# Analysis of Customer Satisfaction and Drug Product Quality in exploring Pharmaceutical Manufacturing Operational Excellence in Lagos state, Nigeria.

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

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I certify that the dissertation entitled:
*" Analysis of Customer Satisfaction and Drug Product Quality to improve Pharmaceutical Manufacturing Operational Excellence in Lagos state, Nigeria*"
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 acknowledgment is given.

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**Abstract**

The thesis analysed customer satisfaction and drug product quality which are both elements of Operational Excellence in the pharmaceutical manufacturing industry in Lagos state, Nigeria through quantitative and qualitative research methods (a questionnaire-based survey and phone interviews). The perspectives of drug consumers and NAFDAC regulatory personnel as regards satisfaction with pharmaceutical products, factors influencing customer satisfaction, level of drug product quality and factors affecting drug quality were evaluated to ascertain the state of Operational Excellence of the local pharmaceutical manufacturing industry and promote recommendations for its improvement.

Both groups of regulatory personnel and customers were compared to determine their perspectives on the quality of drug products and level of satisfaction with locally manufactured drugs in terms of purity levels, appropriate drug components, drug efficacy, safety, availability, affordability and packaging. A total of 280 out of 309 participated in the survey, of which 202 (72.1%) were customers and 78 (27.9%) were NAFDAC regulatory personnel. Interestingly, only 14 (5%) respondents evaluated the overall quality of locally manufactured drugs to be poor with 10 (12.8%) of them being regulatory personnel, while 55 (19.5%) respondents were generally indifferent about the quality of drugs in the state, 40 (51.3%) of them being regulatory personnel. The larger percentage, 211 (75.5%) respondents were either of the opinion that drug quality in the state was somewhat good or very good. Of this category, 69 (24%) respondents, all of which were customers believed locally manufactured drugs in the state were 100% good quality drugs. From the analysis conducted, 193 (68.9%) of the respondents were satisfied with the price, availability, efficacy and safety of locally manufactured drugs in Lagos state, 36 (18.7%) of which were regulatory personnel and 147 (76.1%) being customers. The rest were either indifferent or unsatisfied of which the majority were indifferent.

Inadequate funding of the industry by the government to improve standard of operations and insufficient regulatory checks on manufacturing processes and products remained the most challenging factors affecting product quality of locally manufactured drugs in the state while inadequate training of the manufacturing staff to ensure compliance with standard procedures was the least reported challenge. Frequent regulatory checks on pharmaceutical manufacturing companies, indefinite shutdown of consistently defaulting pharmaceutical manufacturing

companies and seizure or destruction of substandard products will be effective in ensuring utmost quality of locally manufactured drug products in the state. Adequate product evaluation and testing by regulatory authorities before products are released into the market and provision of customer complaint platforms by pharmaceutical manufacturing companies are sustainable recommendations to improve product quality and customer satisfaction with locally manufactured drugs in Lagos, Nigeria.

*Key Words: Customer satisfaction, Product quality, Operational Excellence (OPEX), National Agency for Food and Drug Control (NAFDAC), Pharmaceutical manufacturing industry.*

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**ABBREVIATIONS**

QC- Quality Control.

QA- Quality Assurance.

OPEX- Operational Excellence.

FDA- Food and Drug Administration.

KPI- Key performance indicator.

DMAIC- Define, Measure, Analyse, Improve, Control.

WHO- World Health Organisation.

NAFDAC- National Agency for Food and Drug Control.

GMP- Good Manufacturing Processes.

API- Active Pharmaceutical Ingredient.

PCN- Pharmacists Council of Nigeria.

SON- Standard Organisation of Nigeria.

SOPs- Standard Operating Procedures.

OTC- Over the counter.

PMG-MAN Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria.

ECOWAS- Economic Community of West-African States.

GDP – Gross Domestic Profit.

R&D – Research and Development.

NAIP - Nigerian Association of Industrial Pharmacists.

NAGPP - Nigerian Association of General Practice Pharmacists.

PSN - Pharmaceutical Society of Nigeria.

# CHAPTER 1: INTRODUCTION

## 1.1 Overview

*"The starting point for improvement is to recognize the need."*

*- Masaaki Imai*

The global pharmaceutical Industry is a crucial aspect of the world's health sector that keeps undergoing various changes all in a bid to improve the industry. This is because its efficiency directly affects the health and vitality of humans and consequently, every other sector of the world's economy that requires human input or activity. Over the years, customer expectations of the pharmaceutical industry have evolved as the demand for healthcare services and products keep increasing due to population growth, worsened health conditions and outbreaks of new diseases. Customers now deem the pharmaceutical industry to be efficient when the industry can cater for their ever increasing and evolving needs effectively at an affordable rate.

Inasmuch as the aim of the industry is primarily to satisfy its customers, the fact that the stakes are higher in terms of customer expectations has made the pharmaceutical industry globally make changes to its perspective and definition of excellence and efficiency. Now, the effectiveness of the industry is measured by its ability to meet customer needs by the production of good quality drugs that are effective, safe, easy to afford, sufficient in quantity and readily available to meet the needs of the ever-growing population.

These customer expectations caused the industry to adopt a strategy which has been in use for a while and proven to help other business-oriented industries improve on their operations in such a way that every aspect of their system was enhanced and their operations were more cost effective while they maximized profit. This strategy known as Operational Excellence (OPEX) had the potential of meeting the demand of customers which included quality, safety, efficacy and affordability of pharmaceutical products.

Various available definitions try to explain what quality drugs or good quality pharmaceutical products are. The general deduction derived from these definitions in summary shows that quality drugs are drugs which are efficacious and safe for human use (Jochem and Landgraf, 2010).

However, drug quality as regards meeting regulatory standards of the pharmaceutical manufacturing industry is an important and more specific aspect that determines the efficiency of the industry to a very large extent. This major quality-determining factor has been a huge challenge to the industry in Nigeria as there are various environmental, financial and operational bottlenecks limiting manufacturing companies from being able to fully comply and meet up with laid down manufacturing standards (D'souza et al., 2007).

The pharmaceutical industry is a very broad and complex industry both at the international, national and even individual company levels. A standard pharmaceutical company comprises of the:

- Raw material department
- Quality Control department (QC)
- Quality Assurance department (QA)
- Engineering department
- Research and Development department
- Packaging department
- Clinicals department
- Regulatory Affairs department
- Sales and distribution department
- Manufacturing department.

### 1.1.1 OPERATIONAL EXCELLENCE

A state of OPEX in any industry is when all the activities carried out in the industry is highly optimized with insignificant or entirely no form of wastage. It is when products are manufactured and supplied at the time needed and not in excess, with employees trained and motivated to make positive changes needed to support and improve customer satisfaction while ensuring the company maximizes profit and performs efficiently.(Friedli and Bellm, 2013)

Operational Excellence (OPEX) as defined by the institute of Operational Excellence, is when all the staff in an organisation work towards increasing the flow of value to customers as well as fixing that flow when it breaks down. It ensures that the level of efficiency, quality and speed keeps

increasing and improving while cost decreases. In other words, it ensures that all departments of the industry where it is applied keeps improving. (Found et al., 2018)

However, the introduction of Operational Excellence into the pharmaceutical industry's system is still in its early stages as major initiatives were only implemented around 10 - 15 years ago. Compared to other industries, the pharmaceutical industry was not so quick to adopt the concept of Operational Excellence and other programs that encouraged continuous improvement due to the complexity and rigidity of the industry. At the end of the 19$^{th}$ century, just few actions with very limited scope had been taken in this regard. However, in the first decade of the 20$^{th}$ century, OPEX gained more acceptance after the positive impact it had on improving the efficiency of the industry was noticed. Since then, OPEX has become a priority for almost all pharmaceutical manufacturing companies.

The U.S. Food and Drug Administration (FDA) officially approved and encouraged serious Operational Excellence efforts to be implemented during a meeting of the scientific advisory board in the year 2001. At that time, the increasing number of post-approval manufacturing supplements was a major challenge to the agency. This frequent occurrence of post-approval changes made it difficult for the FDA to carry out their inspection as required. It also showed that the industry was lacking in the scientific mastery of its own production processes hence, the need for the implementation of OPEX (Lee et al., 2015).

### 1.1.2 TOOLS OF OPERATIONAL EXCELLENCE

Since Operational Excellence has been proven to enable the improvement of manufacturing companies, it is expedient to be able to measure the rate and amount of improvement being made and the areas that are improving. Improvement is measured by balanced performance metrics comprising efficiency and effectiveness, thus, providing a mutual basis for an improvement evaluation. These tools refer to key performance indicators (KPIs) that can be used to measure the effectiveness of implemented OPEX business models. (Torkko et al., 2014)

Some business models designed for the improvement of the overall Operational Excellence of an industry such as the pharmaceutical industry, also come with the advantage of measuring these improvements as they occur. Examples are the lean six sigma (DMAIC) model, Porter's competitive analysis (also known as Porter's five forces) and the Balanced Score Card.

Some other Key Performance Indicators (KPIs) that are used in the pharmaceutical manufacturing industry to measure the improvement of Operational Excellence include:

- Decrease/increase in the number of defective products after the end of each batch of production.
- Decrease/increase in the number of complaints gotten from customers.
- Decrease/increase in the number of failed batches.
- Decrease/increase in the number of FDA warning letters issued to companies as regards compliance and quality issues.
- Decrease/increase in the cost and time of production. (Rusev and Salonitis, 2016).

### 1.1.3 ELEMENTS OF OPERATIONAL EXCELLENCE

Every industry is made up of certain operational elements and the efficiency of these elements determines the level of OPEX in the industry. It is imperative to know that different companies place different levels of priority on these elements based on their efficiency needs, company goals, company structure and the type of industry they are. The major elements that always require improvement in the pharmaceutical industry to ensure business success include:

- *Leadership* – This aspect of the industry and element of OPEX improves the industry's overall output by ensuring; leaders develop organisational alignment and focus on sustainable and achievable goals.
- *Customers* – This helps to understand present and future customer needs. These predictions, observations and indications are also used to drive organisational design, strategy and services to ensure customer satisfaction at all times.
- *Systems thinking* – It focuses on continuously improving the industry's system.
- *People* – It focuses on developing and valuing workforce capability so that their skills and creativity can help to restructure and improve the industry.
- *Continuous improvement* – Focuses on developing agility, adaptability and responsiveness based on a culture of continual improvement, innovation and learning.
- *Information and knowledge*: Improve performance through the application of acquired information and knowledge to enhance operational decision making.

- *Corporate and social responsibility* – It focuses on ensuring industries are ethically, socially and environmentally responsible.
- *Product*: Focuses on ensuring pharmaceutical products are efficacious, safe, of good quality, meets all necessary regulatory standards and satisfactorily meets the customer's needs.
- *Sustainable results* - Focuses on outcomes and values that can be sustained.

All the elements mentioned above are referred to as OPEX elements or principles as their improvement or inefficiency affects the Operational Excellence of the pharmaceutical manufacturing industry.

### 1.1.4 EMERGING MARKETS

Emerging markets are the major growth drivers of the pharmaceutical industry worldwide as seven out of ten people live in these markets today and every year, 100 million children are born there. Based on the documented characteristics of an emerging market, it has been shown that Nigeria as a country falls in the range of these markets. Pharmaceutical sales in emerging markets was estimated to be $220 billion in 2018 as the life expectancy in these markets are among the lowest in the world and their healthcare infrastructure is poor. As a result, though the opportunities in these markets are huge, so are the challenges.

The formulation of a design for OPEX in emerging markets will only be effective when the characteristics of these markets are well considered. Table 1 shows some of the characteristics of emerging markets that constitute the major external, environmental influences on manufacturing sites.

| CHARACTERISTIC | MAJOR INFLUENCES |
|---|---|
| **Economic** | • High growth rates, market fluctuations and inflation<br>• Weak financial markets<br>• Dependence on few industries only high income disparities between traditional and industrial sectors |
| **Technological** | • Low spending on technology both per GDP and absolute<br>• Low share of R&D workers per population<br>• Low percentage of autonomously manufactured high-tech products |
| **Infrastructural** | • Excessive amount of institutional voids<br>• Insufficient recognition of the needs for improving soft infrastructure<br>• Deteriorating and unreliable hard infrastructure |
| **Sociocultural** | • Ethnic and cultural fragmentation<br>• Substantial cultural differences to advanced countries<br>• Rapid urbanization |
| **Political** | • High influence of regulatory bodies and institutions<br>• Political instability<br>• Protectionism, tariff and non-tariff barriers, interventions by governments |
| **Nature of business system** | • High relevance of business relationships<br>• High rate of corruption<br>• Seller markets |

*Table 1: Summary of emerging markets' major influences on manufacturing sites* (Bellm, 2015).

The OPEX strategy for every industry therefore varies based on the above listed characteristics of the type of market it is, the type of industry or company, the location and cultural belief system of its customers, the aim or goal of the industry and some other specific attributes of the company or

industry. To achieve operational efficiency at a cost-effective rate, the concept of OPEX is quite flexible as it allows the use of business models that focus on the main elements and market characteristics that exclusively affect a company's efficiency.

### 1.1.3 NIGERIA'S PHARMACEUTICAL INDUSTRY

Nigeria's pharmaceutical industry is made up of over 100 pharmaceutical manufacturing companies which are scattered across the 36 states of the country. However, not all these companies are active manufacturers and not all of them are key players in the industry. The Nigerian Pharmaceutical market report has listed the following companies as the key manufacturing companies in the market from an overall list of over 100 companies.

- Swiss Pharma Nigeria Limited (Swipha)
- May & Baker Nigeria Plc
- Emzor Pharmaceutical Industries Limited
- Fidson Healthcare Plc
- Mopson Pharmaceutical Limited
- Neros Pharmaceuticals Limited
- Glaxosmithkline Consumer Nigeria Plc (GSK Nigeria)
- Chemiron International Limited
- Zolon Healthcare Limited
- New Heights Pharmaceutical Limited (Yahaya, 2019).

Lagos state alone houses 50% of the key market players with over 50 manufacturing pharmaceutical companies in total. According to extant political records, Lagos state is the nation's economic and commercial capital. It is home to 70% of the country's total industrial investment and 65% of its commercial activities, It therefore houses the majority of Nigeria's pharmaceutical manufacturing companies.(Lagos State Government, 2020).

Studies and global economic reports have shown that the pharmaceutical industry has tremendous potential because it is an important element in the economic growth and development of every nation due to its direct impact on health and consequently, labor productivity. Apart from its immense contribution to ensuring a healthy and productive workforce, it also provides good

employment opportunities to citizens and contributes significantly to the gross domestic product (GDP) of all countries, thereby helping to save and also generate foreign exchange for countries (Ephraim Okoro, 2017).

The Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN, 2010) also asserted that the Nigerian pharmaceutical sector has the potential to be a leader in the production and distribution of pharmaceuticals in Sub-Saharan Africa, exporting her products to various ECOWAS countries. There is therefore a need for manufacturers, national regulators, wholesalers and retailers, government ministries and other stakeholders to put in additional effort to create an enabling environment to exploit the full potential of this sector in Nigeria.(Efayena Obukohwo et al., 2018).

However, even with the potential this sector holds, The World Health Organisation during its evaluation of the world's health systems ranked Nigeria as 187$^{th}$ among 191 member states using performance indicators such as; overall level of health, distribution of health in populations, responsiveness and distribution of finance. Clearly, this indicates that there is much to be done to improve the health sector in Nigeria (Magarya, 2017). This poor rating of the industry has been attributed to lack of adequate funds, poor general infrastructure (especially energy), insufficient standard equipment for production and storage of pharmaceuticals, lack of adequate regulatory checks to ensure compliance with standard operating procedures, shortage of well trained workforce, increase in the cases of falsified medicines gaining entry into the country's pharmaceutical market, heavy dependence on import of pharmaceutical raw materials and inputs and many other factors (Odinaka Anudu, 2019).

As a result of the poor efficiency level of Nigeria's pharmaceutical industry, there was a dire need for the integration of the concept of Operational Excellence (OPEX) into the industry's operations as the concept had the potential to tackle the quality and efficiency challenges faced by the industry. Therefore, Operational Excellence (OPEX) was introduced to help improve the industry's operations especially the manufacturing sector of the industry.

### 1.1.4 REGULATION OF NIGERIA'S PHARMACEUTICAL MANUFACTURING INDUSTRY.

The regulation of Nigeria's pharmaceutical industry is carried out by the National Agency for Food and Drugs Administration and Control (NAFDAC). The agency plays a huge role in overseeing and regulating the activities of pharmaceutical manufacturing companies in the country. NAFDAC is responsible for the registration of new and approved medications as well as monitoring manufacturing processes and drug importation. NAFDAC is also responsible for issuing marketing approval for pharmaceutical products sold in and outside the country after the evaluation of their quality has been carried out. Currently, there are about 4,363 registered medicines in the country. The agency also carries out periodic inspection of drug manufacturing facilities to ensure compliance with Good Manufacturing Practices (GMP) and publishes the list of registered drugs in the official gazette. NAFDAC is also in charge of regulating the promotional contents and advertisement of drugs, including the pre-approval of package inserts. The agency has national laboratories and minilabs which it makes use of to carry out drug quality tests to ensure new drugs waiting to be released to the market and those already in the market undergoing post-market approval tests are all of good quality (Federal Ministry of Health, 2010).

### 1.1.5 IMPACT OF CUSTOMER SATISFACTION ON THE PHARMACEUTICAL MANUFACTURING SECTOR.

The goal of the pharmaceutical manufacturing sector is to manufacture products that meet the needs and satisfaction of its customers. This is because without customers, there will be no market and lack of sales will consequently lead to the closedown of the industry. Ensuring customer satisfaction is therefore one of the major aims of the pharmaceutical manufacturing industry.

Various studies that have been carried out on the needs and expectations of Nigerians from the pharmaceutical manufacturing industry in the country have shown that, consumers of pharmaceutical products have insistently raised concerns regarding the safety, efficacy, availability, affordability and quality of pharmaceutical products in the country. Based on these observed trend, it has been evaluated that to successfully satisfy customers, products produced by the industry have to be safe, effective in treating the ailments for which they are administered, affordable for the consumers and readily available.

The observed aftermath trend following the use of unsafe drugs with life threatening adverse reactions has been that implicated manufacturing companies in most cases recorded lower sales and incurred losses as a result of losing the trust of customers by producing poor quality drugs. For cases where these medications were ineffective in treating the intended ailments, apart from the implicated manufacturing companies experiencing a reduction in product demand which consequently led to serious drop in sales, NAFDAC the regulatory body in charge of monitoring the quality and safety of pharmaceutical products has also had to intervene in cases of compromised safety and drug inefficacy. As a result, such companies have lost more revenue due to NAFDAC suspending their production activities for proper investigation to be carried out to ascertain if the implicated companies are truly defaulting and why they are if so. They have also lost revenue due to the confiscation of their faulted manufactured products by NAFDAC thereby causing such companies to lose a huge part of their revenue when NAFDAC has to intervene in product quality issues.

Customer satisfaction is therefore a significant element in determining the Operational Excellence of Nigeria's pharmaceutical industry because the inability to meet customer demands is ultimately a threat to the survival of pharmaceutical manufacturing companies in the country as the demand rates by unsatisfied customers will keep dropping until such customers find better quality products that satisfy their medical needs and that can totally replace substandard products. In addition to the drop in sales as a result of unsatisfactory customer experience, further drop in sales will most likely occur as product referral to potential customers by unsatisfied customers will reduce and be replaced by product disapproval where potential customers are dissuaded from using implicated medications based on the experience of unsatisfied customers (Akenbor, 2014).

