with, RESP: thank you, for educational level I have heard a bachelor degree in Nigeria and masters in pharmaceutical chemistry, I work in the manufacturing sector of the pharmaceutical industry, I work as the CEO of the Miraflash Nigeria limited.

1.what are the challenges your organization is facing in terms of access to quality raw materials?

A. Are quality materials readily available to your company? RESP: the challenges we are facing currently is the non-availability of raw materials, most of the raw materials are not available locally, to purchase it we need foreign exchange and currently there is deficiencies in the foreign exchange in the country this make it a challenge to access raw materials in the pharmaceutical industry.

1b.are the raw materials locally made or imported if they are imported what percentage can you say they are imported? RESP: they are imported, about 80% are imported and maybe 20% locally made

1c. How easy has your organization be able to access this raw material? RESP: it has not been easy access in in this raw material

1d. What is the problem your organization is facing in terms of accessing the quality of materials? Reproable of lack of access to foreign exchange, problem of easy access to the company,

2. What are the challenges undermining capacity of production in your organization in terms of the policy and financial aspects? RESP: lack of availability of raw material as at the time it is needed, it takes a lot of time when you have to bring in raw materials from another country.

2b. In your own opinion can you are quality raw materials expensive? RESP: yes, they are expensive

2c. Most of these materials which countries are they mostly imported from? RESP: mostly imported from India.

3. How would you describe the affordability of raw materials in your organization, these quality raw materials are they affordable? RESP: they are relatively expensive because of the issues attached to importation of these raw materials

3b. Can your organization easily access them, do you contact them directly or you use an intermediary on behalf of the organization to buy this Raw material from this country. RESP: it a combination, you have to use and intermediary with time when you are used to then you came later go to them directly.

4. What are the factors affecting the affordability of raw materials and what can you suggest are the possible solution to solve them. RESP: they major problems is non availability in Nigeria, solutions is for the government to facilitate the production of raw materials f or the pharmaceutical company locally In Nigeria.

5.what are the effects of the high cost of quality raw materials on production capacity generally and as production capacity increase or decrease over time in your organization and the effects of this high cost of quality raw materials on production capacity? RESP: it led to production of expensive product, because the cost of production is high definitely some of the products will not be affordable, as such it has reduced the demand and production as to reduce.

6. What is the measure in place to improve production capacity in your organization? RESP: we are trying to as much as possible to improve on the developing human capacity and and how to put in place strategy to reduce cost in other areas of production.

Interviewer: it is noted that several challenges are facing the pharmaceutical manufacturing industries in Nigeria so what would you suggest given 2-3 points to tackle this challenge facing the pharmaceutical manufacturing industries. RESP: 1. Let raw materials be manufactured locally.2.let there be provision raw materials at affordable rate.3. infrastructural development in the system 4.let there be political will from the government to support the pharmaceutical industries.

Interviewer: I will like to add another one. Power it affects production generally, can you say it has really affected your organization and of yes sir how can you say it has affected your organization? RESP: when I mentioned the political will one the government, power is part of what they are supposed to provide, power affect not only pharmaceutical manufacturing industries but other industries as well. So, the cost of power also affect the production capacity. It affects every facet of production.

Thank you this is the end of the research.