### 1.1.6 IMPACT OF PRODUCT QUALITY ON THE PHARMACEUTICAL SECTOR.

Product quality is measured by the combination of various factors such as: the safety, efficacy, availability, affordability and tested compliance level of the products by certain national and international regulatory bodies. NAFDAC not only carries out manufacturing process inspections, they also test pharmaceutical products to ensure they have the right type and amount of API's and excipients and that they contain no impurities.

NAFDAC's evaluation of the quality of pharmaceutical products at the national level is the ultimate and all other pharmaceutical regulatory bodies such as the PCN are subject to NAFDAC. This makes a lot of customers trust the judgement of NAFDAC as regards the quality of pharmaceutical products.

Over the years, NAFDAC has confiscated a lot of pharmaceutical products in the country and suspended quite a number of manufacturing companies from operation till they met the required standards of operation or till adequate investigation had been carried out on implicated products produced by such companies. The organisation has also closed down few manufacturing companies for the production of falsified and counterfeit drugs. This shows how costly the manufacture and distribution of low quality drugs can be, as implicated manufacturing companies lose revenue when NAFDAC has to step in because of the production of substandard drugs.

### 1.1.7 CHALLENGES AFFECTING OPERATIONAL EXCELLENCE IN THE PHARMACEUTICAL MANUFACTURING SECTOR.

The issue of process understanding by employees all across the various manufacturing companies in the country is a major and common challenge, as a sizeable number of employees are not adequately trained to ensure they fully understand the aspect of the manufacturing process they handle. As a result, various manufacturing errors occur which slows down manufacturing processes, leading to the production of substandard products, or increasing cost and production time. This factor generally affects the quality of the manufacturing process and product. Also, the lack of complete product understanding among manufacturing companies where clinical trials carried out on new drugs are sometimes inadequate making human reactions to such drugs not fully understood and the inefficiency of Post-Market Authorization studies have consequently made the mode of action and side effects of certain drugs all through their shelf life not fully understood. Therefore, certain adverse effects of some drugs are not discovered until few years after they hit the market.

Furthermore, there is the challenge of defining quality requirements for pharmaceutical companies especially for companies involved in offshoring productions. This is because there are usually discrepancies and contradicting quality requirements between NAFDAC and other international

regulatory bodies. Quality requirements therefore sometimes differ and makes it very difficult for offshoring companies to efficiently satisfy national and international standards.

Implementing optimization projects such as cutting down on cost, product release time and other forms of wastages is another challenge faced by the industry. This is because it is usually difficult to implement these projects without affecting every other aspect of the manufacturing system. Consequently, it will take time and extra cost before companies fully adjust to the new changes caused by the implementation of such projects. This therefore makes it difficult for companies in the country to implement certain operational improvement projects.

In individual companies, OPEX has also been affected by other factors such as differing opinions on what is critical at the leadership levels of these companies with operators changing process settings when it is not necessary or operators keeping process settings when change is necessary. (Pharmapproach, 2019). For the pharmaceutical manufacturing industry in Nigeria to overcome all these challenges and improve its operational efficiency as regards customer satisfaction, product quality and its economic value, adequate studies have to be carried out on the elements influencing Operational Excellence in the industry and how these elements can be improved so that the industry can attain its full potential.

## 1.2 RESEARCH PURPOSE

There are quite a number of available studies on Operational Excellence and its determining factors in the pharmaceutical sector of developed countries, but there are very few of such studies on developing countries and emerging markets like Nigeria. Though the growth of the Nigerian pharmaceutical industry has been featured in few studies, based on research, a comprehensive study on the Operational Excellence of the industry and it's determining factors have however not been carried out.

This research study was therefore undertaken with the aim of filling this gap through the analysis of the Operational Excellence in the manufacturing sector of the pharmaceutical industry in Lagos state, Nigeria by focusing on 2 major elements or determining factors of the industry's efficiency which are;

- **Customers**: This study focused on the satisfaction of direct consumers of pharmaceutical products with drugs produced in the state and was targeted at people (including regulatory officials) who had at one time or another used drugs produced by the pharmaceutical manufacturing industry in Lagos state.
- **Pharmaceutical products**: This study focused on the quality of drugs which included all the range of drugs produced in the state.

The researcher also assessed the relationship between these elements and the Operational Excellence of the pharmaceutical industry in Lagos state, Nigeria.

## 1.3 SIGNIFICANCE OF THE STUDY

Over the past two decades, the concept of OPEX has been integrated into the activities of many industries. However, scientific literature on OPEX practice implementations in pharmaceutical manufacturing industries in Africa as a whole and Nigeria more specifically is still scarce. The state of OPEX in the pharmaceutical industry cannot be evaluated from reports of OPEX in other industries as conclusions from other industries might be misleading because the elements and mode of operations of industries differ. Research studies are therefore necessary to assess the obtainability and sustainability of the concept of OPEX within the context of pharmaceutical manufacturing in Nigeria. This study is therefore significant in providing information on the state of Operational Excellence as it focuses on the pharmaceutical manufacturing industry in the most economically crucial part of Nigeria ( Lagos state) by assessing two important elements of OPEX (products and customers) affecting the business success of the industry in Lagos state, Nigeria.

The conclusion of this research is also important as it will shed more light on the main factors affecting these two elements in Lagos state's pharmaceutical industry with recommendations that can be made to improve both elements and consequently the Operational Excellence of the industry in the state.

## 1.4 RESEARCH OBJECTIVES

1. To analyse the state of Product quality and customer satisfaction as key elements of Operational Excellence in Lagos, Nigeria.
2. To identify the factors that are affecting customer satisfaction and product quality.

3. To make recommendations that will be effective in improving both elements

## 1.5 RESEARCH QUESTIONS

1. What is the state of customer satisfaction and product quality of locally manufactured drugs produced in Lagos, Nigeria?
2. What are the main factors affecting drug quality and the satisfaction of customers with drugs manufactured in Lagos state?
3. What Recommendations can be made to improve these elements and the Operational Excellence of the industry?

## *HYPOTHESIS*

*Null Hypothesis*: Operational Excellence in the pharmaceutical manufacturing industry in Lagos state from product quality and customer satisfaction analysis is below average and needs significant improvement.

## 1.6 CONCLUSION

Product quality and customer satisfaction are major elements that contribute immensely to the Operational Excellence of every pharmaceutical manufacturing industry. Regulatory bodies in Nigeria such as NAFDAC continue to ensure pharmaceutical manufacturing processes and products are of standard quality by ensuring companies comply with the laid down Standard Operating Procedures and Good Manufacturing Practices, while customer complaints and product demand levels are indicators of how satisfied customers are with pharmaceutical products. These indicators also contribute their own quota in propelling manufacturing companies to improve their product quality which in turn will improve the level of customer satisfaction and ultimately, the Operational Excellence of the industry. An understanding of both elements of quality and customer value will help understand their significance and impact on Operational Excellence in the pharmaceutical manufacturing industry in Lagos state.

# CHAPTER 2: LITERATURE REVIEW

## 2.1 INTRODUCTION

*Do not find customers for your products, find products for your customers*

- *Seth Godin*

It can be said that OPEX in Nigeria is at a preliminary stage as companies are still in the process of exploring the possible advantages of the concept and tailoring the concept to suit their company needs and area of required improvement(Nelson, 2014).

The main concept of OPEX in its entirety was embraced but not fully implemented in any of the pharmaceutical manufacturing companies in Nigeria until late 2010. This was partly because implementing Operational Excellence (OPEX) had proven to be a huge challenge for manufacturing companies as it entailed changing the mode of operation workers were used to and ultimately changing their mindset towards continuous improvement. This challenge is particularly very typical in the highly regulated pharmaceutical industry which is known for its heritage of reluctance to change. OPEX in Nigeria was not integrated into the manufacturing industry until few years ago when pharmaceutical manufacturing companies were propelled to do so due to the high failure rates of their products during QC, QA and other regulatory monitoring tests as shown in the graphs below.

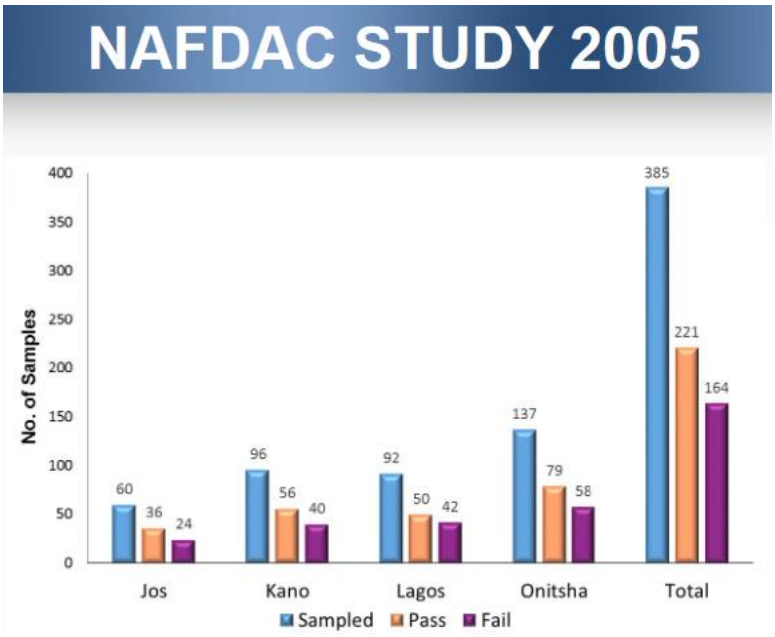


Figure 1: Statistical data on the quality of medicinal products in some states in Nigeria (Lagos state inclusive) (Nelson, 2014)

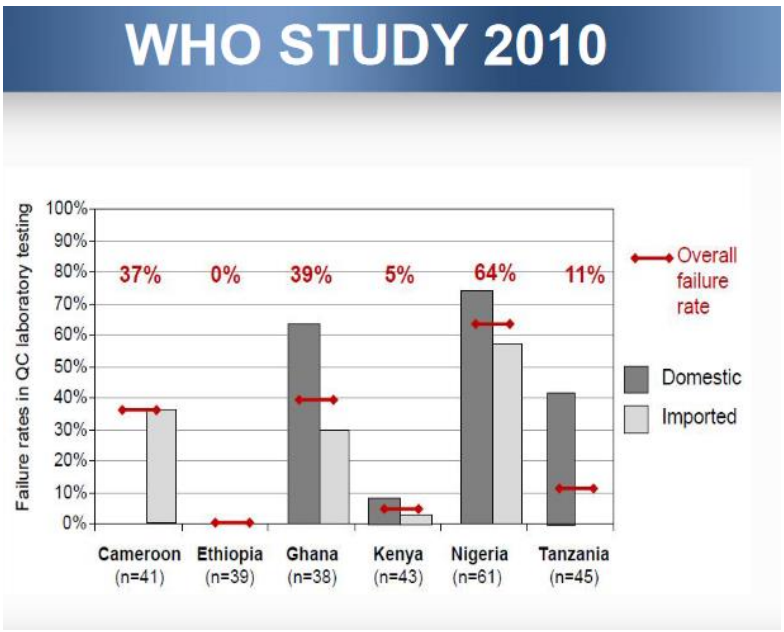


Figure 2: Failure rates of quality control (QC) tests carried out on drugs manufactured in Nigeria and some other African countries (Nelson, 2014)

## 2.2 CURRENT STATE OF CUSTOMER SATISFACTION AND PRODUCT QUALITY IN NIGERIA.

A review of studies carried out on the subject revealed that for decades, customer satisfaction reports on health products in Nigeria have been at very low levels because of the challenge of counterfeit and poor quality health products (Akenbor, 2014). The World Health Organisation (WHO) in 2006 further confirmed this by reporting that 70% of health products in Nigeria were fake or substandard (Writer, 2008). More so, the National Agency for Food and Drug Administration and Control (NAFDAC) estimated that 41% of drugs were counterfeit. This problem of substandard drug proliferation in Nigeria has affected the credibility of pharmaceutical companies and has been reported to exert very harmful effects on customer satisfaction (Akenbor, 2014).

A comparison of the study carried out by Iloh and his colleagues on patients and general consumers' satisfaction in relation to pharmaceutical products in Nigeria and a study carried out by Michael on the same subject (Iloh et al., 2012; Michael, 2017) showed variations in outcomes, reflecting differences in customer characteristics and experiences. These variations were due to the peculiarity of the regions in the country where the studies were carried out, the state of health and financial status of the people used in the study and many other factors. These studies however revealed that satisfaction can be influenced by the customer's socio-demographics such as age, state of health and financial status (Iloh et al., 2012; Michael, 2017). Both studies also revealed that varying proportions of patients had satisfactory levels ranging from 42% to 83% based on their experiences with drugs manufactured in Nigeria (Iloh et al., 2012; Michael, 2017).

As regards product quality, most research on poor quality drugs have focused on counterfeit drugs and failed to draw a distinction between illegal counterfeit products and legal substandard products (Kelesidis and Falagas, 2015). However, WHO has defined counterfeit drugs as medications with a false representation as regarding their identity and source while the organisation has defined substandard drugs as medications formulated by legit manufacturers but do not attain pharmacopeial standards because of inappropriate quality or quantity of APIs, excipients or manufacturing processes (WHO, 2020). This research work however evaluates whether legally produced medications in Lagos state are substandard in quality such as in terms of API proportions and purity levels in general.

A study of the peer reviewed literature by Taylor and Iloh on the quality of drugs produced by Nigeria's pharmaceutical manufacturing industry also showed variations in their results as the quality of drugs produced depends on the region or state the drug was produced, type of drug and company producing the medication, regulatory standards used in evaluating the quality and compliance of the medication and type of quality test carried out on the product (Taylor et al., 2001; Iloh et al., 2012). However, the reports gathered from reviewed literature on the quality of pharmaceutical manufactured products in the country all depicts that the cases of substandard products in the country is still very high with an overall estimate of 35 to 50% of drugs produced in the country being substandard (Taylor et al., 2001).

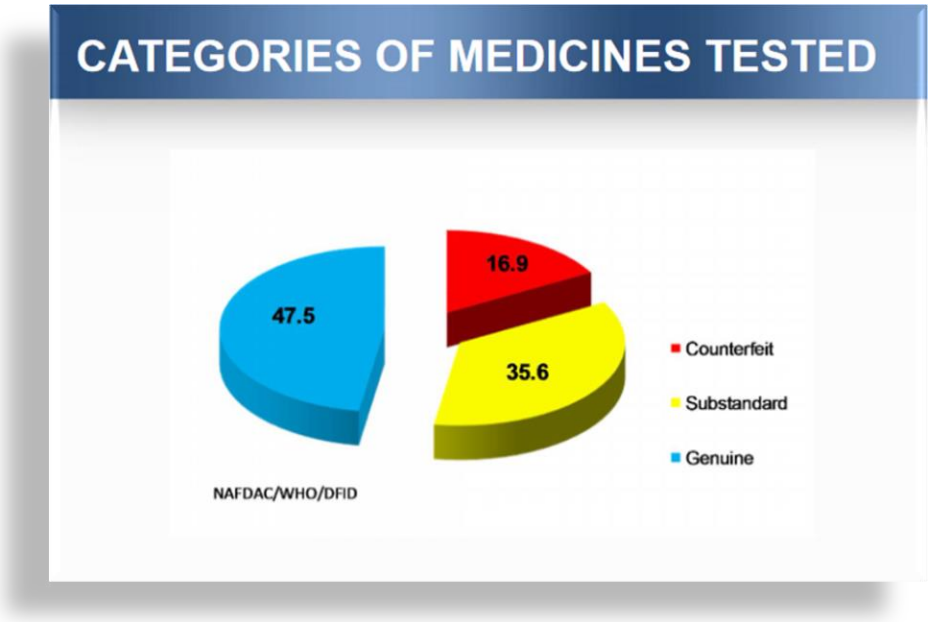


Figure 3: NAFDAC's Statistics of substandard and good quality drugs in Nigeria (Nelson, 2014)

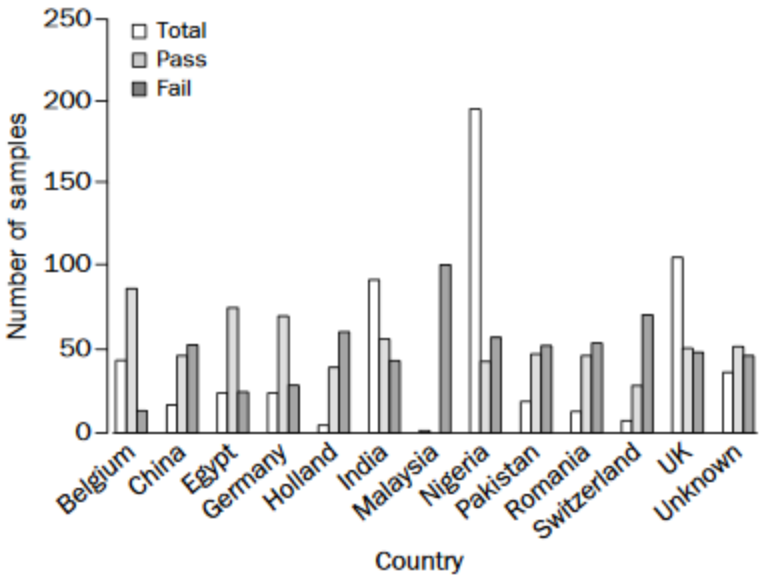


Figure 4: Distribution of country of manufacture (as stated on label) of drugs tested and proportion within and outside British Pharmacopoeia limits. (Taylor et al., 2001)

## 2.3 QUALITY OF DRUG PRODUCTS MANUFACTURED IN LAGOS STATE.

Report has shown that antimalarials, antihypertensives, antibiotics and antituberculosis drugs are part of the top selling drugs in Lagos (Usar, 2014). Studies on the quality of these drugs were therefore considered since they are part of the most frequently purchased drugs in Lagos.

A study was carried out in 2018 on the quality of antihypertensive drugs manufactured and sold in Lagos state with the aim of assessing the quality of antihypertensive drugs based on (1) the appropriateness of APIs as regards type and amount, which identified both falsely labeled drug samples and substandard samples; and (2) their level of purity when compared with the international pharmacopoeia guidelines, which helped to reveal substandard drug samples. The assessment of drug quality was on the basis that good quality drugs met the criteria for both the right type of API in the right concentrations and accepted impurity levels. A cross-sectional survey was carried out which focused on registered pharmacies in 6 selected local government areas in Lagos state. In each local government area, 17 pharmacies were sampled.

The result of the quality tests carried out on the sample products showed that of the 102 drug samples collected, 30 (29.3%) were falsely labeled, 76 (74.5%) were substandard,78 (76.5%) were of poor quality that is, contained inappropriate levels of APIs and impurities and 24 (23.5%) were of good quality. Among the falsely labeled drugs, 2 samples met standards set for purity while 28 did not. Among the 76 substandard drug samples, 28 were also falsely labeled.

This result shows that the prevalence of counterfeit and substandard antihypertensive drugs in Lagos state is quite high and treatment of this condition in the state will require efforts to monitor and assure drug quality. It also shows that regulatory authorities such as NAFDAC are not doing enough to ensure the safety and quality of drugs before approving them as other factors such as impurity content, amount of API and excipient are not adequately considered while determining drug quality.

In conclusion, the author determined that the number of substandard drugs produced in Lagos state is still quite high and that strict measures should be put in place by regulatory authorities in Lagos state to reduce the incidence of low quality drugs. The author also determined that there will be an increase in mortality rate and worsened health conditions in the state if adequate attention is not given to the quality of drugs produced in the state.(Ndichu et al., 2019)

Another study on antimalarial drug quality in Lagos state was carried out from mid-2007 to early-2010. Antimalarial drugs were purchased as samples from different pharmacies in Lagos at three different periods: October 2007, December 2008 and February 2010 and all the samples were tested using the Minilab protocol, which included disintegration and active ingredient assays, visual drug inspection and Raman spectrometry (Bate and Hess, 2010) .

The result of the study showed that the failure rate of the Minilab tests (TLC assay and disintegration) dropped tremendously from the 2007 to the 2010 sampling carried out in Lagos (35% or 7/20 to 10.3% or 9/87), there was a notable improvement in the visual inspection failure rates also from the 2007 sampling to the 2010 sampling: from 15% (3/20) to 6.9% (6/87).

This result showed that the quality of drugs in Lagos state was probably improving, as major decrease in drug test failure rates occurred over time with the means of assessment. However, quite a number of samples still failed the Raman spectrometry test than the Minilab protocol. The discrepancy was most likely caused by the two techniques measuring different aspects of the

medication and hence, according to the author the discrepancy may be the natural variation in these techniques.(Bate and Hess, 2010).

In the conclusion of the study, the author determined that there has been a progressive and impressive improvement in the quality of antimalarials produced in the state. And this might be as a result of the fact that antimalarials are the highest selling drugs in the country and a lot of deaths have been attributed to the sales of substandard and fake antimalaria drugs which has also increased the resistance of the causative organism over the years, special attention has therefore been given to antimalarial drugs produced in the country by NAFDAC in a bid to reduce the death rate in Lagos state and all other states in the country(Bate and Hess, 2010) .

However, this impressive result obtained over the period of 3 years does not rule out the fact that there are still counterfeit and substandard drugs in circulation as shown in the result which are responsible for deaths and the resistant strains being discovered and reported frequently. It however shows the quality of drugs in the state especially antimalarials is improving but that more effort is still needed for the total eradication of counterfeit and substandard drugs in the state.

A survey was carried out in 2001 to evaluate the pharmacopeial quality of drugs sold in Nigerian pharmacies specifically in Lagos and Abuja. The drug samples selected were representatives of the estimated overall drug usage in both states and they consisted of antimalarials, antibacterial and antituberculosis drugs. 581 randomly selected samples of 27 different drugs from 35 pharmacies in Lagos and Abuja, Nigeria were analysed for drug content by validated chromatographic methods. The results obtained were then compared with pharmacopeial requirements. An analysis of the result showed that 279 (48%) samples of the drugs were substandard and were not within set pharmacopeial limits as some of these drugs contained no active ingredient while most had either too much or too little outside the pharmacopeial limit (Taylor et al., 2001).

The author concluded that although related studies carried out on specific drugs might show very low levels of substandard drugs in some states in Nigeria, these results cannot be used in the general evaluation of the quality of drugs in such states except a wide range of different drug products are studied (Taylor et al., 2001). Based on the result of this study, the overall quality of pharmaceutical products in Nigeria is still quite poor. The quality of locally manufactured drugs

in any state can therefore not be adequately evaluated by carrying out studies on a specific medication as such results can be misleading just like the result of this study has shown in comparison to previously reviewed studies above. The pharmaceutical manufacturing industry in Lagos state and Abuja therefore needs to be improved on.

Furthermore, in evaluating drug product quality, a quantitative analysis survey with the use of questionnaires targeted at healthcare workers working in Lagos state showed that 52% (111/211) of all healthcare personnel indicated they had come into possession of a counterfeit or substandard drugs. Interestingly, doctors were the highest to come into possession of a counterfeit or substandard drug (63%, 26/41) and were most likely to destroy the drugs (88%, 23/26) when they did so. Pharmacists were the most likely to alert NAFDAC (44%, 14/32) or to report the incident to the manufacturer or supplier (34%, 11/32). Other healthcare workers were the most likely to do nothing (38%, 20/52). Interestingly, only 2 of 111 healthcare personnel who came into possession of a counterfeit or substandard drug alerted the police and only 17% (19/111) reported the incident to NAFDAC, compared to 55% (61/111) who destroyed the drugs.(Bate et al., 2014).

The study results further proved that substandard products were still very much in circulation in Lagos state as over half of the respondents had been in contact with substandard drugs and this indicates that the pharmaceutical manufacturing industry in the state is averagely efficient and has not obtained a good level of Operational Excellence, as the result of this study and other related studies have determined that the ratio of substandard products in the country is in the range of 35-50% which insinuates that almost half of the drugs in circulation in Lagos state are substandard. This study further shows that the problem of circulating substandard drugs in the state is not only the fault of the pharmaceutical manufacturing industry in the state and regulatory authorities that should monitor the activities and quality of products of the industry, but also the fault of healthcare workers too who fail to report these cases to NAFDAC, SON and other concerned regulatory bodies in the state as quite a number of substandard drugs will remain in circulation if the attention of these regulatory bodies are not drawn to them.

## 2.4 CUSTOMERS' SATISFACTION WITH DRUG PRODUCTS IN LAGOS STATE.

Various studies have been carried out in Nigeria on the evaluation of the quality of manufactured drug products in Nigeria from the regulatory and healthcare professionals' point of view. But very few studies have been carried out based on the final consumer's point of view. Irrespective of this,

a study carried out by Bate and his colleagues in Lagos state in 2014 on the evaluation of drug quality in the state based on customer experience gives an idea of how satisfied customers are with the drugs produced in the state.

They carried out a quantitative analysis with questionnaires distributed to pharmacy personnel, doctors, pharmacists and healthcare workers with questions designed to obtain information on customer reactions based on their experience with the use of drugs produced in the state. The result of the study showed that more than two-thirds 68%, (144/211) of healthcare personnel respondents indicated that patients did not "only buy drugs based on prescription." Of these, 70% (101/144) said that patients knew which drugs were "appropriate to buy" because they had used them before, 63% (90/144) because they asked the pharmacist and 53% (77/144) because they had seen the drug advertised. 62% (130/211) of all healthcare personnel reported that patients said they had bought an ineffective drug; of those, 28% (36/130) said that the patient bought the same drug again. When asked why drugs may have been ineffective, healthcare personnel said that 68%, (88/130) of patients did not use the drugs as prescribed, while the ailment was misdiagnosed in 50% (65/130) of the cases and/or the drugs were substandard or fake in 41% (53/130), or did not contain the right amount of active ingredient in 28% (36/130). However, 18% (23/130) of drugs were not effective because they were expired (Bate et al., 2014).

Based on the result of the study, a huge percentage of consumers were dissatisfied with the drugs they used. Although a larger percentage of dissatisfied customers did not use the drugs as prescribed, various possible factors were identified by the author such as the case of adverse drug reactions and discomfort which could have caused some of their non-adherence (Okuboyejo, 2014). The result also showed that quite a lot of substandard pharmaceutical products were still in circulation in Lagos state. (Bate et al., 2014)

In conclusion, the author determined that customer satisfaction in the state is quite low as more than half of the customers were not satisfied with the effect of the medications they used. The author further stated that the level of dissatisfaction of customers were due to the same quality issues the country has been battling for years with respect to substandard and fake products and that regulatory authorities still have a lot to do to ensure only quality products are in circulation which will consequently lead to improvement in customer satisfactory levels. (Bate et al., 2014)

## 2.5 IMPACT OF DRUG QUALITY ON THE INDUSTRY'S OPERATIONAL EXCELLENCE

A study was carried out on the evaluation of the economic impact of substandard drugs in majority of the states in Nigeria including Lagos state. For the study, a dynamic agent-based SAFARI (substandard and falsified antimalarial research impact) model was created to observe the impact of antimalarial use in Nigeria. The model was designed to gather information on children with malaria infections, their disease progressions, treatment outcomes and incurred costs. Scenario analyses was employed in analysing the impact of substandard and falsified medicines, especially antimalarial resistance. Possible interventions were also recommended to improve the quality of treatment.

The result of the study estimated poor quality antimalarials to be responsible for 12,300 deaths and between $890-$893 million in cost annually in Nigeria. If antimalarial drug resistance keeps increasing, it was simulated that current costs of malaria treatment could increase by 11% which would be around $837-$841 million. The northern regions of Nigeria alone accounts for 9,700 deaths with around $697-$700 million in total economic losses annually due to substandard and falsified antimalarials. (Beargie et al., 2019)

Based on the report from this study (Buckley et al., 2013), the economic impact of the production of substandard medication in the state is quite straining on the government. However, for reported, investigated and confirmed cases of poor quality or substandard products produced by some companies in the state, the resulting impact on the implicated companies ranged from; Loss of revenue from rejected, confiscated or destroyed product, loss of revenue as a result of suspended operations, revocation of production license, increased cost of production and reduction in profit depending on the severity of the damage caused.

These negative economic impact takes its toll on the overall OPEX of these companies as profit optimization while producing good quality medication is really not feasible due to the serious negative impact poor drug quality has on the industry .(Buckley et al., 2013)

| | | Burden of Malaria | | No Substandard or Falsified Antimalarials | | | Antimicrobial Resistance | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Baseline | 95% CI | Potential Savings | Percent Difference | p-value** | Additional Costs | Percent Difference | p-value** |
| Health Impact | Average Number of Cases | 24,000,000 | (23,995,800–24,002,700) | | | | | | |
| | Average Number Hospitalized | 147,000 | (146,900–147,700) | -33,300 | -23% | <0.001 | +19,200 | +13% | <0.001 |
| | Average Number with NS | 8,200 | (8,100–8,200) | -500 | -6% | <0.001 | +800 | +10% | <0.001 |
| | Average Number of Deaths | 78,000 | (77,800–78,300) | -12,300 | -16% | <0.001 | +7,700 | +10% | <0.001 |
| Economic Impact | Total Economic Impact | $7,760,000,000 | (7,729,178,500–7,800,795,900) | -$892,000,000 | -11% | <0.001 | +$839,000,000 | +11% | <0.001 |
| | Direct Costs | $401,000,000 | (400,398,700–401,399,000) | -$29,800,000 | -7% | <0.001 | +$44,600,000 | +11% | <0.001 |
| | Facility Costs | $267,000,000 | (266,997,100–267,799,200) | -$20,000,000 | -7% | <0.001 | +$29,900,000 | +11% | <0.001 |
| | Out-of-Pocket Costs | $134,000,000 | (133,206,400–133,795,100) | -$9,800,000 | -7% | <0.001 | +$14,800,000 | +11% | <0.001 |
| | All Productivity Losses | $7,360,000,000 | (7,328,289,900–7,399,886,800) | -$862,000,000 | -12% | <0.001 | $794,000,000 | +11% | <0.001 |
| | Short-Term* | $3,080,000,000 | (3,042,502,100–3,109,500,200) | -$203,000,000 | -1% | <0.001 | +$369,000,000 | +12% | <0.001 |
| | Lifetime | $4,100,000,000 | (4,086,615,200–4,113,241,200) | -$648,000,000 | -16% | <0.001 | +$405,000,000 | +10% | <0.001 |

ACT—Artemisinin-based combination therapies; CI—Confidence interval; NS—Neurological sequelae

* Short-Term productivity losses included caregiver time during care seeking and hospital stay, and opportunity costs incurred by the community-health worker program. Lifetime productivity losses included losses due to premature death and disability.

** Unpaired t-tests estimated the statistical significance of outputs ($p<0.05$) compared to baseline.

https://doi.org/10.1371/journal.pone.0217910.t002

Figure 5: Shows the economic implication of the production of substandard drugs (Beargie et al., 2019).

## 2.6 IMPACT OF CUSTOMER SATISFACTION ON THE INDUSTRY'S OPERATIONAL EXCELLENCE

The case study of the quantitative research work by Bate and his colleagues on customer reviews on drugs used in Lagos state as earlier analysed in this chapter helps to evaluate the impact of this element on the industry's Operational Excellence. The needed information was elicited from pharmacy personnel, including doctors and healthcare workers who filled the questionnaires for the study which was focused on customer behavior to used medications (Bate et al., 2014).

From the author's analysis based on results obtained, customer satisfaction influences the state of Operational Excellence of the pharmaceutical industry in Lagos state. This is because the efficacy and safety of drugs used by customers determines to a very large extent, if customers will be willing to use such medications again. More importantly, apart from companies advertising their products to get more customers, the author stated that quite a good percentage of profit and new customers made by pharmaceutical manufacturing companies in Lagos state comes from referrals

and recommendations made by satisfied customers to other people and vice versa. (Bate et al., 2014).

Some of the commonly reported impact of poor customer satisfactory levels in the pharmaceutical manufacturing industry in Lagos state have been; An increase in the number of expired and consequently discarded products which is a major aspect of production wastage in the industry as customers who have used such substandard products or that have been informed about the poor quality of certain products have in most cases stopped purchasing such products. Furthermore, companies associated with frequent cases of low customer satisfactory levels have been reported to lose their competitive advantage in the industry which has inevitably led to loss of revenue and in extreme cases, the closedown of such companies (Europe PMC, 2019)

Customers are directly affected when substandard drugs are released into the market. Recorded cases as regards the impact of poor quality of pharmaceutical products on customers in Lagos state and Nigeria as a country all fell into one of these categories; Avoidable illnesses, avoidable deaths, treatment failure or drug resistance.(Newton et al., 2010). The impact of threatened health conditions of customers has also affected the pharmaceutical manufacturing industry's Operational Excellence in that customers begin to lose trust in implicated companies in the state thereby reducing their demand of products from such companies consequently making them lose their competitive advantage in the pharmaceutical market, this in turn will adversely affect the finances of these companies (Newton et al., 2010).

## 2.7 THE RELATIONSHIP BETWEEN PHARMACEUTICAL PRODUCT QUALITY AND CUSTOMER SATISFACTION

To be successful and remain relevant in today's global competitive environment, companies are becoming more customer-oriented and are making customer satisfaction their topmost priority. Customers on the other hand are demanding ever-improving levels of services as regards cost, quality and the choice of innovative new products.

In today's world, quality has become a major competitive variable in both service and manufacturing industries including the pharmaceutical manufacturing industry. Quality is a major factor that determines customer satisfaction in the industry because it entails a product being safe for use, effective for the cause of treatment, affordable and rightly available. Quality sums up

customer needs as far as medications are concerned and so, the better the quality of a pharmaceutical product, the more satisfied customers are. (Akenbor, 2014).

A survey carried out on customer satisfaction and quality cost of health products in Nigeria using 7 top pharmaceutical manufacturing companies in the country with questionnaires administered to the management accountants of these companies as sources of primary data showed that there was a direct correlation between product quality and customer satisfaction based on certain selected and measurable factors such as; sales and product demands, rate of complaints etc. The result showed that the higher the quality of a product, the higher the level of customer satisfaction and consequently the higher the sales rate and profit derived from the product. (Akenbor, 2014)

## 2.8 CHALLENGES AFFECTING PRODUCT QUALITY AND CUSTOMER SATISFACTION IN THE PHARMACEUTICAL MANUFACTURING INDUSTRY IN LAGOS STATE.

The challenges of the pharmaceutical manufacturing industry in Lagos state which has affected the industry's Operational Excellence are quite enormous. They span from challenges presented by regulatory authorities, the political system in Nigeria and the economic situation of the country.

A study on the challenge of substandard and counterfeit drugs in relation to drug regulation and control in Nigeria was reviewed. Relevant data required for the study was obtained through distributed questionnaires and oral interviews carried out to evaluate the views of stakeholders and specific organisations that were relevant to the study such as the; Federal Task Force on Counterfeit and Fake Drugs, The National Agency for Food and Drug Administration and Control (NAFDAC) and the Pharmacists Council of Nigeria (PCN). Some affiliated non-regulatory bodies were also included in the survey which were; The Pharmaceutical Society of Nigeria (PSN), Nigerian Association of General Practice Pharmacists (NAGPP), Nigerian Association of Industrial Pharmacists (NAIP) and the Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG/MAN) bringing the total number of organisations that participated in the survey to seven. The questionnaires issued to these organisations were designed to obtain reasons for the prevalence of substandard and counterfeit drugs in Lagos, Nigeria.(Babalola O.O, 2001)

The result of the study highlighted 7 major reasons for the prevalence of substandard drugs in the state. They included inadequate laws, ineffective enforcement of existing laws, non-health professionals in drug business, lose control systems, greed, ignorance and corruption. All seven organisations agreed that the enforcement of existing regulatory laws was not efficient and that the ignorance level of customers was very high which was why most faulting companies got away with the production of substandard and counterfeit drugs.

Six out of the seven organisations admitted that the laws put in place to checkmate the production and distribution of counterfeit and substandard drugs were inadequate and a lot of non-health professionals and inadequately trained personnel were in the pharmaceutical sector handling critical manufacturing processes. Four of the seven organisations blamed the high number of substandard products in the state on the high level of corruption in the country. While three organisations out of the seven believed greed has been a major factor as companies are willing to make more profit at the expense of quality of their products, Only two organisations believed pharmaceutical manufacturing companies in the state had lose control systems which might have caused the manufacture of a substantial amount of substandard products(Babalola O.O, 2001).

The author recommended that there is a need for the government of the state to implement provisions for the existing regulatory laws by adequately equipping and funding the laboratories used for the analysis of suspected substandard drugs. Such laboratories could also have training facilities for laboratory technicians in drug analysis and that lessons from the World Health Organisation would be useful in this respect. Author also called for a more spirited effort NAFDAC to ensure the registration of all drug products manufactured in the state and the speedy prosecution of all companies falling short of the laid down standards. The state's regulatory task forces on substandard drugs that are not in existence should be reconstituted and invigorated and the drug regulatory task forces should be adequately funded by the government to be able acquire the necessary facilities for their operations. (Babalola O.O, 2001).

Another recommendation made by the author that is directed towards the improvement of pharmaceutical manufacturing companies is the proper funding of the companies by the government to ensure manufacturing equipment, infrastructures, premises and processes for drug production in the state meets regulatory standards (Babalola O.O, 2001)because the prevalence of substandard drugs in Lagos state has also been attributed to the fact that the health and

pharmaceutical sectors are poorly funded by the Nigerian government. This explains the low standard of infrastructure, manufacturing facilities and equipment used by most of these companies for their manufacturing processes. This poor funding has also been implicated as one of the reasons why some companies have a high number of inadequately trained personnel (Ekeigwe, 2019).

However, some more specific challenges which have been affecting the efficiency of the pharmaceutical manufacturing industry in Lagos state based on other studies carried out showed that; Communication between companies and their regulators such as NAFDAC, SON and PCN has been very inadequate. Some reports have shown that some top officials at some of these companies have complained that most times, regulatory authorities change manufacturing guidelines and policies under short notice without seeking their opinion. This has resulted in huge financial stress and time wastage as companies would be required to resubmit applications to meet these new rules. (Ekeigwe, 2019).

Furthermore, there is the intellectual property issue. For fear of compromising the IP of their products and processes, most companies find it difficult to trust regulatory authorities with sensitive information about their products due to the level of corruption in Nigeria. This further reveals the need for professionalism and integrity in regulation so that regulators can be trusted to safeguard the intellectual properties of pharmaceutical manufacturing companies (Ekeigwe, 2019).

According to the report on the situational analysis of medicines registration harmonization in Africa for ECOWAS done in 2011, regulatory authorities in Lagos and all other states in Nigeria have a shortage of quality control laboratories with only a few that have been pre-qualified by the WHO. (Ekeigwe, 2019). Reports have also shown that there is insufficient number of qualified personnel, funds and other material resources needed by regulatory authorities in Nigeria. All these have limited the frequency and quality of GMP inspections (Ndomondo-Sigonda et al., 2017).

| **AUTHORS** | **PUBLICATION YEAR** | **SAMPLE SIZE** | **KEY POINTS FROM ARTICLE** | **CONCLUSION FROM ARTICLE** |
|---|---|---|---|---|
| Ndichu et al. | Evaluating the quality of antihypertensive | 102 hypertensive drugs | 30 (29.3%) were falsely labeled, 76 (74.5%) were | Thorough quality test should be carried out by |

| | | | | |
|---|---|---|---|---|
| | drugs in Lagos State, Nigeria. 2019 | | substandard 78 (76.5%) and 24 (23.5%) were of good quality. | NAFDAC before the approval of drugs to reduce cases of substandard medications |
| Bate and Hess | Anti-malarial drug quality in Lagos and Accra - a comparison of various quality assessments. 2010 | 87 anti-malarial drugs (From 2007-2010) | Reduction in TLC assay and disintegration test failure rate from 35% or 7/20 to 10.3% or 9/87 and reduction in visual inspection failure rate from 15% (3/20) to 6.9% (6/87) from 2007-2010 | There has been tremendous improvement in the reduction of substandard antimalarial drugs, but more work must be done by regulatory authorities to maintain this achievement and further reduce the present statistical figures of antimalarial substandard drugs |
| Taylor et al., | Pharmacopeial quality of drugs supplied by Nigerian pharmacies.2001 | 581 randomly selected antimalarial, antibacterial and antituberculosis drugs | 279 (48%) samples of the drugs were substandard and did not comply with set pharmacopeial limits | Results obtained from the study of a single product cannot be used in the overall evaluation of the quality of the pharmaceutical industry in Lagos and based on the |

| | | | | |
|---|---|---|---|---|
| | | | | result of the study, more industry still has a long way to go in tackling the issue of substandard drugs in Lagos state |
| Bate et al., | Drug use in Nigeria. 2014 | 211 questionnaires were distributed to healthcare workers across Lagos state | 52% (111/211) of all healthcare personnel indicated they had come into possession of a counterfeit or substandard drug | The result obtained from the study showed that a lot of substandard drugs are still in circulation in Lagos state and healthcare workers have not been efficient in playing their part in eradicating these drugs by reporting such incidences to NAFDAC and all concerned regulatory authorities. |
| Bate et al., | Drug use in Nigeria. 2014 | 211 questionnaires were distributed to pharmacists, doctors and other healthcare personnel | 62% (130/211) of all healthcare personnel reported that patients said they had bought an ineffective drug. When asked why drugs may have been ineffective, healthcare personnel | The result of the study determined that satisfactory level of customers with pharmaceutical products produced in Lagos state was on an average level and more attention |

| | | | | |
|---|---|---|---|---|
| | | | said that patients did not use the drug as prescribed (68%, 88/130), the ailment was misdiagnosed (50%, 65/130) and/or the drugs were substandard or fake (41%, 53/130) or did not contain the right amount of active ingredient (28%, 36/130). 18% (23/130) said drugs were not effective because they were expired | should be paid to the quality of the drugs produced by the industry by NAFDAC. |

Table 2: Summary of publications from literature review.

## 2.9 RECOMMENDATIONS FOR THE IMPROVEMENT OF PRODUCT QUALITY AND CUSTOMER SATISFACTION IN THE INDUSTRY.

The common challenges affecting product quality as observed in the literature review has revolved around the inefficiency of manufacturing companies, regulatory authorities and the government. The most commonly reported challenges have been; the lack of adequate regulatory checks and tests carried out by NAFDAC to ascertain the quality of medicinal products, inadequate funding of the industry by the government, the presence of too many manufacturing companies that are not well equipped enough to be independent producers, inadequate training of the industry's workforce. For there to be significant improvement in the quality of drugs produced in the state, these challenges have to be addressed because though they are not all the factors limiting the quality of pharmaceutical products in the state, they are however the main factors which have a rather huge impact on drug quality and customer satisfaction.

NAFDAC and other regulatory bodies in the state should carry out more frequent and unannounced regulatory checks on manufacturing companies to ensure they comply with the necessary manufacturing standard procedures. The frequency of the checks will also help to ensure companies do not relax on maintaining quality standards. Also, NAFDAC should ensure adequate laboratory tests are carried out on drugs before approving them to be released to the market because drug recall in the country is quite a challenge due to the large population of the country, quite a number of which lack access to vital information such as a product recall and because drugs produced in Lagos state also get transported to other states for sale.

There will also be tremendous improvement in the quality of drugs produced in the state if the pharmaceutical companies are adequately funded by the government. As earlier stated in this research, Nigeria's health sector is one of the most poorly funded health sectors in Africa. As a result, most manufacturing companies must make do with low quality manufacturing equipment and cut down cost of production in ways that eventually reduce the quality of drugs they produce. Adequate funding of the industry will therefore help drug manufacturing companies perform effectively and will also reduce the number of companies that are not fully equipped to effectively function independently that are struggling for survival.

## 2.10 CONCLUSION

After a thorough study and evaluation of literature review on research studies pertaining to product quality and customer satisfaction and its influence on pharmaceutical manufacturing Operational Excellence, reviewed reports have shown that the concept of OPEX is still quite new in the pharmaceutical manufacturing industry in Nigeria and so, has not been fully integrated into the system. As a result, its potential in improving the quality of pharmaceutical manufacturing processes and products and ultimately improving customer satisfaction levels for the industry in Lagos state has not been harnessed.

The review of available and relevant literature in regards to this topic have all shown that the level of product quality and customer satisfaction obtained from products of the pharmaceutical manufacturing industry in Lagos is still quite low because a lot of companies in the state produce substandard drugs. Some of the prominent factors implicated in the high levels of substandard

drugs in the state are the poor funding of the industry by the government and inadequate quality inspection of products by regulatory authorities such as NAFDAC and inadequate training of manufacturing personnel.

The study shows there is a need for the improvement of product quality and customer satisfaction elements of the pharmaceutical manufacturing industry in Lagos state for there to be significant improvement in the industry's Operational Excellence.

## CHAPTER 3: RESEARCH METHODOLOGY

### 3.1 Overview

| Section. No | Primary Data | Part A | Part B |
|---|---|---|---|
| 1 | Approach | Quantitative analysis | Qualitative analysis |
| 2 | Philosophy | Positivism | Interpretivism |
| 3 | Source | Questionnaire:<br>Microsoft forms app distributed online | Phone interviews |
| 4 | Structure | 4 sections in the survey, made up of 14 questions in total. | 10 – 15 minutes of phone conversations |
| 5 | Subjects | Customers (202),<br>NAFDAC officials (78) | NAFDAC officials (5)<br>Customers (5) |

Table 3: Research Methodology and Primary Data collection

### 3.2 Research Approach

To determine the state of product quality and customer satisfaction elements in the pharmaceutical manufacturing industry in Lagos state, the author made use of quantitative and qualitative research methods by using questionnaire surveys and phone interviews respectively.

The survey was distributed to both consumers of pharmaceutical products and NAFDAC officials in the state electronically and were requested to answer the survey questions accordingly. This helped the author obtain appropriate and applicable information required for statistical analysis. The questions sought to evaluate the level of customer satisfaction and drug quality of pharmaceutical products in Lagos. By determining how satisfied customers were with pharmaceutical products and the evaluation of drugs by regulatory officials, the author determined the quality of drugs and level of customer satisfaction which were useful in evaluating the Operational Excellence of the pharmaceutical industry in Lagos. The author was also able to draw reasonable conclusions on their state, factors limiting their improvement and proposed recommendations that are sustainable.

Phone interviews were conducted for the qualitative approach, to understand the perspectives of experienced drug regulatory officials at NAFDAC and well educated and informed customers towards understanding the factors affecting customer satisfaction and product quality of pharmaceutical products in Lagos and recommendations for improvement which were achievable and sustainable. Analysis of information obtained from both groups was compared to the literature findings to structure the author's concluding thoughts on the study being carried out.

### 3.3 Research Philosophy

The philosophy underlying this research work was majorly that of positivism because the study was implemented to explain information acquired from respondents and draw applicable conclusions based on these findings. Also, the practical implication of this research hinged on quantifiable observations which helped to obtain statistical analysis of information gathered from respondents. The research aimed to progress through hypothesis and deductions as factors being studied were measurable and required large numbers of both groups of respondents.

Customers of pharmaceutical products which also included NAFDAC officials were provided with structured questionnaires from which data was obtained, analysed and objectively interpreted.

The application of interpretivism to information obtained from the qualitative approach which employed the use of phone interviews resulted in primary data that was solely based on personal perspectives and values of NAFDAC officials and customers. Information obtained were therefore inclined to be subjective, trustworthy and valid due to the level of depth and interest expressed by customers and regulatory officials while discussing.

### 3.4 Research Strategy

The strategy of the research was to evaluate the Operational Excellence of the pharmaceutical manufacturing industry by obtaining information about the current state of drug quality and customer satisfaction in Lagos state and to understand the factors affecting the efficiency of both elements. As observed in the literature review conducted, it was apparent that no research aimed at understanding and evaluating the state of Operational Excellence in the state's pharmaceutical industry had been done and no studies were carried out on the factors affecting product quality and customer satisfaction in the industry's Operational Excellence in Lagos.

The customers and NAFDAC officials who the survey was sent to were informed about the purpose of the research project conducted by the author as part of the academic requirements for the completion of her Masters program. The questionnaire was put together in an easy-to-answer format and was administered to over 300 participants which were customers and regulatory officials who were all residents of Lagos state and who had within the past one year, used drugs locally manufactured in Lagos State.

*Survey questionnaire for customers and regulatory officials:*

The questionnaire was made up of 14 questions segmented into 4 sections to achieve the aim of the study of pharmaceutical customers and products. Using the Microsoft forms application, the questionnaire was distributed electronically and in the absence of the author to further reinforce the philosophy of positivism and encourage the expression of opinions without any form of bias or hesitation.

The first question was designed to gain consent from respondents, permitting the use of their answers for the purpose of the research study. They were however assured that the data generated from the survey was handled in line with general data protection regulation (GDPR) and therefore kept strictly confidential. The question was mandatory for respondents to answer for them to participate further in the survey.

### 3.5 Collection of Primary Data

As stated in the research strategy, primary data was obtained using questionnaires, structured for both customers and NAFDAC officials. All 14 questions were formulated to ascertain the opinions of customers and NAFDAC officials in Nigeria thereby successfully achieving the objectives of the research.

*For the customers and Regulatory officials' questionnaire.*

Section 1 on the demographics of respondents consisted of five questions. The questions were to determine the gender, age, educational level, which of the respondent either customer or regulatory official was completing the survey and how long the respondent has been resident in Lagos state.

Section 2 on analysis of the current state of product quality and customer satisfaction with locally manufactured drug products in the state consisted of four questions aimed at eliciting information

on how often residents purchased locally manufactured drugs, the factors influencing their level of satisfaction with these drugs and their level of satisfaction with purchased drugs as regards price, availability, effectiveness and severity of side effects. It also sought to obtain information on the perception of respondents on the quality of drugs produced in the state based on drug purity, correct APIs and excipients, right amount of drug components and drug packaging.

Section 3 on evaluation of product quality of drugs produced in Lagos consisted of three questions aimed at eliciting information on how routinely NAFDAC performs regulatory checks on drug products, challenges affecting product quality of pharmaceutical products and measures effective in improving quality of drugs in the state.

Section 4 This consisted of a question that aimed at ascertaining the respondent's opinion on possible recommendations to improve customer satisfaction and pharmaceutical product quality in the state.

### 3.6 Sources

The survey questionnaire was distributed to NAFDAC officials and customers of the pharmaceutical industry over the internet using Microsoft forms application. The author gathered information from 280 participants comprised of 202 customers and 78 NAFDAC officials. The author then made use of the Microsoft excel sheet in the evaluation of collated information and used pie and bar charts for proper articulation and presentation of the findings and to compare the responses between customers and NAFDAC officials.

Also, phone interviews were scheduled with experienced NAFDAC officials and some customers in Lagos state on their evaluation of the quality of drugs in the state, how satisfied they were with these drugs, the factors they perceive to be affecting pharmaceutical product quality in Lagos and their recommendations for improvement.

*Selection of customers*

The author reached out to public internet forums in Lagos state and NAFDAC officers and explained the research topic to them. Most participants showed interest to partake in the survey questionnaire.

*Selection of NAFDAC officials*

Author reached out to the Director, Drug laboratories of NAFDAC in Lagos state and explained the relevance of the research topic and obtained a positive feedback to take part in the survey questionnaire. She also got recommendations for other officials who were willing to participate in the survey especially some highly experienced officials who were interested in participating in the phone interviews.

### 3.7 Access and ethical issues

A brief introductory explanation of the research topic was provided to all the customers and NAFDAC officials partaking in the survey questionnaire and interviews as they were all duly informed about the research project as part of an academic requirement by the author in fulfillment of her masters' program. In structuring the questions contained in the survey, caution was taken to ensure no question requested any personal information of the respondents and that the questions posed were strictly relevant to the research study and its objectives. It was clearly noted to be voluntary participation during which the participants had full prerogative to partake in the survey and were permitted to withdraw from participation at any time.

### 3.8 Inclusion and Exclusion Criteria

The customers included in this study were all residents of Lagos state who have at one point or another used medications locally produced in the state in the past one year and were all over 18 years of age. Participants who declined to answer the questionnaire were considered to be excluded from the study. These were the only inclusion and exclusion criteria considered for participants in this study and subsequent data analysis.

An introductory letter was also attached to the survey questionnaire with a required answer for participants consent before proceeding to fill the survey. It was also at the full discretion of the customers and NAFDAC officials to participate or withdraw from the survey exercise if they wanted to. Of the group of customers and NAFDAC officials who received the link to the questionnaires, those who were unwilling to participate were encouraged to ignore the forwarded link while those who submitted a completed questionnaire were implied to have participated voluntarily.

### 3.9 Conclusion

For the research study, a quantitative approach using survey questionnaires which consisted of 14 questions were distributed among two major groups. The questionnaires were designed for customers of the pharmaceutical industry and NAFDAC officials. The survey was underlined by a positivism philosophy which ensured deductions made were objective and obtained from measurable facts. Phone interviews were carried out for qualitative approach which further provided insights on the research study.

The data obtained was analysed and compared to the findings obtained from the literature review. The author hoped to ascertain the perceptions of customers and NAFDAC officials needed to evaluate the current state of product quality and customer satisfaction and how both elements can be improved, consequently improving the Operational Excellence of the pharmaceutical manufacturing industry in Lagos state.

# CHAPTER 4: FINDINGS AND ANALYSIS

## 4.1 Overview

The insights obtained from the data helped the author to understand the perspective of customers and regulatory personnel on the quality of locally manufactured drugs in Lagos state and to evaluate the level of customer satisfaction and the factors affecting both elements. Results obtained from the study also provided the basis for conclusion needed to improve customer satisfaction and product quality elements to ensure Operational Excellence in the pharmaceutical manufacturing industry in Lagos state.

The analysis from the phone interviews conducted with experienced regulatory officials at NAFDAC helped to further establish most of the insights obtained from the survey questionnaire results, literature review and the personal perspective of the author regarding customer satisfaction and product quality of drugs manufactured in Lagos state.

## 4.2 Demographic Data (Questions 1-6)

*4.2.1 Response rate*:

The survey was distributed to 309 people, consisting of 209 customers and 100 NAFDAC officials. However, a total of 280 accepted responses were obtained, a response rate of 90.6%.

202 of the total number of participants who responded were customers with 110 of them being male and 92 being female while the remaining 78 respondents were NAFDAC officials, 48 of which were male and 30 were female.

*4.2.2 Age, educational level and period of residency:*

Out of the 280 respondents that completed the questionnaire, 168 were however young adults between ages 18 to 30 years while 46 respondents were 31 to 40 years with 42 respondents being within the age bracket of 41 to 50 years and just 24 respondents being 51 years or older.

Academically, most of the respondents- All 78 regulatory officials and 111 customers were post-graduates while 78 customers were undergraduates with just 11 customers being high school graduates and only 2 with no formal education.

Many of the respondents- 48 regulatory officials and 121 customers had been resident in Lagos state for 5 years or more while 20 regulatory officials and 24 customers had been in Lagos for 2 to 5 years. Just 10 regulatory officials and 21 customers had been in Lagos for a period of 6 months to 2 years with 36 customers who had been in the state for less than 6 months.

| **Respondents** | **Educational level** | | | | **Duration of Residency** | | | | **Gender** | | **Total Respondents** | **Response Rate** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **P** | **U** | **H** | **N** | **Less than 6 Months** | **6 Months – 2y** | **2 – 5y** | **Greater than 5y** | **M** | **F** | | |
| Regulatory Personnel | 78 | 0 | 0 | 0 | 0 | 10 | 20 | 48 | 48 | 30 | 78 out of 100 | 78% |
| Customers | 111 | 78 | 11 | 2 | 36 | 21 | 24 | 121 | 110 | 92 | 202 out of 209 | 96.7% |

*Key: P=Post-graduate, U= Undergraduate, H=High school, N=No formal education, Y= years, M= Male, F=Female.

Table 4: Demographics.

### 4.3 Current state of product quality and customer satisfaction with locally manufactured pharmaceutical products (Questions 7-10).

The responses generated from this section were varied and remarkable. It was apparent from the survey that the evaluation made by the survey participants were genuine.

Question 7:

*Findings:*

In the evaluation of how often participants purchased drug products locally manufactured in Lagos state, it was discovered that 58.2% of respondents (120 customers and 43 regulatory officials) rarely purchased drugs manufactured in the state, while 32.9% purchased them monthly (58 customers and 35 regulatory officials), just 7.9% (21 customers) purchased drugs on a weekly basis and only 1.1% (3) customers purchased them daily.

*Analysis:*

Though the average life expectancy in Nigeria is quite low due to the various health challenges faced by the country, coupled with the high poverty level of a greater percentage of citizens and the lack of access to basic health amenities in most states as earlier depicted in this study, a greater percentage of citizens in Lagos state are however in good health conditions. This is attributed to the fact that Lagos is the most economically influential and buoyant state in Nigeria with the highest level of urbanization and standard of living. As a result, a greater percentage of residents in the state are able to afford to live healthy and enjoy health benefits that are not available in other states since the state has the highest number of industries, pharmaceutical companies and social amenities and infrastructures. This explains the low number of health challenged individuals requiring the use of medications regularly- see Figure 6a.

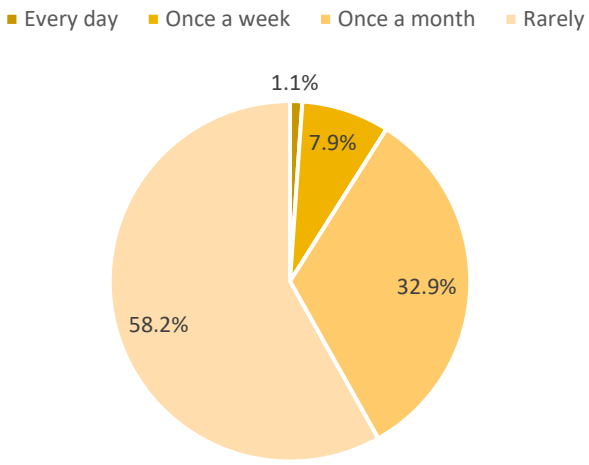


Figure 6a: How frequently respondents purchased drugs manufactured in Lagos state.

*Findings:*

It is interesting to note that a bit above the average number (59%) of customers and (55%) of regulatory officials rarely purchased locally manufactured drugs in Lagos state while few customers (28.7% ) and quite a number of regulatory personnel (44.9% ) purchased locally manufactured drugs at least once a month. 11.9% of customers purchased locally manufactured drugs in Lagos at least once a week or once a day. However, few regulatory officials purchased drugs monthly, but none did on a weekly or daily basis.

*Analysis:*

NAFDAC regulatory personnel are more likely to lead healthier lives in Lagos state because they monitor the quality of food and drugs produced in the state. They are therefore less likely to purchase low quality and counterfeit drugs that might affect their state of health negatively. This explains why they are less likely to purchase drugs as frequently as other customers. Quite a number of regulatory personnel however make use of multivitamins and other health supplements which explains why some of them purchase drugs on a monthly basis and not necessarily because they have health challenges- see figure 6b.

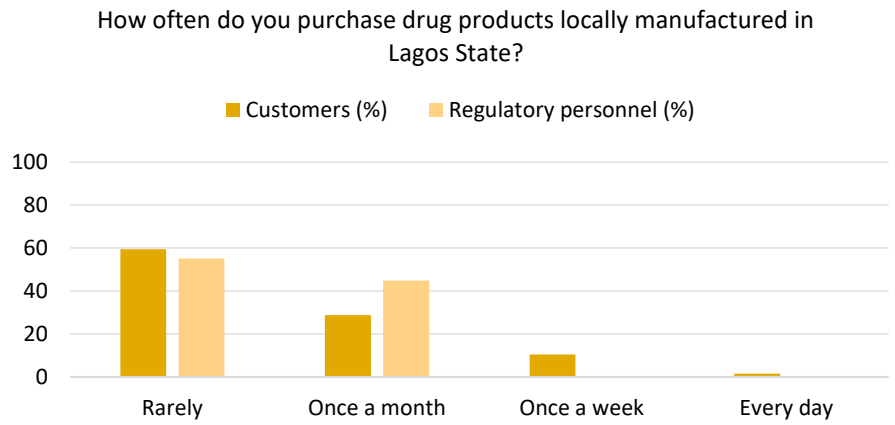


Figure 6b: Comparison of drug purchase frequency between customers and regulatory personnel in Lagos, Nigeria.

Question 8:

The next question that followed was to ascertain to what extent certain factors which included; NAFDAC approval, reputation of drug manufacturing companies, drug availability and price influenced the level of satisfaction of customers and regulatory officials with drugs produced in Lagos state. The level of influence was measured on a scale of 1 to 5 with 1 being the least and 5 being the highest level of influence.

*Findings:*

10.7% of respondents (30 customers) revealed that the approval of a drug by NAFDAC had no influence whatsoever on how satisfied they were with locally manufactured drugs in the state, while 6.1% of respondents (17 customers) claimed drug approval by NAFDAC had very little influence on their level of satisfaction with drugs produced in the state, 18.9% respondents (53 customers) were however indifferent while 16.1% (45 customers ) claimed NAFDAC approval of drugs influenced their level of satisfaction to some extent. Interestingly, 48.2% of respondents (57 customers and all 78 regulatory personnel) claimed approval by NAFDAC had a great influence in determining their level of satisfaction with locally manufactured drugs in the state.

As regards company reputation, 11.1% of respondents (31 customers) claimed the reputation of drug manufacturing companies in the state in no way affected or influenced their level of satisfaction with locally manufactured drugs. 9.6% of respondents (27 customers) however claimed company reputation had very little influence on their level of satisfaction. 18.9% of respondents (53 customers) were indifferent about the reputation of pharmaceutical manufacturing companies. 25.4% of respondents (41 customers and 30 regulatory officials) however claimed company reputation was a determining factor of how satisfied they would be with locally manufactured drugs while 35% of respondents (50 customers and 48 regulatory officials) claimed company reputation was a major influence that would definitely affect their level of satisfaction with drugs produced in the state.

As regards drug availability, 6.8% of respondents (19 customers) showed that how available locally manufactured drugs were, in no way influenced their level of satisfaction, this was closely followed by the result obtained from 7.5% of respondents (21 customers) that showed drug availability had very little influence on how satisfied they were with these drugs. Surprisingly, 25.4% of respondents (35 customers and 36 regulatory personnel) were indifferent while 35.4% of respondents (65 customers and 34 regulatory personnel) claimed drug availability influenced their level of satisfaction to a good extent. 25% of respondents (62 customers and 8 regulatory personnel) however revealed that the availability of drugs had a huge impact on their level of satisfaction with locally manufactured drugs.

*Analysis:*

Based on the results obtained from respondents on this question, it is quite evident that though 64.3% of respondents knew the importance of purchasing drugs only approved by NAFDAC to

prevent the use of counterfeit and low quality drugs that could have serious adverse effect on their health, 16.8% of respondents were still not aware. However, the 18.9% of respondents who were indifferent about the influence of NAFDAC approval of drugs on their level of satisfaction with locally manufactured drugs in the state were most likely aware of the implications of purchasing drugs that were not approved but purchased them anyway because they were cheaper than approved drugs and probably proved to be effective also with little or no side effects.

As regards the reputation of pharmaceutical manufacturing companies in Lagos state, the result shows that 39.6% of respondents were not aware if these companies had a good reputation with regulatory authorities in terms of compliance with quality or whether they were constant regulatory defaulters. As a result, it had no influence on their level of satisfaction. while 60.4% of respondents claimed it influenced their level of satisfaction.

Most respondents claimed how available locally manufactured drugs in the state were influenced their level of satisfaction to some extent. Quite a number were however indifferent while some claimed it had no influence whatsoever on their level of satisfaction. The fact that 58.2% of respondents rarely purchased locally manufactured drugs in the state because of their good state of health explains why some respondents claimed drug availability had no influence on their level of satisfaction and why quite a number of respondents were indifferent about this factor - see Figure 7a.

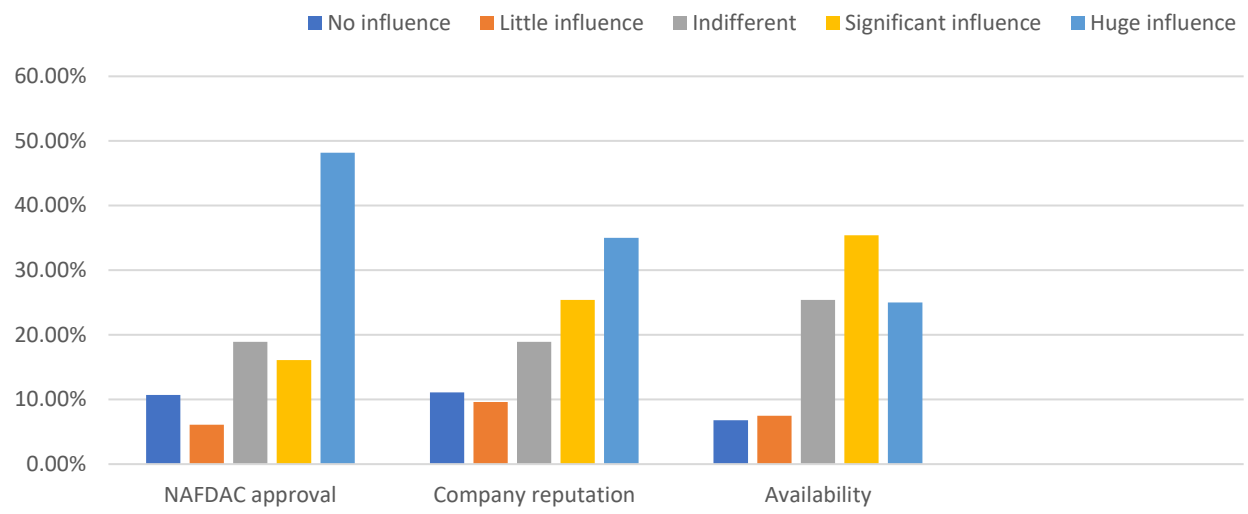


Figure 7a: How strongly NAFDAC approval of drugs, reputation of manufacturing companies and drug availability influence customer satisfaction.

*Analysis on the comparison of findings:*

A comparison of the results obtained from customers and regulatory personnel showed 50.2% of customers claimed NAFDAC approval of drugs was a major factor that affected their level of satisfaction with locally manufactured drugs while the remaining average were either indifferent or claimed NAFDAC approval had little or no influence on their level of satisfaction with drug products.

This showed that an average number of customers were well informed about the importance of using drugs only approved by the agency while the rest were either not informed, bought unapproved drugs because they were cheaper and effective or did not trust NAFDAC's judgement on drug safety, efficacy and quality. All regulatory personnel as expected, claimed NAFDAC approval of drugs was a significant factor that determined their level of satisfaction with drugs manufactured in Lagos as they were all better informed being regulatory officials.

The reputation of manufacturing companies was a determining factor influencing the satisfaction of all regulatory officials and 45.1% of customers. The larger proportion of customers however claimed it had little or no influence on their level of satisfaction while the rest were indifferent. This shows about 54.9% of customers were not informed about the reputation of manufacturing companies in the state unlike regulatory officials who were in the field and had good information

about companies known for compliance with regulatory standards and those who were perpetual defaulters known for the manufacture of drugs not in accordance with laid down standards.

62.9% of customers claimed drug availability was a determining factor as to how satisfied they were with drugs produced in the state. While 17.3% were indifferent, very few claimed drug nh-availability was of little or no significance to them in terms of how satisfied they were with drug products. Interestingly, 46.2% of regulatory officials were indifferent about drug availability influencing their level of satisfaction with pharmaceutical products in the state. Quite a number admitted it influenced their level of satisfaction to some extent while very few admitted it significantly influenced their level of satisfaction.

The fact that most regulatory officials and most customers rarely use drugs produced in the state explains why drug availability has no significant influence on their level of satisfaction- see Figure 7b.

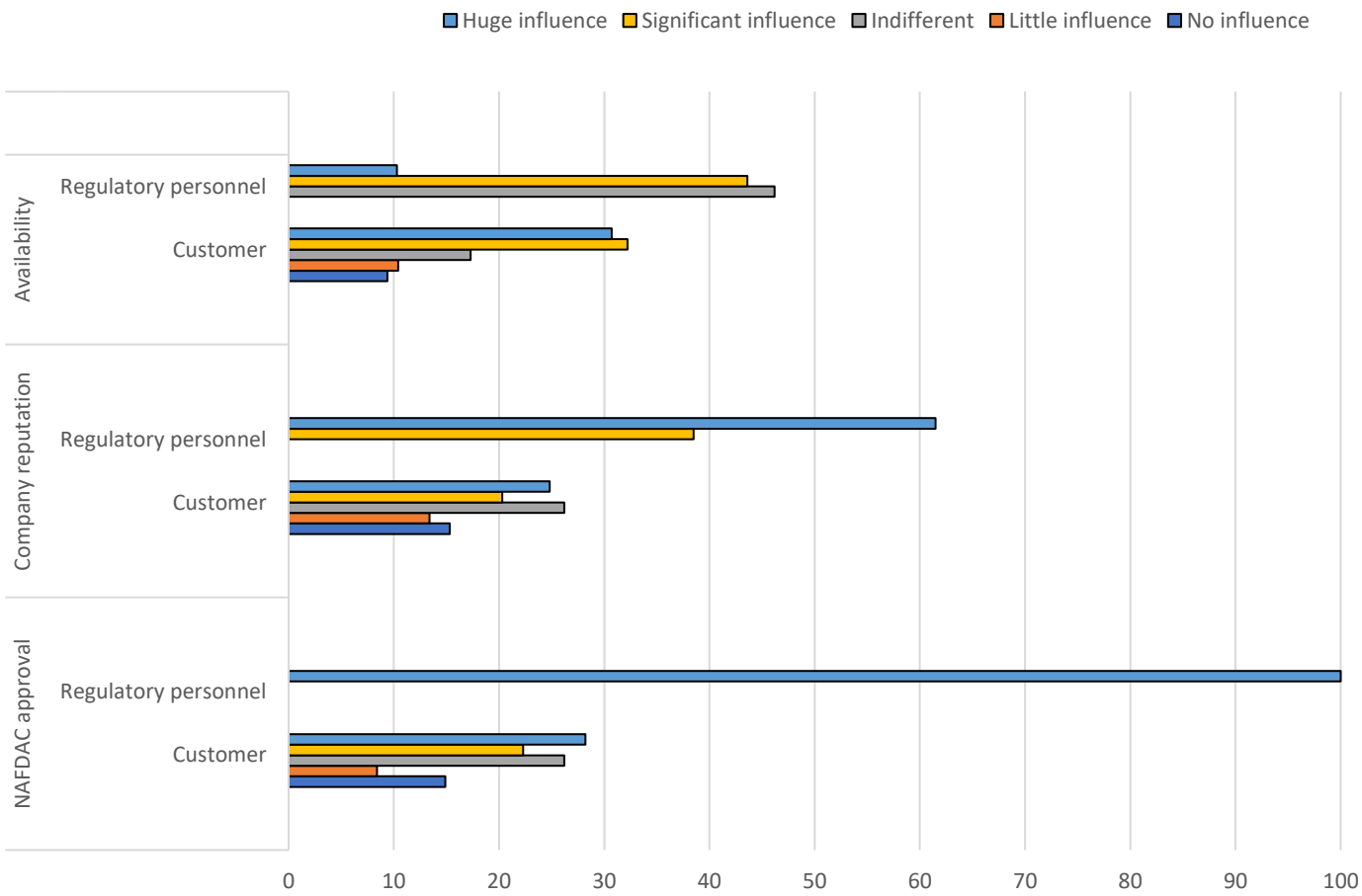

Figure 7b: Comparison on the varying extent to which NAFDAC approval, company reputation and drug availability influence the level of satisfaction of customers and regulatory personnel as regards drugs manufactured in Lagos state.

Question 9:

*Findings:*

In determining the level of satisfaction of respondents in terms of drug availability, price, efficacy and severity of side effects, 26.4% of the respondents (43 customers and 31 regulatory personnel) were very satisfied with drug availability. 50% (93 customers and 48 regulatory personnel) were somewhat satisfied while 21.1% of the respondents (59 customers) were indifferent and just 2.5% (7 customers) were unsatisfied.

However, just 18.6% of the respondents (43 customers and 9 regulatory personnel) were very satisfied with the price of locally manufactured drugs in the state. 46.4% of the respondents (79 customers and 51 regulatory personnel) were somewhat satisfied while 27.9% of the respondents (60 customers and 18 regulatory personnel) were indifferent. Just 7.1% (20 customers) were not satisfied with the cost of locally manufactured drugs in Lagos state.

In terms of the efficacy of the drugs manufactured in Lagos state, 27.1% of the respondents (64 customers and 12 regulatory personnel) indicated that they were very satisfied with the efficacy of locally manufactured drugs in the state. 54.3% of the respondents (86 customers and 66 regulatory personnel) indicated they were somewhat satisfied while 14.3% of the respondents (40 customers) indicated they were indifferent and just 4.3% of respondents (12 customers) claimed to be unsatisfied with drugs produced in the state.

As regards the severity of side effects of locally manufactured drugs, 17.1% of respondents (45 customers and 5 regulatory personnel) indicated they were very satisfied with the minimal level of side effects experienced, while 35.7% of respondents (73 customers and 30 regulatory officials) claimed to be satisfied. However, 36.8% of respondents (63 customers and 40 regulatory personnel) remained indifferent while 10.4% of respondents (18 customers and 3 regulatory personnel) were unsatisfied with the severity of side effects of locally manufactured drugs in Lagos state- see Figure 8a.

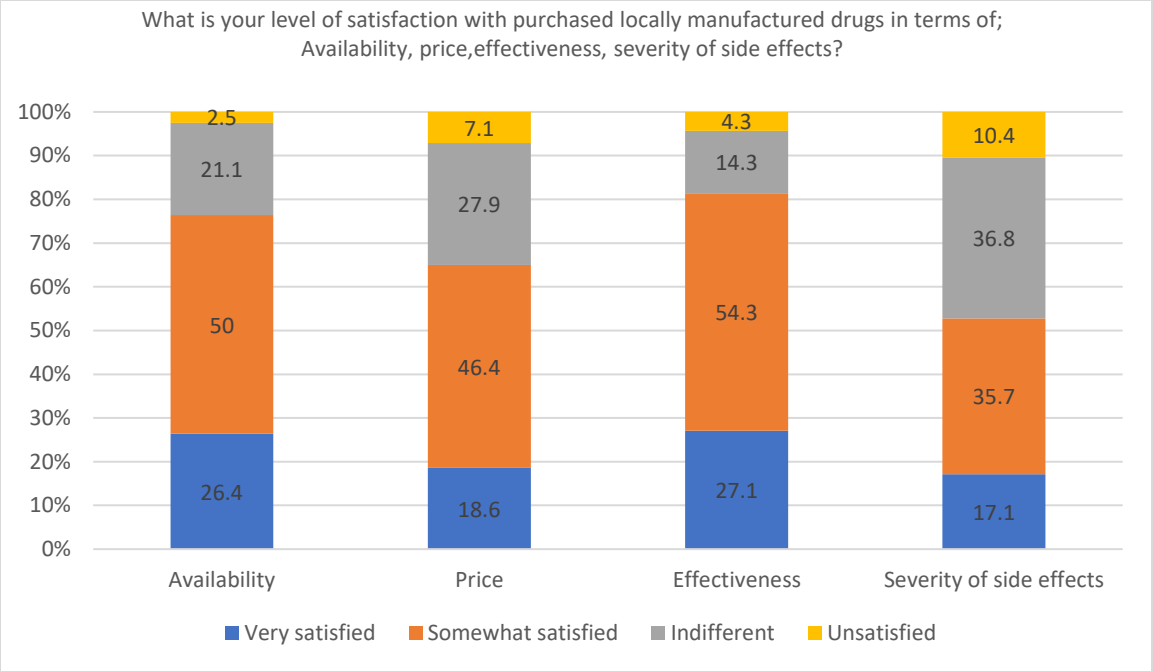


Figure 8a: Level of satisfaction of respondents with locally manufactured drugs in Lagos in terms of availability, price efficacy and severity of side effects.

*Analysis:*

As depicted from the result obtained, most of the customers and regulatory officials were satisfied with the availability of locally manufactured drugs in the state while very few customers were indifferent and unsatisfied. This shows that locally manufactured drugs are very much available, well distributed and easy to access in the state. There is a high possibility that those who were indifferent did not know if locally manufactured drugs were very much available because they rarely purchased drugs. It is also possible that those who were dissatisfied experienced drug scarcity because they purchased drugs that were not frequently demanded due to the uncommon nature of the ailment for which it was formulated and as a result, is being produced in limited quantities by manufacturing companies.

Most customers and regulatory officials were satisfied with the price of locally manufactured drugs in the state, while 29.7% of customers and few regulatory officials were indifferent, very few customers were dissatisfied with the price of drugs manufactured in the state. This depicts that price of locally manufactured drugs in the state is quite affordable for a larger percentage of residents. This also further buttresses the point that the level of poverty in Lagos state is not as

high as in other states of the country, but it however does not rule out the fact that quite a number of people still cannot afford the price of drugs produced in the state.

Majority of the customers and regulatory personnel were satisfied with the efficacy of locally manufactured drugs in Lagos state. Just few customers were indifferent, a very small percentage of customers also indicated they were unsatisfied with the efficacy of locally manufactured drugs in Lagos state. This reveals that most of the drugs produced in the state are effective in treating the ailments for which they were formulated. For the small percentage who were not satisfied with the efficacy of drugs in the state, apart from these drugs being totally ineffective, as earlier mentioned in this research, there is also the possibility of drug inefficacy being as a result of customers not fully adhering to drug prescriptions as reported in previous studies.

As depicted by the result, most customers and regulatory officials were either somewhat satisfied or remained neutral as to how satisfied they were regarding the severity of side effects of locally manufactured drugs. Just a few of both categories were very satisfied and dissatisfied. This shows that mild discomfort or severe adverse reactions experienced from the use of drugs produced in the state is still a huge challenge that needs to be improved upon. Some of the cases of dissatisfaction or indifference could however be a result of non-adherence to prescription - see Figure 8b.

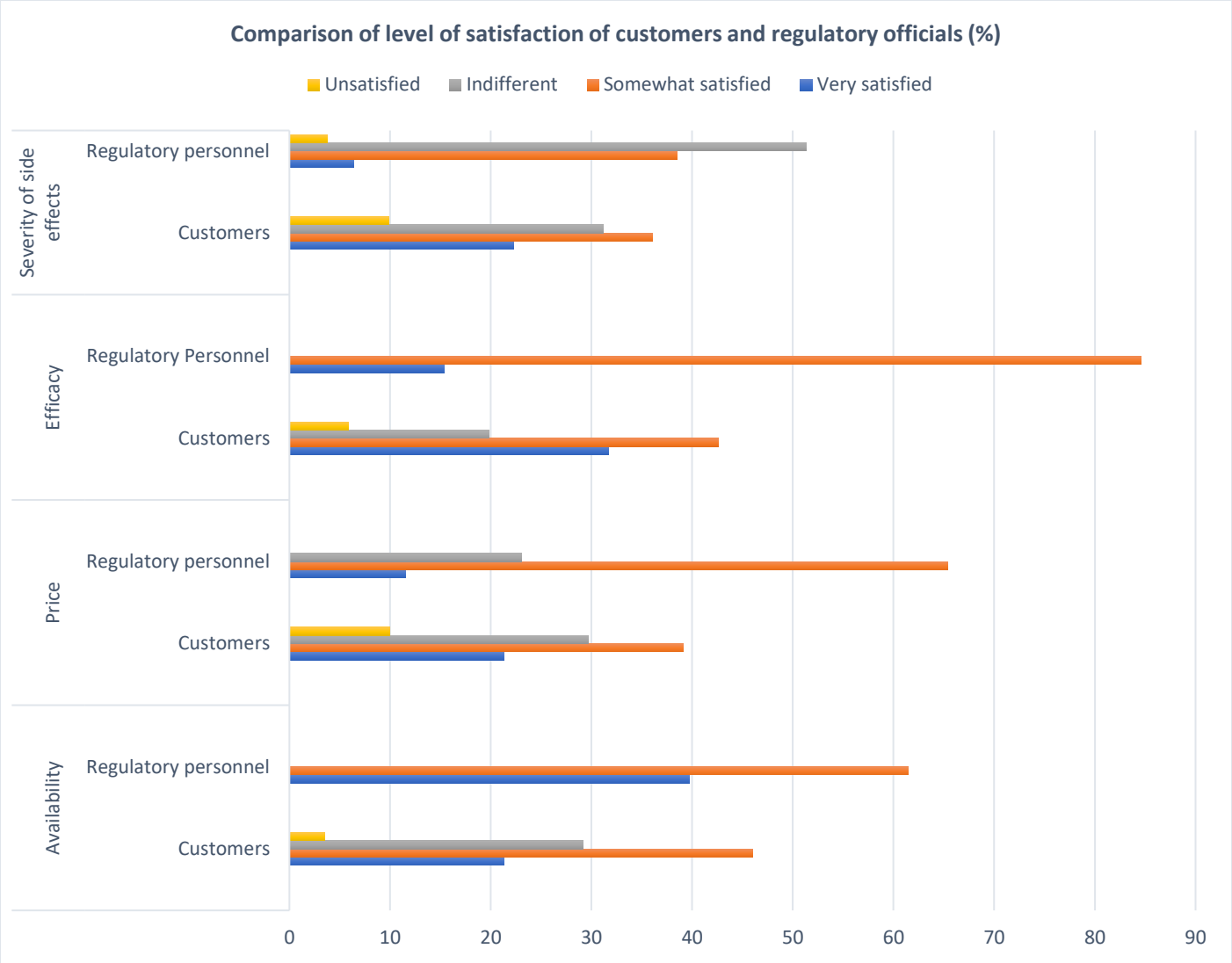


Figure 8b: Comparison of the level of satisfaction of customers and regulatory officials with locally manufactured drugs.

Question 10:

*Findings:*

The relevance of this question was to evaluate the quality of locally manufactured drugs in terms of their purity levels, correct drug excipients, right amount of APIs and proper packaging. 20% of respondents (56 customers) claimed the purity levels of drugs manufactured in the state were very good, 55.7% of respondents (101 customers and 54 regulatory personnel) claimed drug purity levels was somewhat good while 18.6% of respondents (42 customers and 10 regulatory officials)

remained indifferent. Interestingly, just 5.7% of respondents (3 customers and 14 regulatory personnel) believed drug purity levels of locally manufactured drugs in the state were poor.

As regards drug components, 23.2% of respondents (61 customers and 5 regulatory personnel) claimed drug quality in Lagos state was very good as regards containing the correct excipients, 54.6% of respondents (100 customers and 52 regulatory personnel) thought drug quality was somewhat good in this regard while 18.9% of respondents (32 customers and 21 regulatory personnel) remained indifferent. Just 3.2% of respondents (9 customers) claimed the quality of locally manufactured drug products in the state as regards containing the correct excipients was very poor.

However, 24.3% of respondents (68 customers) believed that as regards containing the right amount of APIs, the quality of drugs locally manufactured in the state was very good, 45.4% of respondents (101 customers and 26 regulatory personnel) were of the opinion drug quality in this regard was somewhat good while 24.6% of respondents (31 customers and 38 regulatory officials) remained indifferent. Interestingly, 5.7% of respondents (2 customers and 14 regulatory personnel) claimed the quality of locally manufactured drugs in relation to containing the right amount of APIs was poor.

In relation to proper packaging of drugs locally manufactured in Lagos state, 28.9% of respondents (81 customers) claimed drug packaging in the state was very good, while 48.2% of respondents (76 customers and 59 regulatory officials) claimed the level of proper drug packaging in the state was somewhat good. 16.1% of respondents (26 customers and 19 regulatory officials) however remained neutral while 6.8% of respondents (19 customers) claimed the quality of drug packaging in the state was poor-see Figure 9a.

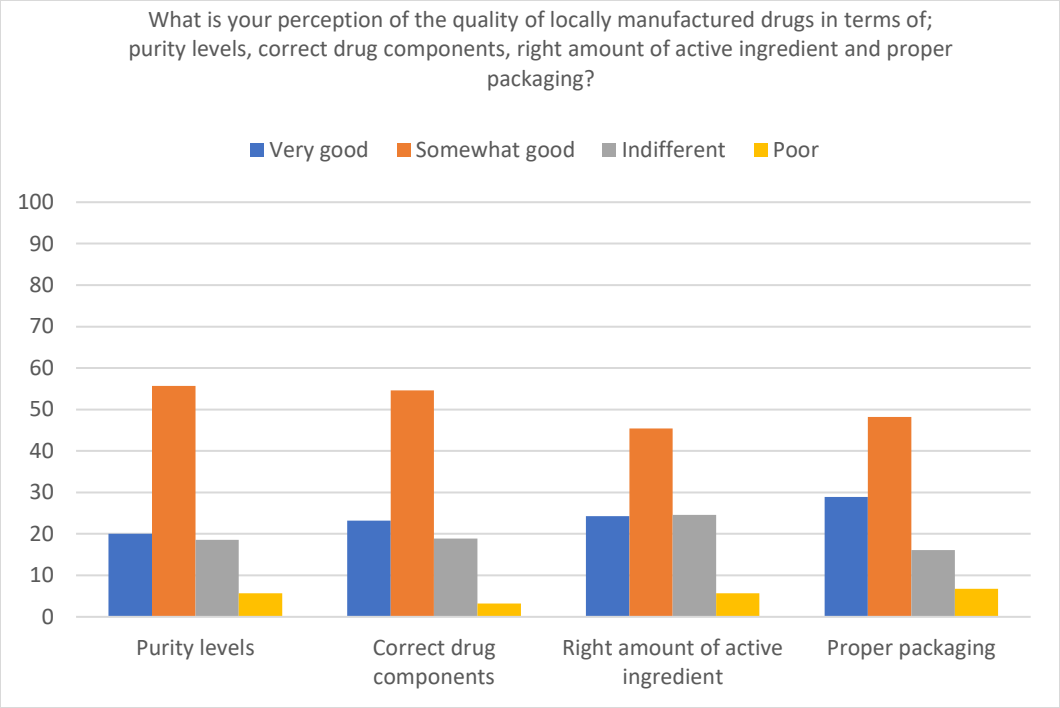


Figure 9a: Respondents perception on the quality of locally manufactured drugs in Lagos state.

*Analysis:*

Regulatory personnel are more informed about the quality of drugs produced in Lagos state as regards the above considered factors. Their responses will be highly considered in this analysis compared with that of other customers.

Results obtained from both groups however showed that the purity levels of locally manufactured drugs in the state are quite good enough to ensure drug efficacy. However, there is a lot of improvement to be made to achieve the accurate level of purity required of the industry. The shortcomings of the industry in this area is most likely due to the lack of adequate funding of the industry to acquire the required infrastructure and equipment needed to achieve the level of purity required. This somewhat good but not accurate levels of purity could also be a contributing factor to the high level of side effects experienced by customers.

Customers and regulatory personnel also share quite similar opinions in their evaluations that most drugs contain correct drug components. The results obtained however still showed that companies were not fully compliant in meeting the requirements of expected drug components as several regulatory officials remained indifferent. This is majorly a result of trying to cut down on

production cost by manufacturing companies that are not well funded by the government. Greed of some companies to make more profit at the expense of quality is also a possible factor. Incorrect drug composition could also be a contributing factor to adverse drug reactions experienced by some customers.

The obtained result shows that the quality of manufactured drugs in Lagos state as regards containing the right amount of APIs is quite poor which is as a result of poor funding of the industry to acquire the needed infrastructure and equipment needed to achieve the level of accuracy required.

As depicted by the result, a lot of regulatory personnel and customers are quite satisfied with the packaging of drugs in the state. However, the result also shows that drug packaging could still be improved upon- see Figure 9b.

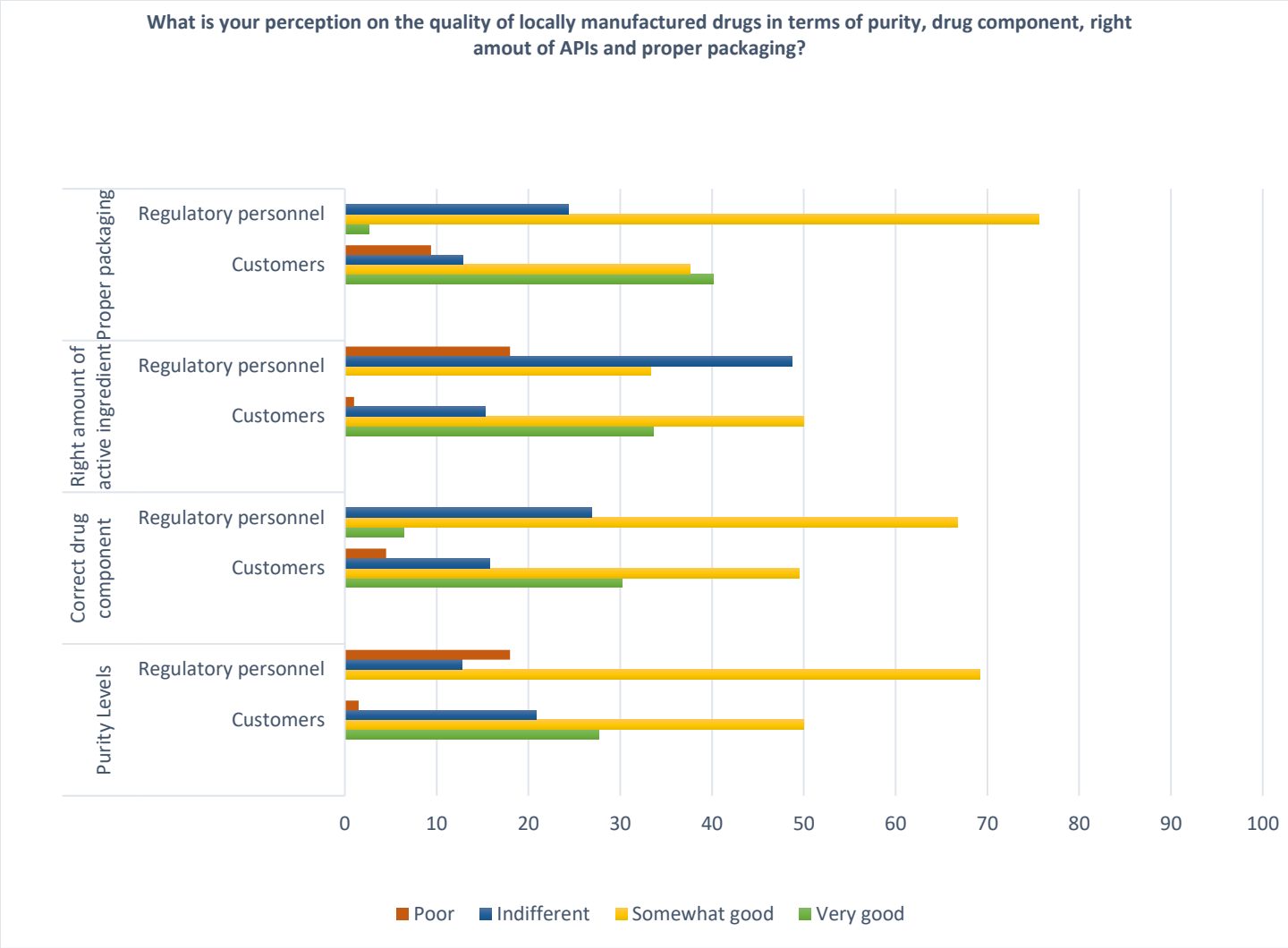


Figure 9b: Comparison of the perspectives of customers and regulatory officials on the quality of drugs manufactured in Lagos state.

### 4.4 Evaluation of the quality of locally manufactured drugs (Questions 11-13)

Question 11:

This question is a follow-up on question 10 as how routinely NAFDAC performs regulatory checks on locally manufactured drug products determines to a large extent how good the quality of drugs in the pharmaceutical market will be.

*Findings:*

13.2% of respondents (30 customers and 7 regulatory personnel) claimed the agency carried out regulatory checks all the time. 49.6% of respondents (68 customers and 71 regulatory personnel) claimed they carried out checks quite often while 36.8% of respondents (103 customers) claimed NAFDAC rarely carried out regulatory checks on pharmaceutical manufacturing companies. Just 0.4% (1 customer) claimed NAFDAC never carries out regulatory checks on manufactured products.

*Analysis:*

The result obtained shows NAFDAC carries out regulatory checks quite often but not often as required to ensure only good quality drugs are produced and approved, as most regulatory officials indicated regulatory checks were not carried out all the time. These regulatory checks are also not adequate to ensure that all pharmaceutical manufacturing companies in the state are complying with standard manufacturing practices- see Figure 10.

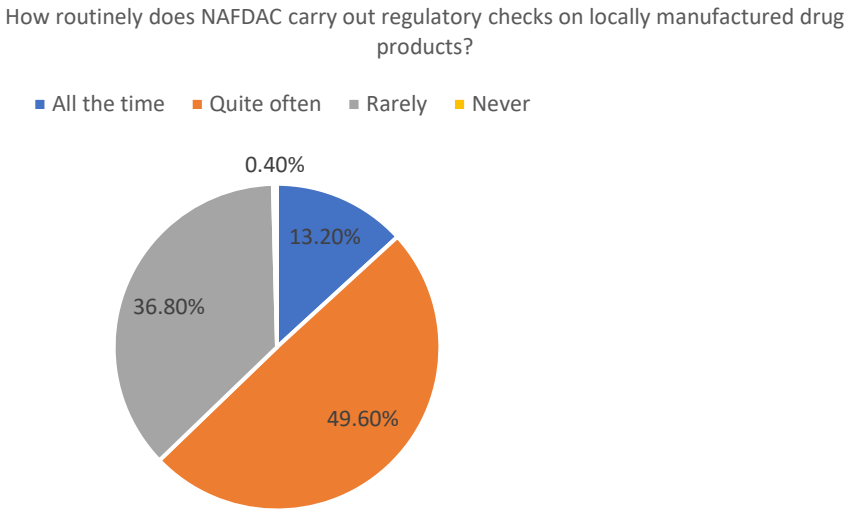


Figure 10: How frequently NAFDAC carries out routine checks on locally manufactured drugs in Lagos state.

Question 12: This question was centered at determining which of the three common challenges affected product quality of locally manufactured drugs in Lagos state.

*Findings:*

35% of respondents (101 customers and 56 regulatory personnel) claimed insufficient regulatory checks on manufacturing processes and products is a major factor affecting product quality of locally manufactured drugs in Lagos. 40.6% of respondents (104 customers and 78 regulatory personnel) were of the opinion that inadequate funding of the industry by the government was a major factor affecting the quality of locally manufactured drugs in the state. 24.3% of respondents (80 customers and 29 regulatory personnel) claimed inadequate training of the manufacturing staff to ensure compliance with standard procedures was a major challenge affecting the quality of drugs manufactured in Lagos state-Figure 11a.

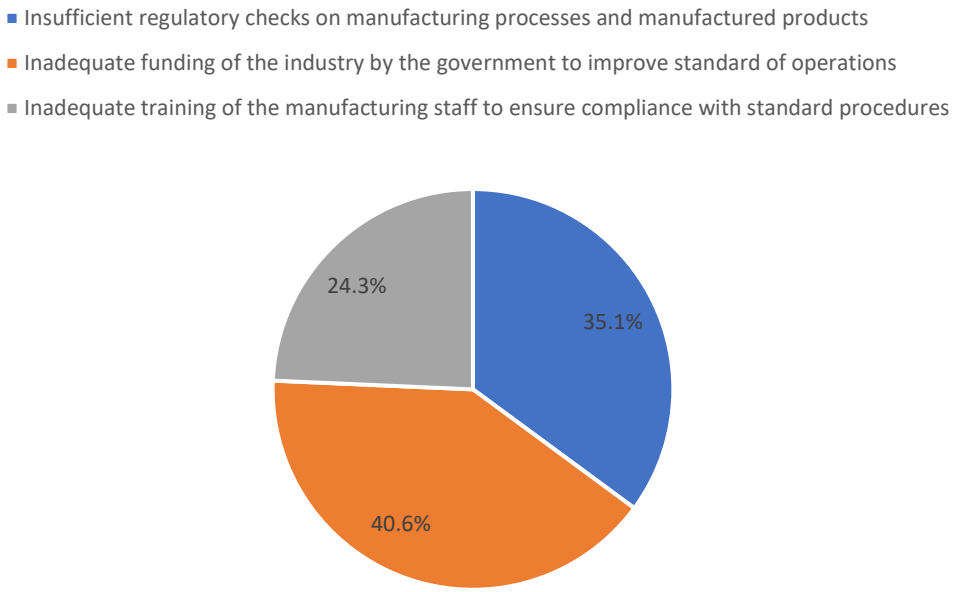


Figure 11a: Challenges affecting product quality of locally manufactured drugs in Lagos state.

*Analysis:*

A comparison of the results obtained from customers and regulatory personnel showed that 50% of customers and 71.8% of the regulatory personnel indicated that insufficient regulatory checks on manufacturing processes and products was a major factor affecting product quality of locally manufactured drugs.

However, 51.5% of customers and all regulatory personnel (100%) claimed inadequate funding of the industry by the government was a major factor affecting drug quality in the state.

While 39.6% of customers and 37.2% of regulatory personnel indicated inadequate training of the manufacturing staff was a major challenge affecting drug quality in Lagos state- see Figure 11b.

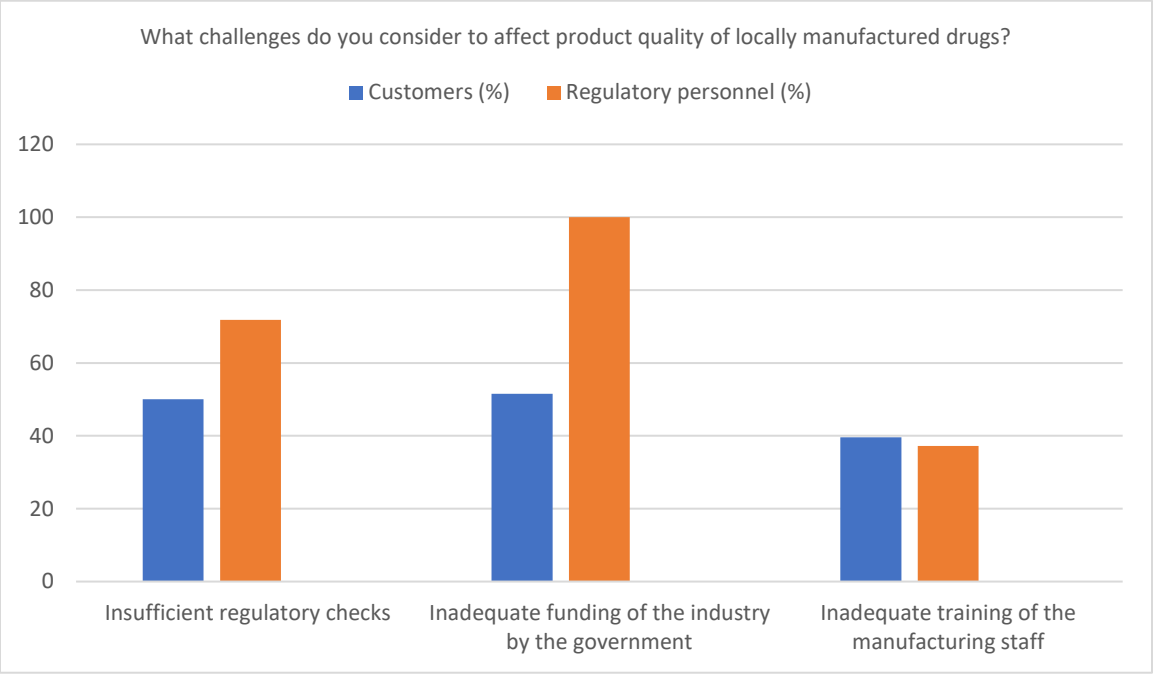


Figure 11b: Comparison of the response between customers and regulatory personnel as regards challenges affecting product quality of locally manufactured drugs in Lagos state.

Question 13:

*Findings:*

In determining effective measures required to ensure utmost quality of locally manufactured drug products in the state, 32.6% of respondents (140 customers and 65 regulatory personnel) indicated that frequent regulatory checks on pharmaceutical manufacturing companies was an effective measure in achieving this goal.

Just 14.8% of respondents (40 customers and 56 regulatory personnel) indicated that issuing of regulatory warning letters to defaulting companies was an effective measure.

16.1% of respondents (38 customers and 66 regulatory personnel) however indicated monetary fines and suspension of defaulting pharmaceutical manufacturing companies was an effective measure.

17% of respondents (37 customers and 78 regulatory personnel) indicated that the indefinite shutdown of consistently defaulting pharmaceutical manufacturing companies was an effective measure.

While 19.5% of respondents (78 customers and 48 regulatory personnel) indicated seizing and destroying substandard or low-quality drugs was an effective measure in ensuring utmost quality of locally manufactured drug products in Lagos state-see Figure 12a.

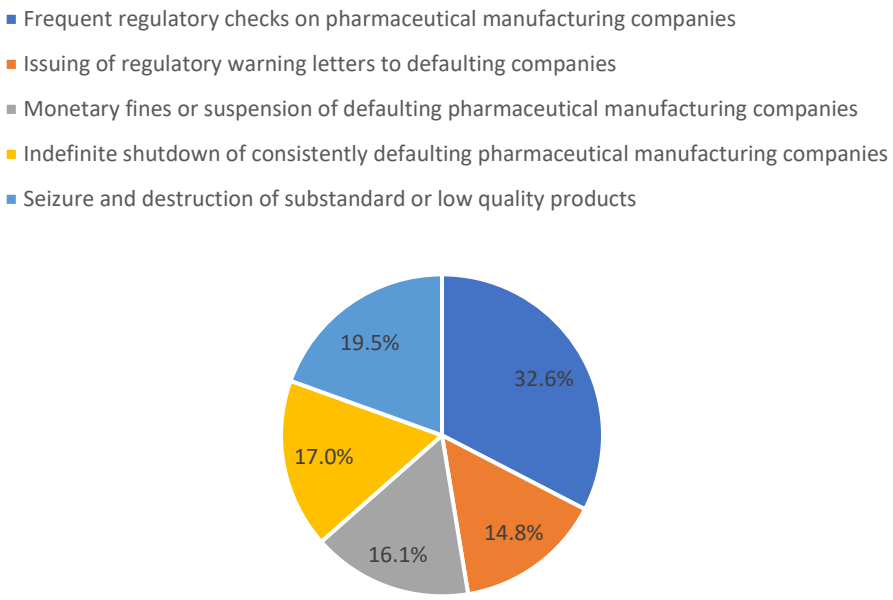


Figure 12a: Respondents perspectives on the measures effective in ensuring utmost quality of locally manufactured drug products.

A comparison of the perspectives of customers and regulatory officials as to what measures were effective in ensuring utmost quality of locally manufactured drugs in the state showed that most 83.3% regulatory personnel and 69.3% of customers agreed frequent regulatory checks was an effective measure in ensuring product quality.

Although very few customers (19.8%) agreed that the issuing of regulatory warning letters to default companies was an effective measure, most regulatory officials (71.8%) claimed it was an effective measure in ensuring product quality of drugs in the state.

18.8% of customers also agreed that monetary fines or the suspension of defaulting pharmaceutical manufacturing companies was an effective measure in ensuring product quality. However, most regulatory officials (84.6%) thought otherwise as a good number of them indicated it was an effective measure.

All regulatory personnel (100%) were also of the opinion that the indefinite shutdown of consistently defaulting pharmaceutical manufacturing companies was an effective measure in ensuring drug quality very few customers (18.3%) were of the same opinion.

38.6% of customers and 61.5% of regulatory personnel agreed that the seizure and destruction of substandard or low-quality products was an effective measure in ensuring utmost quality of drugs manufactured in Lagos state.

*Analysis:*

As depicted by the obtained result, all the aforementioned factors are effective in improving the quality of locally manufactured products in the state. Their ability to improve product quality however varies based on the level of impact they have on different pharmaceutical manufacturing companies, as different companies are affected differently financially and as regards their company reputation. However, frequent regulatory checks and the indefinite shutdown of consistently defaulting companies have the most impact on all pharmaceutical manufacturing companies irrespective of their financial stability and reputation -see Figure 12b.

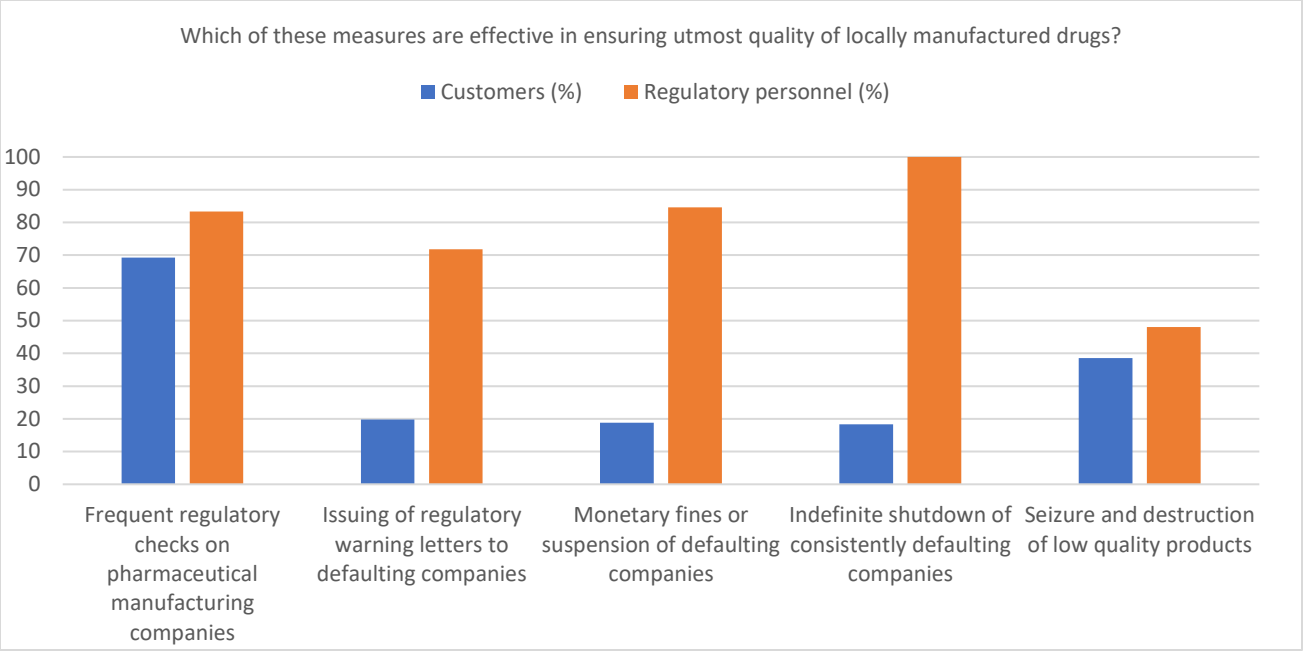


Figure 12b: Comparison of the perspective of customers and regulatory personnel on effective measure to ensure utmost quality of locally manufactured drugs.

### 4.5 Effective recommendations for improving customer satisfaction and product quality of locally manufactured drugs (Question 14).

Question 14:

*Findings:*

Drawing from the entire sections of the survey, this question aimed to provide considerations for the respondents to select from. 14% of respondents (107 customers and 10 regulatory personnel) indicated that the reduction of product price by pharmaceutical companies would be effective in improving the level of satisfaction of customers.

23% of respondents (150 customers and 46 regulatory personnel) indicated that the provision of customer complaint platforms by pharmaceutical manufacturing companies would be effective in improving the level of customer satisfaction.

Interestingly, 26% of respondents (140 customers and 78 regulatory personnel) indicated that adequate product evaluation by regulatory authorities before products are released into the market would be effective in improving the quality of locally manufactured drugs in the state.

17% of respondents (118 customers and 20 regulatory personnel) indicated that ensuring product availability by manufacturing companies for scarce products would improve the level of satisfaction of customers with locally manufactured drugs.

20% of respondents (136 customers and 30 regulatory personnel) indicated that ensuring adequate training of the manufacturing workforce would improve the quality of locally manufactured drugs- see Figure 13a.

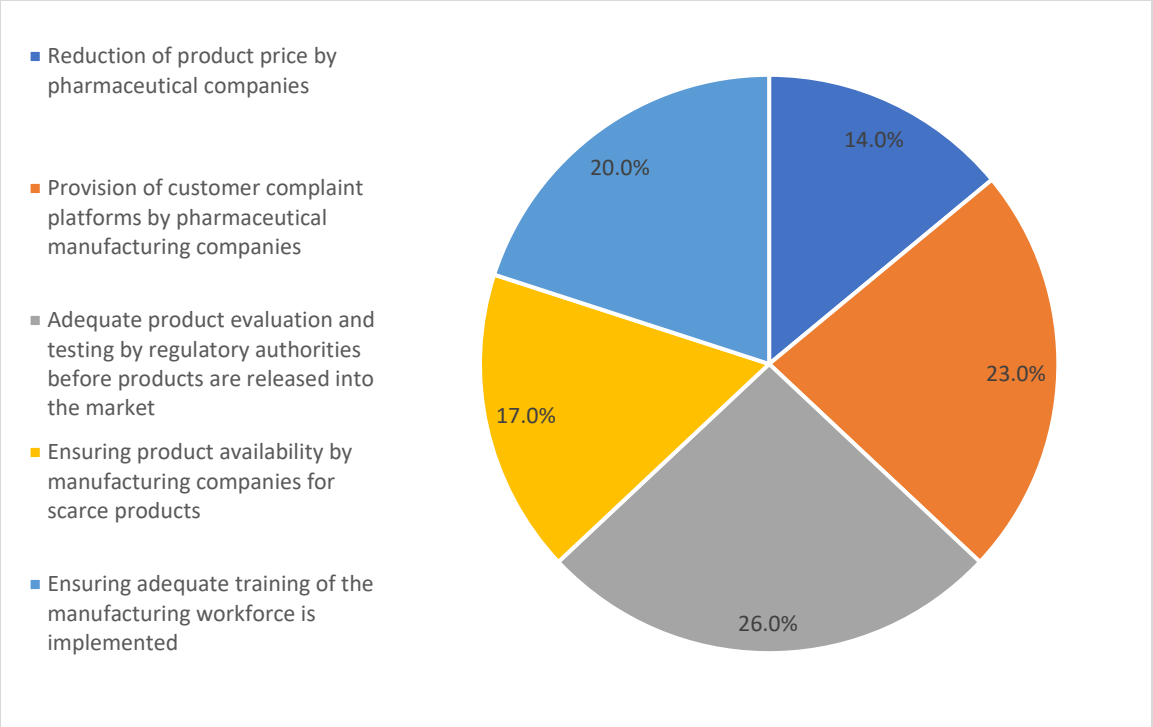


Figure 13a: Recommendation of respondents for the improvement of customer satisfaction and product quality.

As depicted in the result obtained, a comparison between the recommendations made by customers and regulatory personnel showed that 53% of customers indicated that reduction of product price by pharmaceutical companies would be effective in improving the level of satisfaction of customers while very few regulatory personnel (12.8%) shared the same opinion.

74% of customers and 59% of regulatory personnel however indicated that the provision of customer complaint platforms by pharmaceutical manufacturing companies would be effective in improving the level of customer satisfaction in the state.

69.3% of customers and all regulatory personnel (100%) indicated that adequate product evaluation by regulatory authorities before products are released into the market would be effective in improving the quality of locally manufactured drugs in the state.

58.4% of customers and 25.6% of regulatory officials indicated that ensuring product availability by manufacturing companies for scarce products would improve the level of satisfaction of customers with locally manufactured drugs.

38.5% of regulatory personnel and 67.3% of customers indicated that ensuring adequate training of the manufacturing workforce would improve the quality of locally manufactured drugs in Lagos state.

*Analysis:*

Certainly, all the mentioned factors will contribute to the improvement of customer satisfaction and product quality of locally manufactured drugs in Lagos state. Though their level of contribution will vary. From the result obtained, it is however evident that adequate product evaluation by drug regulatory bodies in the state and the provision of customer complaint platforms by pharmaceutical manufacturing companies will however contribute immensely to the improvement of both elements of Operational Excellence- see Figure 13b.

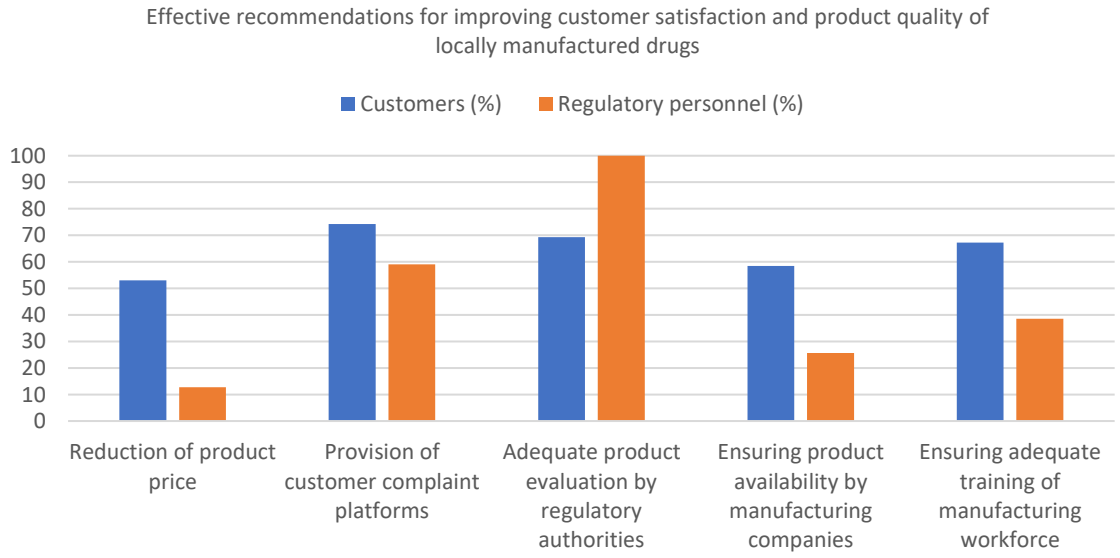


Figure 13b: Comparison of the recommendations made by customers and regulatory personnel on the improvement of drug quality and customer satisfaction.

## 4.6 Qualitative Analysis

4.6.1 Phone interview with highly experienced NAFDAC officials (Over 15 years)

The author explored her good relationship with the Director, Drug laboratories of NAFDAC in Lagos state for contacts of 5 top NAFDAC managerial staff: 2 Head of Departments and 3 top inspection officers. She then had a phone interview with them to explore their perception on the quality of locally manufactured drugs in Lagos state. They all agreed to participate in the interview so far as their identities were kept anonymous. However, the interviewed respondents were all over 50 years of age and had been practicing in their field for over 15 years, they all had also been resident in Lagos state for not less than 2 years.

Three of the officials admitted the purity levels of drugs manufactured in the state with right amount of APIs and correct drug components were somewhat good but needed to be improved while two officials were neutral. One of the two officials said; "*a good number of drugs tested by the agency shows that most of them usually have a little above the accepted purity levels with a bit more or less APIs most of which the agency has had to overlook if they were not a threat to the health of customers because quite a number of manufacturing companies do not have the level of technology required to produce drugs with certain purity levels".*

All the officials stated the packaging of locally manufactured drugs in the state was quite good. They pointed out that though they were quite satisfied with the quality of drug packaging in the state, as it was not a cause of serious concern to the agency currently, it still could be better.

When asked about the factors they deemed to have affected the quality of drugs manufactured in Lagos state, all the officials admitted the pharmaceutical industry was not adequately funded by the government and as a result, had not been able to function optimally in delivering its best in terms of drug quality. Just one of the officials stated inadequate training of manufacturing workforce was a factor affecting the quality of drugs manufactured in the state.

Interestingly, three of the officials admitted the regulatory checks carried out by the agency were insufficient and inadequate. The explanation given by one of the officials however summarised the reasons stated by the remaining two. *The official said; " over fifty pharmaceutical manufacturing companies are situated in Lagos state and the agency is not only involved in the monitoring, regulating and controlling of drug manufacturing processes and products, but also*

*does the same for food processing companies which are even more than pharmaceutical companies in the state. The agency currently doesn't have enough manpower in place to constantly carry out regulatory checks and tests as often as it should to efficiently obtain and sustain the level of drug quality desired and required*".

All four officials however admitted the agency and other associated drug regulatory bodies in the state needed to improve their level of efficiency in adequately evaluating drugs produced in the state. They pointed out that a restructuring of the regulatory system in Lagos state and improvement in the strategy and manner of approach of carrying out regulatory checks and tests was required for significant improvement in quality of locally manufactured drugs in the state to be achieved.

4.6.2 Phone interview with customers

The author took advantage of her alumni group platform for the contact of 5 Post-graduate Microbiologists who had all been resident in Lagos for over 2 years and had also filled the questionnaire used in the quantitative analysis of this research work as customers. They were all not less than 27 years of age. A phone interview was scheduled with all five customers to ascertain their level of satisfaction with locally manufactured drugs in Lagos state. They all agreed to the interview and gave their consent for the information obtained to be used for this research as long as their identity was not disclosed.

All 5 customers disclosed they only used drugs occasionally because they had no health issues that required them to use drugs at regular or periodic intervals. When asked how satisfied they were with the price of drugs based on their experience, three of them stated they were somewhat but not totally satisfied while two were indifferent. When asked why they were indifferent, one of the costumers said; "*it depends on the drug being purchased, commonly purchased drugs such as antimalarials and antimicrobials are quite affordable because they are frequently purchased OTC drugs. However, a good number of drugs such as antihypertensives are quite expensive and not easy to afford, my level of satisfaction with drugs manufactured in the state is therefore relative as it depends on the type of drug I am buying*"

All five customers stated they were somewhat satisfied with the availability of drugs in the state, while three stated they were somewhat satisfied with the efficacy of drugs manufactured in the

state. Two however stated they were unsatisfied as they had used ineffective drugs quite a number of times and have had to use a combination of different medications a couple of times to treat certain ailments as single drug treatments were sometimes ineffective.

Four customers stated they experienced little or no side effects when they used locally manufactured drugs in the state. One of the customers was however not satisfied as she stated she had experienced severe side effects a good number of times after the use of locally manufactured drugs in Lagos state.

All the customers stated NAFDAC approval of drugs was an important factor that influenced their level of satisfaction with locally manufactured drugs in the state. Just two of them however said the reputation of manufacturing companies was an influencing factor for them. However, the others were indifferent as they had little knowledge about drug manufacturing companies in Lagos and their reputations.

However, they all complained of the inability to lodge complaints in cases where they were dissatisfied with purchased drugs, as drug sellers could not be held accountable or responsible for the inability of purchased drugs to meet their expectations. They therefore recommended that drug manufacturing companies create a functional platform where customers can lodge their complaints and be well attended to.

### 4.7 Conclusion

As deduced from the analysis and findings presented above, it is apparent that though the quality of locally manufactured drugs in the state in terms of purity, correct and appropriate amount of APIs and excipients cannot be classified as being poor, they also cannot be classified as being very good either. Evidence gathered most especially from the quantitative and qualitative analysis of regulatory officials show that drug manufacturing companies in Lagos state to a very large extent, are still not meeting regulatory standards in terms of purity and the right amount of APIs. Though their level of deviation from standard acceptable levels are quite minute, it still does not rule out the fact that they are lacking in these aspect of quality as drugs are very potent and sensitive substances and a high degree of accuracy is required in their formulation to ensure efficacy and prevent adverse drug reactions.

Varying results were obtained in the level of satisfaction of customers with locally manufactured drugs because customer satisfaction was relative. How affordable drugs are for customers in Lagos state is dependent on the health issues faced by customers and apparently, the type of drugs required in treating such health issues. This is because, as stated by an interviewed customer, some locally manufactured drugs are way more expensive than some others. It was also dependent on the financial status of the customer as drugs that were quite affordable for one customer were too expensive for some others. All these customer peculiarities and many more that will be discussed in the next chapter were responsible for the variations in the obtained results. However a notable similarity between all the customers of locally manufactured drugs in Lagos state was that almost all of them were either satisfied or indifferent about the price, availability, level of side effects of the drugs and their efficacy, very few were totally unsatisfied with drugs produced in the state.

The factors posing as challenges to the improvement of the quality of locally manufactured drugs in the state which were in line with the quantitative and qualitative analysis made were the inadequate funding of the industry by the government, with inadequate regulatory checks by regulatory authorities being a factor posing as a challenge to the improvement of both drug quality and customer satisfaction of locally manufactured drugs in Lagos state. However, provision of appropriate complaint platforms for customers and adequate regulatory checks on the quality of drugs produced in the state were among the highest rated recommendations for the improvement of customer satisfaction and the quality of drugs produced in Lagos state respectively.

## CHAPTER 5: CONCLUSIONS

## 5.1 Answering the four main research questions:

*Question 1: What is the state of customer satisfaction and product quality of locally manufactured drugs in Lagos, Nigeria?*

From the responses in the survey and as acknowledged by experienced drug regulatory personnel during the phone interview, it is apparent that the quality of locally manufactured drugs in Lagos state is on an average level as regards to the parameters used in evaluating drug quality which included- purity level, correct and right amount of excipients, right APIs and proper packaging. This was similar to the responses obtained from experienced regulatory officials during the phone interviews as all of them were quite indifferent in their evaluation of drug quality in the state. They all claimed a lot of work still had to be done in improving the quality parameters being considered to ensure drug safety for customer use. Though results obtained from customers and regulatory officials from the survey as regards quality parameters such as correct amount of APIs and excipients were not totally in alignment, it is understandable that most customers do not have the facts about purity levels and the appropriateness of the amount of excipients in the drugs they use. A greater part of their judgment on drug quality is most likely influenced by the level of efficacy and severity of side effects observed.

It was however deduced from the survey and from the interviews conducted that the level of satisfaction of customers with locally manufactured pharmaceutical products in Lagos state is quite good as just few of them claimed the parameters being analysed (drug price, availability, efficacy and safety) were poor. A higher percentage of respondents were however quite satisfied in terms of all the parameters used in evaluating the level of customer satisfaction with drugs manufactured in Lagos state except with the varying levels of satisfaction in terms of the severity of side effects. Though 58.2% of customers claimed they were quite satisfied as they observed little or no side effects with used drugs, the remaining 41.8% of respondents were either indifferent or not satisfied based on the level of severe side effects they experienced. The variation however was relative to customer peculiarities, as also pointed out when customers were interviewed. Different customers therefore reacted to drugs differently while some drugs had more severe side effects than others based on the peculiarity of the ailment for which they were formulated. The level of satisfaction of customers based on this parameter was most likely varied based on the type of ailment they

frequently experienced which determined the type of drugs they used often and as a result, the side effects they experienced.

*Question 2: What are the main factors affecting drug quality and the satisfaction of customers with drugs manufactured in Lagos state?*

As evidenced by the survey and phone interviews conducted, regulatory officials claimed inadequate funding of the pharmaceutical manufacturing industry is a major factor seriously affecting the quality of locally manufactured drugs, as the industry is not well funded enough to afford the level of technology required to provide the utmost level of quality expected of it.

Inadequate regulatory checks by drug regulatory agencies is the second most significant factor affecting the quality of drugs in the state. Results from the survey and phone interview with regulatory officials showed regulatory checks by NAFDAC is not quite often enough to effectively monitor and regulate pharmaceutical manufacturing processes and products in the state.

*Question 3: What Recommendations can be made to improve these elements and the Operational Excellence of the industry?*

Since regulatory checks and tests carried out by NAFDAC and other drug regulatory agencies in the state are not adequate in ensuring drugs produced and approved in the state are of utmost quality, drug regulatory bodies in the state need to be more proactive to ensure customers are satisfied with purchased approved drugs and that the quality of drugs produced in the state is improved. As deduced from the quantitative and qualitative analysis, both regulatory personnel and customers agreed that adequate product evaluation by regulatory authorities would go a long way in improving customer satisfaction, product quality and consequently, the Operational Excellence of the pharmaceutical manufacturing industry in Lagos state.

Provision of customer complaint platforms by manufacturing companies was the second highly recommended approach by both regulatory authorities and customers in improving customer satisfaction and consequently, the Operational Excellence of the pharmaceutical manufacturing industry in Lagos state.

## 5.2 Comparing and contrasting results from primary and secondary research.

The average level of the quality of locally manufactured drugs in Lagos state is quite encouraging when compared to similar studies from the literature review. The percentage quality of drugs in all the related reviewed literature showed drug quality was a bit below average in the state with most of the sampled drugs having inappropriate levels of APIs and impurities. These observed levels of drug quality in the state all show regulatory authorities are not quite efficient in ascertaining the safety and quality of drugs before approving them. Strict measures however have to be put in place by regulatory authorities in the state to increase the quality of drugs, or there will be a consequential increase in the mortality rate and worsened health conditions of residents in the state(Ndichu et al., 2019).

Though very few reviewed literature are available on the level of satisfaction of customers with locally manufactured drugs in Lagos state, the level of customer satisfaction as deduced from the results obtained from the primary research was however very encouraging when compared with the available related literature which reported that customers were highly dissatisfied with locally manufactured drugs in the state, as most of them complained the drugs they purchased were either ineffective or had severe side effects that prevented them from using the medications as prescribed by pharmacists. Though customer satisfaction is linked to the quality of drug products, customer peculiarities as to their preference of certain drugs and their availability, adherence to the use of drugs as prescribed and other factors as earlier mentioned affects the level of customer satisfaction differently(Bate et al., 2014).

The challenges observed in all the related previous studies as regards product quality and customer satisfaction with locally manufactured drugs also revolved around the pharmaceutical industry in the state not being adequately funded by the government and the inefficiency of NAFDAC and other regulatory authorities in carrying out quality checks on products and manufacturing processes. An improvement on both stated challenges has also been a reoccurring theme in previous studies on the recommendations for the improvement of the quality of locally manufactured drugs in Lagos state (Babalola O.O, 2001).

## 5.3 Concluding thoughts

### *5.3.1 Contributions and limitations of the research*

The research was completed after data was obtained from survey questionnaires and phone interviews of Two hundred and ninety (290) respondents in total. Analysis was then carried out on

the obtained data and provided in form of tables and charts for better interpretation and perception. Though most research papers on products of pharmaceutical manufacturing companies focused on just quality, this research compared both product quality and customer satisfaction elements of Operational Excellence in one study. The survey questionnaire received responses from both customers and drug regulatory personnel in Lagos, Nigeria.

The main limitation was the few number of regulatory personnel in comparison to the quite satisfactory number of customers who filled the survey.

A second limitation was the few number of regulatory officials and customers interviewed over the phone. Other factors such as personal bias of the respondents could also impact the interpretation of results obtained.

While insights into NAFDAC's level of efficiency in performing their regulatory role of ensuring good quality of locally manufactured drugs in the state has been evaluated to be inadequate, factors affecting their level of efficiency and possible solutions to their challenge of inadequacy has not been obtained.

The author believes that the analysis of customer satisfaction and product quality elements of OPEX in the pharmaceutical manufacturing industry in each state in Nigeria should be considered as the efficiency of drug regulatory authorities will differ in all states.

The author assessed that the contributory factors with the most agreeing responses from regulatory personnel for improving drug quality in the state were the indefinite shutdown of consistently defaulting companies which was closely followed by the fining or suspending of defaulting companies. Other factors elicited were met with more disagreeing responses than was expected, limiting the perception of effective measures and leaving room for further research.

### *5.3.2 Recommendations for future research*

Further research needs to be done that will include other regulatory bodies such as the SON in carrying out quality control tests and other regulatory tests on the manufacturing processes and products of pharmaceutical manufacturing companies to ensure that the regulatory system is efficient, as NAFDAC alone might not have the full workforce required to carry out adequate and quality regulatory inspections.

Additionally, healthcare professionals such as doctors, pharmacists and nurses should also be studied and identified independently and not categorized as general customers, after which they

should be compared with regulatory personnel and other non-healthcare customers in determining the level of product quality in Lagos state. This is quite important as healthcare professionals get a lot of feedbacks on the quality and level of satisfaction obtained from drugs. They will therefore be very helpful in making more accurate evaluations on the quality of locally manufactured drugs in the state.

There is however a need to carry out research on drug quality and level of customer satisfaction in each state in Nigeria, as results obtained from these states can be compared to determine the unique challenges faced by each state of the country. Also, states having better product quality and customer satisfactory levels can offer suggestions on how to increase product quality of locally manufactured drugs.

Further study also need to be carried out on regulatory authorities to determine the challenges affecting them from being fully efficient in ensuring utmost quality of pharmaceutical products locally manufactured in Lagos state.

### 5.4 Final conclusions

In concluding this research on the analysis of customer satisfaction and drug product quality to improve pharmaceutical manufacturing Operational Excellence in Lagos state, Nigeria. After appropriate literature had been reviewed on the topic, the author found the process very helpful in understanding the perspective of both customers and regulatory personnel as regards drug quality and factors influencing and affecting customer satisfaction.

As deduced from the literature review on quality of pharmaceutical products in the country, Nigeria's pharmaceutical industry is one of the most poorly funded in Africa and this has definitely taken its toll on the quality of drugs produced by the pharmaceutical manufacturing industry in Lagos state. However even with this challenge, the author concludes that the pharmaceutical manufacturing industry in Lagos state has however been able to obtain an average level of drug quality compared to its below average level reported in previous studies.

As regards the level of customer satisfaction with locally manufactured drugs in Lagos state, the author further concludes that significant improvement has been achieved generally and more specifically in the aspect of drug availability, price and safety compared to results from past available studies.

The author concludes that though the pharmaceutical manufacturing industry in Lagos state still has a long way to go in improving product quality and customer satisfaction, the industry has however made encouraging improvements despite the numerous challenges limiting its development. The implementation of recommendations made such as adequately funding the industry and proper evaluation of manufacturing processes and products by regulatory authorities will help in boosting the Operational Excellence of the pharmaceutical manufacturing industry in Lagos state, Nigeria.

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# Analysis of Drug Quality and Customer Satisfaction in the Pharma Manufacturing Industry.

Dear Respondent,
I am Omotayo Temitope Babatunde, a post-graduate student at Griffith College Dublin, Ireland. I am carrying out a dissertation research on the Impact of customer satisfaction and product quality on the operational excellence of the pharmaceutical manufacturing industry in Lagos state, Nigeria as part of the requirement for the degree of Masters (MSc) in Pharmaceutical Business and Technology.

Customer satisfaction and Product quality are critical elements of the Operational Excellence of the pharmaceutical manufacturing industry. Customer satisfaction is dependent on the degree of product quality and this relationship impacts the industry's Operational Excellence. This survey seeks to gather information on factors influencing product quality and customer satisfaction regarding locally manufactured drugs in Lagos, Nigeria. The information obtained will help in the analysis of the current state of Operational Excellence of the pharmaceutical manufacturing industry.

This survey is made up of 4 sections and 14 questions in total aimed at collecting information on respondent demographics, current state of customer satisfaction and product quality, evaluation of product quality, factors influencing customer satisfaction and product quality and recommendations for the improvement of Operational Excellence in the industry.

Please kindly answer the questions by selecting your preferred options. The privacy of every participant and response given is strictly confidential. All data generated will be handled in line with the General Data Protection Regulation (GDPR).

Thank you for your participation.

* Required

1. Participant Agreement *

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

Next

* Required

## DEMOGRAPHICS

2. What is your gender? *

- ○ Female
- ○ Male
- ○ Undisclosed

3. What is your age group? *

- ○ 18 to 30
- ○ 31 to 40
- ○ 41 to 50
- ○ 51 or older

4. What is your level of education? *

- ○ No formal education
- ○ High School
- ○ Undergraduate
- ○ Post-graduate

5. How long are you resident in Lagos? *

- ○ Less than 6 months.
- ○ 6 months to 2 years.
- ○ 2 years to 5 years.
- ○ 5 years and above.

6. Who is filling this survey? *

- ○ Drug customer.
- ○ Regulatory Personnel.

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* Required

## Current state of customer satisfaction and product quality

7. How often do you purchase drug products locally manufactured in Lagos State? *

| | Every day | Once a week | Once a month | Rarely |
|---|---|---|---|---|
| | ○ | ○ | ○ | ○ |

8. How strongly do these factors influence your level of satisfaction with locally manufactured drugs? *

| | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| NAFDAC appoval | ○ | ○ | ○ | ○ | ○ |
| Company reputation | ○ | ○ | ○ | ○ | ○ |
| Availability | ○ | ○ | ○ | ○ | ○ |
| Price | ○ | ○ | ○ | ○ | ○ |

9. What is your level of satisfaction with purchased locally manufactured drugs in terms of; *

| | Very satisfied | somewhat satisfied | Indifferent | Unsatisfied |
|---|---|---|---|---|
| Availability | ○ | ○ | ○ | ○ |
| Price | ○ | ○ | ○ | ○ |
| Effectiveness | ○ | ○ | ○ | ○ |
| Severity of side effects | ○ | ○ | ○ | ○ |

10. What is your perception of the quality of locally manufactured drugs in terms of; *

| | Very good | Somewhat good | Indifferent | Poor |
|---|---|---|---|---|
| Purity levels | ○ | ○ | ○ | ○ |
| Correct drug components | ○ | ○ | ○ | ○ |
| Right amount of active ingredient | ○ | ○ | ○ | ○ |
| Proper packaging | ○ | ○ | ○ | ○ |

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* Required

## Evaluation of drug product quality

11. How routinely does NAFDAC perform regulatory checks on locally manufactured products? *

| | All the time | Quite Often | Rarely | Never |
|---|---|---|---|---|
| | ○ | ○ | ○ | ○ |

12. What challenges do you consider to affect product quality of locally manufactured drugs? *

- ☐ Insufficient regulatory checks on manufacturing processes and manufactured products.
- ☐ Inadequate funding of the industry by the government to improve standard of operations.
- ☐ Inadequate training of the manufacturing staff to ensure compliance with standard procedures.

13. Which of these measures are effective in ensuring utmost quality of locally manufactured drug products? *

- ☐ Frequent regulatory checks on pharmaceutical manufacturing companies.
- ☐ Issuing of regulatory warning letters to defaulting companies.
- ☐ Monetary fines or suspension of defaulting pharmaceutical manufacturing companies.
- ☐ Indefinite shutdown of consistently defaulting pharmaceutical manufacturing companies.
- ☐ Seizure and destruction of substandard or low quality products.

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* Required

## Recommendations

14. Effective recommendations for improving customer satisfaction and product quality of locally manufactured drugs includes;
(Tick all that apply) *

- [ ] Reduction of product price by pharmaceutical companies.
- [ ] Provision of customer complaint platforms by pharmaceutical manufacturing companies.
- [ ] Adequate product evaluation and testing by regulatory authorities before products are released into the market.
- [ ] Ensuring product availability by manufacturing companies for scarce products.
- [ ] Ensuring adequate training of the manufacturing workforce is implemented.
- [ ] Other

Back Submit